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Intraocular Architecture of Secondary Implanted Anterior Chamber Iris-claw Lenses in Aphakic Eyes evaluated with Anterior Segment Optical Coherence Tomography

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Abstract:

<u>Aim</u>: To evaluate the intraocular stability and safety of secondary iris-claw IOLs in aphakic patients.

<u>Methods</u>: 18 eyes of 16 patients received iris-claw intraocular lenses (IOLs) to correct for aphakia. Primary outcome measurements included visual acuity (6m Snellen charts), central endothelium cell count (cECC) and intraocular position of the IOL assessed with anterior segment optical coherence tomography (OCT).

<u>Results:</u> Sixteen patients (mean age 66 years; range 16-84 years, axial length 24.44mm) were re-examined 22 months postoperatively (range 12 - 38months). Preoperative decimal BCVA was 0.51, IOP 15.3mmHg, and central ECC 1816/mm². Postoperative BCVA was 0.68, IOP 13.1mmHg, and central ECC 1626/mm² (difference over time $176/mm^2 = 10.5\%$, p>0.05). The anterior chamber depth was 4 mm for the eyes <24mm, and 4.34mm for \ge 24mm.

<u>Conclusion</u>: Secondary anteriorly iris-claw IOLs appear to be a safe choice to correct aphakia with no significant intermediate postoperative central endothelium cell loss especially in eyes \geq 24mm, as distances of the IOL to the central and peripheral cornea proofed consistent.

The safety and efficacy of secondary IOL-fixation in aphakia has come to attention due to lens design changes during the last two decades. Posterior chamber IOL-fixation (sulcus, trans-sclerally or iris-sutured) is the "classic option" and has the advantage of preserving the natural anatomy of the eye, especially in younger patients. Surgical risks include uveal/choroideal bleeding, especially with scleral sutured IOLs, damage to the blood/aqueous barrier in the ciliary body due to mechanical pressure of the haptics, cystoid macular edema (CME), endophthalmitis because of scleral suture erosion, and in comparison to anterior-chamber IOL implantation a longer surgical time.¹⁻³ The anterior chamber allows for either angle-supported or iris-claw IOL-implantation, which were very popular until the 1980s, until severe complications, such as pseudophakic bullous keratopathy (PBK), uveitis-glaucoma-hyphema syndrome, and chronic cystoid macular edema were associated with primary⁴ and secondary IOL-implantation.^{5, 6} Major advances in modern lens design (open-loop, one-piece all-PMMA IOL) and surgical technique have resulted in less complications^{7, 8} placing the previously poor reputation of these lenses under new scrutiny.

The first iris-claw IOL⁹ demanded a big wound size and induced surgical astigmatism (SIA). The Artisan lens was also condemned of causing PBK or corneal edema leading to decompensation.⁴ This was explained by mechanical irritation to the corneal endothelium because of dynamic IOL-densis in aphakic eyes with scant intraocular distances.⁸ Recently Menezo and Guell et al. didnot notice any of these complications, demonstrating a convincing and safe refractive outcome.^{10, 11} They valued the short operating time with easy insertion and replacing/removing possibility (if neccessary) postoperatively. The preoperative rational regarding intraocular position of secondary IOL-implantation should consider various aspects, which primarily depend on the individual eye (e.g. age of patient, condition of anterior and posterior segment, surgical expertise).

Today the position of anterior chamber IOLs can easily be determined with the use of a precise non-contact anterior segment optical coherence tomography (OCT, figure 1). In comparison to posterior chamber (PC) IOLs there is a scarcity of data concerning irisclaw aphakic IOLs and to our knowledge no report about the intraocular position of the IOL has been investigated yet.

Methods

This retrospective case-series compromised 18 eyes of 16 patients (table 1; 5 female, 11 male) with secondary anteriorly iris-claw IOL-implantation (Artisan® Ophthec BV, Groningen, The Netherlands) by the same surgeon (TK) between October 2003 and December 2005 at the Goethe University Frankfurt /Main, Germany, Department of Ophthalmology. Two patients received bilateral implantation. IOL-implantation was performed in aphakic eyes because of lack of capsular support primarily after failed phacoemulsifacation (n = 10), after trauma (n = 3), complicated retinal detachment (n = 2), intracapsular cataract extraction (n = 2), and lens luxation (n = 1). Anterior vitrectomy was performed in eight and complete vitrectomy prior to secondary IOL implantation in two eyes. In one Marfan's disease patient the subluxated IOL was removed, while in another patient a capsular tension ring was originally implanted and then explanted together with the luxated IOL (table 1).

Indications for surgery were unsatisfactory correction with spectacles or contact lenses for medical, professional, or personal reasons. Exclution criteria were any visually severe preexisting corneal, uveal or retinal disease, or pathology related to the optic disc, and endothelial cell pathologies with dysmorphic or low endothelial cells (less than 1000 cells/mm²). All consented to the possible risks/benefits of the surgery in accordance to the tenets of the declaration of Helsinki.

The following pre- and postoperative data were collected: best corrected visual acuity (BCVA) tested with Snellen charts at a 6m reading distance; intraocular pressure (IOP) measured by applanatory technique; endothelial cell count with the non-contact specular microscope SP8000® (Konan Robo, CA, USA); three consecutive measurements were aquired per timepoint (mean/median values calculated). Biometry was performed with the Holladay IOL-Consultant programme (www.docholladay.com, Houston, USA) using an a-constant of 115.6 and K-readings, white-to-white distance, anterior chamber depth, and axial length assessed with the IOL-master® (Carl Zeiss, Jena, Germany). Surgery (TK) under peribulbar anesthesia with 4ml lidocainhydrochlorid (Xylocain 2%®, AstraZeneca, Wedel, Germany) injection was uneventful and commenced with the preparation of a 5-mm scleral tunnel in the 12 o'clock position and paracenteses at 2 and 11 o'clock. After injecting acetylcholine (Myostat®, Alcon, Rt. Worth, Tx, USA) in the

AC, hvaluronic acid injection (Healon®, Pfizer, New York, NY, USA) was added if necessary. If anterior vitreous prolapsed anterior vitrectomy was performed. The iridectomy at the 12 o'clock position was done with scissors in the eyes without preexisting patent iridectomy (long-standing aphakia, history of previous intracapsular cataract extraction) to prevent a postoperative pupillary block. The IOL was injected (Artisan available in powers from 2 to 30 diopters, 5mm optic and a total diameter of 8.5mm, haptic angle of 0.95 by Ophtec, Groningen, Netherlands) in the AC and rotated into the 3/9 o'clock position and enclavated into the iris. After irrigation of the ocular viscoelastic device (OVD) via the main incision, the scleral tunnel was closed with a 10.0 nylon suture. Topical therapy included combined antibiotic and anti-inflammatory eve drops postoperatively 4 times daily (Isoptomax®, Alcon, Ft. Worth, USA). At the last follow-up visit, anterior segment images were obtained with the anterior segment OCT (Visante[®], Carl Zeiss, Jena, Germany). Seven landmarks were marked by a trained investigator (M.K.) to measure the intraocular distances depicted in Figure 2. Statistical evaluation was performed using the BIAS software (Windows Version 8.2, epsilon-Verlag, Darmstadt, Germany). The Wilcoxon Signed Ranks Test was performed for comparisons between preoperative and postoperative intravariable parameters. Regression analysis was performed to determine how white-to-white measurements related to the AC diameter measurements taken by the Visante OCT (table 5, figure 2) using the method of assessing agreement between two measurements as described by Bland and Altman.¹²

Results

The mean age of all patients was 65.6 ± 17.6 years. The mean axial length was 24.44 mm, with an axial length of smaller than 24mm in 10 eyes (table 3). Mean preoperative BCVA was 0.51 ± 0.29 at 6m Snellen (0.37 LogMar). The spherical equivalent (SE) was preoperatively 9.49 with a cylinder of -0.29 diopters (D). Average IOP was 15.3 ± 3 mmHg. Average central endothelial cell count (cECC) was 1816 ± 731 /mm². The last follow-up examination was performed 22 months postoperatively. Postoperative BCVA was 0.68 ± 0.28 (Log Mar 0.24; p>0.05) and SE was -0.15 with a mean cylinder of -1.0 D. There was no reported postoperative IOP elevation with a mean IOP of

13.1±2mmHg (p>0.05). One case of pupil ovalization and mild iris pigmentation on the vitreous base were without visual symptoms. No intraocular inflammation, retinal damage or other severe adverse events like perioperative bleeding or macular edema occured.

Central ECC was $1626\pm591/\text{mm}^2$ (p<0.05) with a mean endothelial cell loss of $176/\text{mm}^2$, equivalent to 10.5% at the follow-up visit at 22 months. We found no significant difference regarding CECC loss between smaller eyes (<24mm) with smaller ACDs and longer eyes (p>0.15).

The distance from the central corneal endothelium (cCE) to the anterior surface IOL (2) was 2.87 ± 0.34 mm and the distance of the posterior surface of the IOL to the pupillary aperture (4) 0.38 ± 0.16 mm with an anterior chamber depth centrally of 3.25mm (figure2). Peripheral corneal endothelium (pCE) to the anterior surface IOL was temporally (1) 2.34 ± 0.29 mm and nasally (3) 2.38 ± 0.38 mm. The pupillary aperture (5) was 2.9 ± 0.6 mm wide and corneal thickness in the apex of the cornea (7) was 0.56 ± 0.05 mm. The thickness for the IOL was 0.38 ± 0.05 mm, yielding a complete anterior chamber depth of 4.2mm ±0.39 mm as an addition of D2, IOL, D4 and D7). The iridocorneal angle was inclined temporally by $44^{\circ}\pm7.9^{\circ}$ and nasally by $45.7^{\circ}\pm7.5^{\circ}$. Anterior chamber width (6), measured from one corneal reccus to the opposing one, was 11.72 ± 0.5 mm, white-to-white measurements of the IOL Master demonstrated 11.68 ± 0.5 mm values. The Kruskal Wallis test revealed no statistical significant difference between the longer to the smaller eyes (<24mm, marked with * in table 3) in regard to O-ACD (p>0.1) and temp (p>0.6) and nasal iridocorneal angle (p>0.89).

Discussion

The first iris-claw Artisan® (model 205) for the correction of aphakia had a planoconvex configuration and was launched in 1978 by Jan Worst. The pseudophakic bullous keratopathy (PBK) due to corneal endothelial cell loss was hereby described as the most severe late postoperative complication.^{4, 8} The lens was redesigned to a bi-convex configuration, which is available since 1997 and fixated in the midperipheral iris and centered over the pupil thus theoretically not interacting with iris vascularisation. One study however recently indicated iris ovalization after phakic iris-claw IOL-implantation

and associated the ovalization with a lack of iris perfusion on the basis of secondary ischemia.¹³ Mechanical irritation in the anterior chamber from an IOL placed too close to the corneal endothelium, or more likely due to greater IOL-donesis than in phakic eyes, was claimed to be one of the reasons for the greater endothelial cell loss in comparison to posterior chamber IOLs. Amar¹⁴ suggested in 1979 a retrograd implantation to avoid this mechnical irritation, which is still performed ¹⁵ mostly after penetrating keratoplasty^{16, 17} to keep a safe distance to the corneal endothelium. Especially in hyperopic eyes with the danger of iridocorneal angle closure or anterior chamber depth shallowing this may apply, while we could not detect any of these pathologies, with safe anterograd enclavation. The comparison between our smaller (<24mm, marked with a * in table 3) to our longer eyes in regard to postoperative ACD (table 4) leading to a statistical significant difference, which might point to a posterior enclavation in our smaller eyes in the future.

Postoperative endothelial cell loss was 10.5% in our study over 20 months, with two eves indicating a gain of central endothelial cells (patient 1,8). The reason for this increase is speculative and may be attributed to peripheral cell migration after surgery following the termination of an aphakic soft contact lens. The greatest decrease in endothelial cell density is observed during the first 12 to 20 months (10.5%) and most likely related to the surgical trauma similar to the one year decrease of 7.78% after phakic iris-claw IOLimplantation as found in the studies by Menezo and colleagues.¹⁸ Guell et al. reported a slightly higher cumulative loss of 10.9% in the first three years after secondary Artisan-Verysise aphakic implantation.¹⁰ The non-contact anterior segment OCT is unique as it does not compromise the corneal architecture and squeeze the AC and thus providing exact intraocular measurements including details of the engrasped iris and both iridocorneal angles (figure 2). Our recordings were performed in sitting position, which has been previously shown to be reproducible.¹⁹ No Artisan dislocation or major IOLdonesis although we admit that non-dynamic intraocular distances might be different when reclining or in the supine position were detected. The sitting position is much more clinically relevant in terms of everyday life conditions, whereas examinations with the contact anterior segment ultrasound would mimic much more the sleeping position at night, which has a higher likelihood of IOL and corneal endothelium narrowing. We

correlated the OCT distance between the angles (6) to the postoperative white-to-white values of the IOL Master®. The IOL Master detects the corneal limbus automatically by comparing the grey-scale steps and then calculates the corneal diameter. The mean difference between both distances was 0.04mm, which is far smaller than comparisons in phakic healthy eyes.¹⁹ No IOL-revision due to cramped intraocular distances was performed.

We confirmed excellent refractive results, consistent with other groups.^{10, 11} The mean preoperative spherical equivalent (SE) was reduced from 9.97 diopters (D) to -1.24D postoperatively. Postoperative BCVA improved in 15 of 16 patients from 0.51 (0.38 LogMar) to 0.68 (0.23 LogMar), with only one female patient (number 1), losing one line in the one eye. In our opinion this was due to the increased SIA caused by the incision being placed at 12 o'clock. The mean preoperative cylinder was -1.28D, which increased to -2.00D postoperatively and could not be corrected. Refractive predictability and efficiency were satisfactory with over 75% of our patients proving a final visual acuity of 0.5 or better. None of our patients had iris dispersion after surgery, while slight pupil ovalization occured in one patient (number 11) and iris pigmentation of the anterior vitreous in one other (number 5), both undisturbing to the patients. In three patients mild cornea guttata was noted. No CME was detected in any of our patients and we suspect that this was due to the shorter operating time with undilated pupil.²

Shortcomings are the small patient number, the variable postoperative follow-up visits, the diversity of pathology and the varied number of secondary iris-claw aphakic eyes, limiting the comparisons that could be made.

Iris-claw aphakic IOLs offer similar or even better BCVA than with the posterior chamber secondary aphakic IOLs, which is not always possible and feasible, whereas the iris-claw surgery technique has a quick and easy learning curve. Apart from the aphakic indications, the lens has the potential to serve as a low-cost, easy implantable option after uncomplicated intra-capsular cataract extraction (ICCE) in developing countries, where cataracts are the leading cause of blindness and microsurgical technology is limited. It would mean a viable alternative to aphakic spectacle correction in millions of people. In 2002 a new silicone iris-claw 6mm optical zone with newly designed PMMA haptics was introduced allowing for a smaller incision (2.75 / 3.2mm) and resulting in less SIA. This

successful introduction of the flexible iris-claw IOL (Artiflex) in phakic eyes, especially in highly myopic eyes, offers an additional alternative in the correction of aphakia, which has already been demonstrated in some patients.²⁰

The evaluation of safety and efficacy of modern AC IOLs in comparison to PC IOLs has been ongoing. Wagoner et al. presented a comprehensive literature review of 89 articles (summarizing data between the years 1980 and 2001) and Donaldson et al compared newer AC IOLs to PC IOLs in a large comparative clinical study with 189 eyes. Neither could provide evidence to demonstrate superiority of one lens type over the other.²¹ With the comparison of clinical data to modern anterior segment images, like the OCT, we could demonstrate convincing evidence in favor for secondary iris-claw IOLs with excellent stability and efficiency in longstanding and compromised aphakic eyes. Reference

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Figure legends:

Figure 1. Secondary Irix-Fixated Artisan IOL in an Aphakic Eye; note the enclavation of the iris claw

Figure 2. Sketch of the Artisan with the 7 Landmarks set in the Anterior Chamber

Figure 3. Bland Altmann Plots comparing the Horizontal AC Diameter using the Visante and the WTW value of the IOL Master

Case No.	Eye/Age/Sex	History	Follow-Up (months)	Surgical Management
1	L/84/F	FP	31	IE
2	R/84/F	FP	31	IE
3	L/61/M	FP	18	IE, IP
4	L/56/W	FP	15	IT
5	L/80/M	LL	14	-
6	R/63/W	FP	29	IE, rCTR
7	L/16/M	M,IC	20	-
8	L/68/M	FP	38	IE, aV
9	L/75/M	FP	21	IE, aV
10	R/68/F	AG,IC	17	IE, aV, S
11	L/76/F	AG,FP	14	IT, aV
12	L/78/M	FP	12	IE, aV
13	R/78/M	FP	12	IE, aV
14	L/37/M	RD	12	IP, V
15	L/74/M	Р	28	IE
16	R/74/M	Р	32	CS
17	R/47/M	RD	34	IE, V
18	R/63/M	P, IC	17	aV

Table 1. Epidemiology and History of the Patients;

R right eye, L left eye, M male, F female, A lack of capsular support, B aphakia after trauma FP failed Phaco, M Marfan's syndrome, LL lens luxation, P perforation, IE, irdiectomy, IC intracapsular cataract extraction, IT YAGiridotomy, aV anterior Vitrectomy, V vitrectomy,AG acute Glaucoma, rCTR removal of capsular tension ring, S synechiolysis, RD retinal detachment, IP irisplastic, CS corneal suture

Case	PreOP	PostOP	PreOp	PostOp
No.	BCVA	BCVA	LogMar	LogMar
1	0.40	0.32	0.40	0.50
2	0.40	0.50	0.40	0.30
3	1.00	1.00	0.00	0.00
4	0.63	1.00	0.20	0.00
5	0.63	0.80	0.20	0.10
6	0.10	0.80	1.00	0.10
7	0.32	0.67	0.50	0.18
8	0.20	0.32	0.70	0.50
9	0.80	1.00	0.10	0.00
10	0.63	0.50	0.20	0.30
11	0.40	0.50	0.40	0.30
12	0.50	0.63	0.30	0.20
13	0.67	1.00	0.18	0.00
14	0.10	0.10	1.00	1.00
15	0.32	0.67	0.50	0.18
16	0.32	0.40	0.50	0.40
17	1.25	1.00	-0.10	0.00
18	0.50	1.00	0.30	0.00
Mean	0.51	0.68	0.38	0.23
Median	0.45	0.70	0.35	0.18

Table 2. Pre- and Postoperative VisualAacuity; Best Corrected Visual Acuity =BCVA, converted to LogMar

Case No.	AC width (D 6)	White to White
1	11.48	11.50
2	11.49	11.50
3	12.48	11.00
4	11.93	11.90
5	11.20	10.70
6	11.83	11.80
7	11.90	11.90
8	11.77	12.20
9	12.42	12.50
10	11.33	11.30
11	10.52	10.90
12	11.91	11.90
13	11.80	11.80
14	12.55	12.80
15	10.93	11.60
16	12.74	11.30
17	11.94	11.80
18	12.13	11.90
Mean	11.72	11.68
Median	11.82	11.80
SD	0.53	0.53
Minimum	10.52	10.70
Maximum	12.55	12.80

Table 5. Anterior Chamber (AC) Width equals D6 (please see figure 2a,b) measured with the Anterior Chamber OCT versus White-To-White measurement of the IOL Master

Case No.	Axial Length	PreOP AST	PostOP AST	PreOp SE	PostOP SE	PreOP cECC	PostOP cECC	F/U	PostOP Varia
1	26.3	-2.00	-2.00	7.00	-1.00	1400	1788	31	-
2	26.75	-1.00	-5.50	6,75	1.00	1800	1800	31	-
3	26.71	-0.25	-0.50	7.50	-2.50	1942	1574	18	-
4	28.97	-1.75	-2.00	5.00	-1.50	1589	1501	15	-
5	24.91	-0.25	-1.50	9.00	-1.75	1450	1381	14	PoV
6	23.09*	0.00	-1.00	10.00	-1.00	1600	1385	29	-
7	23.7*	-3.50	-1.00	9.50	-1.50	4000	3200	20	-
8	23.71*	-1.75	-1.75	11.50	-0.50	1100	1600	38	-
9	23.30*	0.00	-0.50	11.75	0.75	1869	1700	21	-
10	21.65*	-1.75	-1.50	16.00	-1.75	2457	1900	17	-
11	21.49*	0.00	-3.75	15.00	-2.00	1153	1017	14	PO
12	25.64	-2.50	-3.00	10.25	-0.25	2000	1480	12	-
13	25.1	-2.00	-5.00	9.50	-2.00	1600	1600	12	-
14	29.12	0.00	-0.50	4.75	-0.25	2750	2700	12	-
15	22.65*	-3.25	-2.25	14.00	-2.00	1000	741	28	CG
16	22.76*	-2.00	-3.00	10.75	-2.50	1000	700	32	CG
17	23.0*	0.00	-1.75	11.75	-0.25	2300	1657	34	-
18	24.56	-0.25	-0.50	9.50	-0.25	1680	1550	17	CG
Mean	24.44	-1.28	-2.00	9.97	-1.24	1816	1626	21.9	
Median	24.14	-1.38	-1.75	9.75	-1.50	1640	1587	19	
SD	2.26					731	591	8.7	
Minimum	21.5					1000	700	12	
Maximum	29.1					4000	3200	38	

Table 3. Pre- and Postoperative; Axial length in mm, eyes smaller than 24mm are marked with a *, Refractive Parameters; Subjectiv Corrected Astigmatism = AST, Spherical Equivalent = SE, F/U = follow-up in months, Central Endothelial Cell Count = cECC, CG = Cornea Guttata, PoV = Pigment on Anterior Vitreous, PO = Pupil Ovalization

Case No.	D 1	D 2	D 3	IOL	D 4	D 5	D 7	O-ACD	A Temp	A Nasal
1	2.89	3.43	2.77	0.37	0.24	2.69	0.61	4.65	57.2	48.2
2	2.66	3.24	2.39	0.31	0.37	2.10	0.62	4.54	51.1	59.5
3	2.12	3.14	2.33	0.33	0.31	2.59	0.53	4.31	48.8	52.5
4	1.90	3.24	1.57	0.41	0.35	2.73	0.56	4.56	40.3	42.2
5	2.11	2.73	2.19	0.45	0.21	2.70	0.55	3.34	38.2	40.1
6	2.16	2.80	2.17	0.37	0.31	2.04	0.52	4.0*	57.5	41.1
7	1.97	2.19	2.19	0.34	0.33	4.57	0.54	3.4*	32.8	45.3
8	2.17	2.66	2.48	0.29	0.39	2.53	0.51	3.85*	46.4	47.7
9	2.59	2.94	2.84	0.34	0.26	2.73	0.51	4.05*	46.8	50.5
10	2.33	2.83	2.41	0.37	0.22	2.48	0.56	3.98*	40.1	50.7
11	2.05	2.16	1.60	0.41	0.31	3.84	0.55	3.43*	38.4	26.2
12	2.38	2.88	2.27	0.44	0.43	3.42	0.59	4.34	35.8	48.3
13	2.63	3.02	2.73	0.43	0.30	2.87	0.58	4.33	58.2	41.3
14	2.53	2.96	2.69	0.41	0.71	3.00	0.63	4.71*	43.5	51.9
15	2.01	2.62	2.14	0.37	0.65	2.87	0.55	4.19*	42.2	41.2
16	2.62	3.05	2.80	0.43	0.20	3.10	0.55	4.23*	35.9	40.1
17	2.68	3.11	2.79	0.45	0.65	3.02	0.48	4.69*	40.6	53.9
18	2.38	2.70	2.39	0.49	0.59	2.45	0.65	4.33	37.6	40.8
Mean	2.34	2.87	2.38	0.38	0.38	2.87	0.56	4.2	43.9	45.6
Median	2.35	2.91	2.39	0.38	0.32	2.73	0.55	4.27	41.4	46.5
SD	0.29	0.34	0.38	0.05	0.16	0.60	0.05	0.39	7.87	7.47
Minimum	1.90	2.16	1.57	0.29	0.20	2.04	0.48	3.4	32.80	26.20
Maximum	2.89	3.43	2.84	0.45	0.71	4.57	0.65	4.7	58.20	59.50

Table 4. Mean, Median, Standard Deviation (SD), Minimum, Maximum Results of the Intraocular Distances 1-7 (please see figure 2a,b) measured in mm; Distance 1 thru 7 = D 1-7, Anterior Chamber Angle temporally = A Temp, Angle nasally = A Nasal; measured in Degrees, eyes smaller than 24mm are marked with a *.







Figure 1. Secondary iris-claw Artisan IOL in an aphakic eye; note the enclavation of the iris claw



Figure 2. Sketch of the Artisan iris-claw with the 7 landmarks set in the anterior chamber



Figure 3. Bland Altmann plots comparing the horizontal AC diameter using the Visante and the WTW value of the IOL Master