

■ **Review article**

Intraocular lens tilt and decentration: A concern for contemporary IOL designs

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Abstract

Purpose: To review published studies reporting the posterior chamber intraocular lens tilt and decentration after surgically uneventful implantation. Potential influences of normally occurring misalignment of modern designs of IOL on the optical performances are discussed.

Materials and methods: Published theoretical and clinical studies in relation to primarily implanted posterior chamber intraocular lenses and reports relating to more recent development of intraocular lens technologies were reviewed.

Results: Capsulotomy type and integrity, ocular pathology, fixation position of the haptics are some of the important factors causing the misalignment. On an average, a 2-3 degrees tilt and a 0.2 -0.3 mm decentration are common, and which remain clinically unnoticed for any design of IOL. However, theoretical studies predict deterioration of retinal image quality particularly with customized wavefront correcting IOLs. More than a 10 degrees tilt and above 1 mm decentration are occasionally reported even with modern cataract surgery in about 10 % of pseudophakic population.

Conclusions: The rate and extent of the complication have lowered substantially concomitant with developments in surgical techniques and IOL designs. While emerging designs of modern IOLs offer improved quality of postoperative vision, optimum performance is vastly influenced by the position of the device in the eye. Therefore, additional precision in alignment of modern designs of IOL may be warranted.

Key words: IOL misalignment, Intraocular Lens, modern IOL, consequences of misalignment

Introduction

Introduction of the IOL dates back to 1949 with the first implantation performed by Sir Harold Ridley. While far from perfect, the procedure worked well enough to encourage further refinement in design; and since the mid 1960s, the IOL became popular and clinically successful (Apple *et al* 1984). Today, implantation of the IOL has become a standard method of visual rehabilitation following cataract

removal and virtually all cataract patients have the benefit of the device. A constantly rising demand for long-term, post-operative perfect vision has led to the proliferation of more sophisticated surgical techniques and novel IOL designs. Consequently, today's cataract surgery is no more a mere cataract removing procedure but has become a regular component of refractive surgery. Beyond the correction of spherical refractive error in an aphakic eye with implantation of accurately calculated power of the IOL, it is now able to customize IOL designs to control higher order aberrations in a pseudophakic eye (Altmann, 2004; Bellucci and Morselli, 2007; Holladay *et al* 2002).

Amid significant improvements, several post-operative complications associated with surgical

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technique and IOL design still persist. Misalignment of IOL, including tilt and decentration, is one of the most common complications (Apple *et al* 1984; Mamalis *et al* 2008b) which occurs even after uneventful implantation. Several reports investigating tilt and decentration have proposed a number of factors associated with the complication. The rate and extent of the complication has substantially decreased with improved IOL designs and surgical techniques (Linnola and Holst, 1998); nonetheless, publications reporting extreme misalignment requiring explantation (Table 1) are still not uncommon (Gimbel *et al* 2005, Mamalis *et al* 2008a).

For a conventional monofocal IOL, a certain degree of tilt and decentration go clinically unnoticed (Baumeister *et al* 2009, Mester *et al* 2009). However, theoretical studies have shown that even a small misalignment of modern IOL designs, particularly multifocal and customized aberration correcting IOLs, leads to significantly-reduced performance (Altmann *et al* 2005). Therefore, increasing interest in correcting aberrations in a pseudophakic eye by means of IOL technology demands additional precision in IOL centration.

In the present manuscript, we reviewed publications that investigated the tilt and decentration of posterior chamber IOL following an uneventful cataract surgery and attempted to identify the important

factors associated with the complication. We also assessed the clinical and theoretical reports investigating the optical and visual impacts caused by normally-occurring misalignments of conventional and modern IOL designs.

Materials and methods

A PubMed search was conducted using the term 'intraocular lens tilt and decentration'. The reference list on the retrieved articles was reviewed for further publications not included in the PubMed database. Clinical studies reporting the tilt and decentration of primarily-implanted posterior chamber intraocular lens and theoretical studies analyzing effects of the misalignment were included. Reports with secondary implantation, zonular abnormalities (e.g. zonular dehiscence and subluxated lens), and suture fixated IOL (e.g. transcleral suture fixation) were excluded from the analysis. The main outcome measures included an extent of tilt and decentration, factors affecting the misalignment, effect on higher-order aberrations and vision. Meta-analysis (only to the randomized studies) was carried out with Comprehensive Meta Analysis V2 (Biostat Inc., 2006). Outcome measures of the studies which could not be meta-analyzed due to insufficient metrics reported or due to a limited number of studies but are important from clinical standpoint are also tabulated for comparison, when deemed necessary.

Table 1
Rate of explantation of PCIOL due to decentration/dislocation (Dec/Dis) alone

Author	Year	Total eyes	Dec/Dis	Note
(Lyle and Jin, 1992)	1992	101	36 %	Bullous keratopathy observed in 87 %
(Mamalis, 2000)	2000	226	18 %	56 % 3pc IOL & 31 % multifocal
(Mamalis and Spencer, 2001)	2001	259	26 %	64 % 3pc IOL & 15 % multifocal
(Mamalis, 2002)	2002	286	23 %	69 % 3pc IOL & 9 % multifocal
(Mamalis <i>et al</i> 2004)	2004	273	26 %	52 % 3pc IOL & 6 % multifocal
(Jin <i>et al</i> 2005)	2005	51	37.3 %	4 ACIOL, incidence of total = 0.77 %
(Mamalis <i>et al</i> 2008a)	2008	142	25 %	42 % 3pc IOL & 24 % multifocal
(Leysen <i>et al</i> 2009)	2009	128	37 %	IOL opacification observed in 31 %

Results

Factors affecting the alignment of IOL fixation site

The position of the haptics can be categorized as symmetric (both haptics in the bag or bag-bag fixation and both in the ciliary sulcus or sulcus-sulcus fixation) or asymmetric (one haptic in the bag and another in the ciliary sulcus or bag-sulcus fixation). A higher rate of the misalignment has been reported when an IOL is asymmetrically fixated (bag-sulcus) compared to symmetrically fixated IOL (bag-bag or sulcus-sulcus). Tilt and decentration with fixation sites are summarized in Table 2.

Capsulotomy type and integrity

At least 14 controlled studies reported the effect of capsulotomy type and its integrity on the alignment of an IOL. The can-opener technique was reported to be the least effective capsulotomy type compared to the envelope and Continuous Curvilinear (Circular) Capsulorhexis (CCC). While the intact CCC was the best method, presence of tear showed reduced effectiveness which is similar to other two methods. The summary of the meta-analysis results of the studies reporting decentration of IOL with various types of capsulotomy is presented in Table 3.

Table 2

Effect of symmetric (bag-bag and sulcus-sulcus) or asymmetric (bag-sulcus) fixation of haptics on tilt and decentration. Double dash represents unavailable data.

Author	Fixation site (Tilt/Dec.)			Notes
	Bag-Bag	Bag-Sulcus	Sulcus-Sulcus	
(Akkin <i>et al</i> 1994)	5.43/0.43	8.8/1.24	--	Envelope capsulotomy
(Assia <i>et al</i> 1993)	-- /0.31	--/0.66	-- /0.39	Difference significant for position ($p < 0.01$) but not for loop type
<i>J loop</i> <i>C loop</i>	-- /0.25	-- /0.63	-- /0.54	
(Hayashi <i>et al</i> 1999b)	3.18±1.66/0.29±0.21	2.93±1.81/0.47±0.47	-- /0.65	Bag-sulcus had capsule tear
(Caballero <i>et al</i> 1991)	-- /0.46	-- /0.91	--	
(Legler <i>et al</i> 1992)	-- /0.20±0.05	-- /0.68±0.28	--	
(Hansen <i>et al</i> 1988)	-- /0.40	-- /0.80	--/0.60 (max 2.31)	Postmortem eyes, $p = <0.05$

All values are mean ± SA of tilt/decentration. Tilt is measured in degrees and decentration in millimeter. Due to the inhomogeneous nature of the studies and reported data, meta-analysis was not possible.

Table 3

Decentration of IOL in various types of capsulotomy

Effect of capsulotomy type and integrity				
Capsulotomy	n	N	Point Estimate	95% CI
Intact CCC	5	246	0.22973	0.227 - 0.233
CCC with tear	5	186	0.40814	0.389 - 0.427
Can Opener	2	77	0.6818	0.617 - 0.747
Envelope	2	417	0.46023	0.458 - 0.462
Overall	14	926	0.39373	0.392 - 0.395

N – total number of subjects examined, n – number of studies

meta-analyzed, CI – confidence interval. Studies included in the meta-analysis are: Intact CCC and CCC with tear (Assia *et al* 1993, Caballero *et al* 1995, Hayashi *et al* 2008, Legler *et al* 1992, Oner *et al* 2001); Can Opener (Lu and Shen, 1999, Oner *et al* 2001)& Envelope (Caballero *et al* 1995, Oner *et al* 2001)

Table 4
Meta-analysis of IOL tilt and decentration with various designs and materials

Effect of IOL Construction and Material						
Construction material	n	N	Decentration		Tilt	
			Point estimate	CI (95%)	Point estimate	95% CI
1Pc PMMA	3	193	0.242	0.187 - 0.296	2.838	2.653 - 3.024
3Pc PMMA	2	164	0.370	0.319 - 0.421	2.780	2.490 - 3.070
1Pc Acrylic	2	99	0.292	0.194 - 0.390	2.192	2.011 - 2.374
3Pc Acrylic	5	228	0.307	0.234 - 0.381	2.454	2.336 - 2.572
Overall	12	684	0.308	0.285 - 0.332	2.505	2.425 - 2.586

N – number of subjects, n – number of studies included in the analysis, CI – confidence interval. Studies included in the meta-analysis are: 1Pc PMMA (Hayashi et al 1997, Hayashi et al 1998d, Mutlu et al 1998); 3Pc PMMA (Hayashi et al 1997, Hayashi et al 1998d); 1Pc Acrylic (Hayashi and Hayashi, 2005, Mutlu et al 2005); 3Pc Acrylic (Hayashi et al 1997; Hayashi and Hayashi, 2005; Mutlu et al 1998; Mutlu et al 2005; Taketani et al 2004) Pathology

Due to complex cellular reaction and biological changes, shrinking of the capsular bag is reported to be marked when the eye is predisposed to some pathologies such as pseudoexfoliation (Davison, 1993; Hayashi *et al* 1998a), diabetes (Kato *et al* 2001), glaucoma (Hayashi *et al* 1999a) and retinitis pigmentosa (Nishi and Nishi, 1993; Hayashi *et al* 1998b). Davison reported marked contraction of the anterior capsule in a patient with pseudoexfoliation syndrome requiring YAG laser capsulotomy (Davison, 1993). Hayashi *et al* (Hayashi *et al* 1998a) found reduction in capsulorhexis opening size by 45% in retinitis pigmentosa patients which was significantly higher compared to the control patients (5%). Values of tilt and decentration for various pathologies are compared in *Table 4*.

IOL material and construction

The effect of IOL construction, 1-piece or 3-piece, on tilt and decentration is equivocal. No difference between 1-piece and 3-piece IOL made with PMMA (Auffarth et al 1995) and acrylic (Nejima et al 2006; Iwase and Sugiyama, 2006) materials were reported. In contrast, Mutlu et al (1998) reported significant differences between 1-piece PMMA and 3-piece acrylic IOLs. The results of meta-analysis for studies reporting tilt and decentration for various IOL constructions are reviewed in the *Table 4*.

Table 5
Effect pre-existing pathology on tilt and decentration of IOL Double dash represents unavailable data

Author	Pathology (n)	IOL description	Tilt/Decentration	p (tilt/dec.)
(Hayashi <i>et al</i> 1998a)	PE (53) Control (53)	Both group had Soft acrylic IOL 6mm optic	3.66±2.12/0.28±0.18 2.77±1.97/0.30±0.15	0.024/ 0.36
(Hayashi <i>et al</i> 1998c)	RP (47) Control (47)	Both group had 1pc PMMA IOL 6mm optic	3.54±2.78/0.40±0.32 2.46±1.23/0.26±0.14	0.048/0.002
(Hayashi <i>et al</i> 1999a)	CAG (29) AOG (23) Control (52)	All received soft acrylic foldable IOL	3.99±2.07/0.33±0.26 3.38±2.33/0.30±0.16 2.71±1.93/0.27±0.10	0.03/0.32

All values are mean \pm SA of tilt / decentration. Tilt is measured in degrees and decentration in millimeter. PE – Pseudoexfoliation, RP – Retinitis Pigmentosa, CAG – Closed Angle Glaucoma, AOG – Open Angle Glaucoma, PMMA-Polymethylmethacrylate.

Other factors

The effects of the total diameter of the IOL and the configuration of the loop have been debated. Caballero et al (Caballero *et al* 1995) found significantly less decentration for IOL with a total diameter of 11.0 mm than with those which had overall diameter of 13.5 mm. The authors suggested that the C or J loops comprise of short-contact arch resting against the bag equator, and hence the asymmetric fibrosis, may easily displace the lenses in one direction. In contrast, Legler *et al* (1992) found no difference between IOLs with various loop diameters (12-14 mm). Nejima *et al* (2006) also did not find any difference with haptic angulations (0° & 10°) and materials (acrylic & PMMA). No differences in alignment were observed with optic diameter (Mutlu *et al* 1998, Taketani *et al* 2004), surfaces design (Ohtani *et al* 2009, Taketani *et al* 2005), monofocal or multifocal (Hayashi *et al* 2001, Jung *et al* 2000) and optics material (Baumeister *et al* 2005, Hayashi *et al* 1997).

Discussion

The capsulotomy type and position of the haptics are the two major factors governing the centration of an IOL. In-the-bag implantation of IOL after CCC appears to be the most effective technique (Caballero et al 1995; Colvard and Dunn, 1990). However, capsular tear during CCC, which occurs as high as in 18 % of the cases (Caballero et al 1995), shares a similar effectiveness as can opener and envelope techniques. The capsular tear often extends onto or beyond the equator of the bag creating asymmetric fibrosis and an uneven cul-de-sac which offers uneven resistance to the pressure of the loop (Caballero et al 1995). The haptics closer to the tear therefore may not withstand the force from the opposite haptics allowing the lens to displace towards the direction of the tear (Davison, 1986). Often the lens escapes from the bag in about 30 % by 6 months (Caballero et al 1995), eventually resulting in the effect of asymmetric fixation. It is interesting to note that, unlike an accidental capsular tear, a planned relaxing incision using YAG laser does not affect the centration (Hayashi et al 2008) perhaps

because the relaxing incisions do not extend onto the equator maintaining equal forces from all the directions.

An average tilt and decentration of conventional IOL possesses no adverse clinical impact. Only a large amount of the misalignment may induce clinically significant refractive error which in turn deteriorates the visual acuity. According to a rough criterion, more than 1 mm decentration and a greater than 5° tilt optically impairs visual quality (Guyton et al 1990). An average tilt and decentration of 3° and 0.25 mm respectively, are well below the criteria to affect clinically-observable visual acuity. Optically, $> 0.25D$ of spherical defocus is required to drop Snellen visual acuity by at least one line. Again, an average tilt and decentration, which are equivalent to 0.12D and 0.17D defocus, would not be sufficient to decrease the vision. Nevertheless, a portion of cases falling under the upper limits of normally-occurring misalignment cannot be ignored. About 10 % of the eyes suffer $> 5^\circ$ tilt and > 0.5 mm decentration after an uneventful implantation of PCIOL (Hayashi *et al* 1999a). This is an alarming rate, considering the fact that $> 5^\circ$ tilt may sufficiently deteriorate the retinal image quality even for the conventional IOL.

Theoretical studies suggest that modern designs of IOL, specially multifocal and customized wavefront - correcting, are more sensitive to the misalignment compared to conventional IOLs. Multifocal IOLs, often called pseudoaccommodative IOL (PIOL), represent an early attempt to solve the problem of pseudophakic presbyopia which typically consists of zonal or diffractive zones. When these IOLs are decentered, the zones are asymmetrically exposed in the pupil area which may worsen the visual discomfort (Olson, 2008). While some clinical studies found no adverse effect of average misalignment (Hayashi and Hayashi, 2004; Hayashi *et al* 2009), other studies reported that PIOLs are the most frequently explanted for decentration/dislocation (Table 1).

Aspheric IOL, another modern design of IOL, has gained significant popularity among the ophthalmic surgeons in the last decade (Montes-Mico et al 2009). Aberration-free (designed to produce zero spherical aberration of lens only, e.g. SofPort, Bausch & Lomb) and aberration-correcting IOLs, also called customized wavefront correcting IOL (designed to

partially or completely correcting the corneal aberration e.g. Tecnis, Abbot Medical Optics), are two major categories of aspheric IOLs. According to theoretical reports, these lenses are more sensitive to misalignment (Eppig et al 2009, Montes-Mico et al 2009, Pieh et al 2009). More rapid degradation of the retinal image quality was observed when tilt and decentration were imposed on wavefront correcting IOLs compared to aberration-free and spherical IOLs (Altmann, 2004; Pieh et al 2009; Taberner et al 2007; Taberner et al 2006). Significant coma was observed even within 0.3 mm decentration of wavefront correcting IOLs (Eppig et al 2009). Holladay *et al* (2002) indicated that when the IOL is decentered more than 0.4 mm and tilted more than 7°, the performance of aspheric IOL is worse compared to that of spherical IOL. Altman *et al* (2005) warned the advantage of aspheric IOL is lost when it is decentered by more than 0.5 mm. Wang and Koch (Wang and Koch, 2005) theoretically evaluated the performance of wavefront customized IOL and found that centration accuracy of 0.1 mm is required at 3 mm pupil to exploit the maximum advantage of these IOLs. Contradicting most of the theoretical predictions, a comparative clinical study (Mester et al 2009) found no difference in aberrations when spherical and aspheric IOLs were misaligned. However, the value of precise centration of IOL and accurate measurement of pre-operative aberration of the eye may not be over emphasized to exploit maximum benefit from the customized IOLs.

Accommodating IOL (AIOL), another new development in implant technology, has emerged with rapid progress (Assia, 1997; Dick, 2004; Doane and Jackson, 2007; Menapace *et al* 2007). Performance of such optical device is reported to severely deteriorate in presence of misalignment. 'Z-syndrome' is another name given for specific characteristics of the misalignment (vaulting) of the accommodating IOL (Cazal *et al* 2005, Yuen *et al* 2008, Daniela *et al* 2006). Fibrosis and opacification of the capsules, which are reported to occur in as high as 86 % of the cases (Dogru *et al* 2005), are the major causes. Fortunately, the performance can be restored with the help of YAG capsulotomy (Hancox *et al* 2006).

In summary, excluding some reports of extreme mispositioning (Auffarth et al 1995, Oshika et al

2005), 2 - 3 degree tilt and 0.2 - 0.3 mm decentration represents common misalignment following surgically-uneventful implantation of PCIOLs. Capsule contraction after cataract surgery, to some extent, is a normal phenomenon that may influence the long-term positioning of a lens. Performing CCC as a regular procedure (Gimbel & Neuhann, 1991), complete aspiration of the lens material (Peng et al 2000), capsule polishing (Apple et al 2000), implantation of capsular tension ring (CTR) (Lee et al 2002, Takimoto et al 2008) and atraumatic surgery (Nishi, 1999) are some of the methods suggested to minimize epithelial migration, capsular contraction and fibrosis, which may eventually enhance the better centration of an IOL.

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Conflict of interest: none