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Comparing Ultrasound applanation Biometry and Partial Coherence Interferometry, for Axial length Measurement and Intra ocular lens Power Calculation: A Randomized Clinical Trial

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Abstract

Objectives: This study was done to evaluate and compare PCI and AUS measured axial lengths and accuracy of IOL power calculation using UBII IOL power calculation formula.

Methods: patients undergoing cataract surgery underwent ocular biometry and IOL power calculation using PCI and AUS using Universal Barrett II formula. The subjects were randomized into 2 groups PCI and AUS respectively to receive the IOL power accordingly. The post op refractive spherical equivalent was evaluated and the groups were compared using residual refractive error and absolute residual refractive error at 6 weeks post-op.Comparison of axial length, IOL power between the two groups was done using the Bland-Altman plot and the agreement between the predicted refraction and the final refraction in both groups was compared using paired student-T test or Mann-Whitney test.

Results: Total 119 subjects were analyzed with 61 and 58 subjects in the Group PCI and AUS respectively. The two groups (PCI and AUS) comparable with reports to age, gender and laterality. The average axial length, predicted IOL power, residual refractive error and absolute residual refractive errors were statistically similar between both the groups.

Conclusions: The PCI and AUS are similarin measuring ocular axial length and can be used interchangeably with UBII formula for reasonable post cataract surgery refractive accuracy.

Keywords: PCI (Partial Coherence Interferometry); AUS (Applanation Ultrasound biometry); IOL (Intra Ocular Lens), Universal Barrett II; IOL master 500; PSC ((Posterior Subcapsular Cataract); Mature Cataract; Immature Cataract; Keratometry; Axial Length.

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Introduction

Inaccuracies in ocular biometry, either arising from the measurements themselves or associated underlying assumptions, account for 27% of the refractive surprises.[1] Hence the accuracy of measurement of axial length is of pivotal importance to achieve the desired refractive outcome. Presently the two most popular methods of measuring the axial lengths are Optical biometry (Partial Coherence Interferometry; PCI) and Applanation Ultrasound biometry (AUS).[2] Though the literature has sided with PCI as the more accurate method,[3,4,5] the PCI fails to measure axial lengths with optimum signal to noise ratio in cases with significant media opacities and this can range from 10% to 36%.[6,7,8,9,10] When it comes to developing countries, the cataracts are denser and there is a higher prevalence of white cataracts, where the PCI fails to measure the axial length. Many centers are not equipped with the more expensive optical biometers and use AUS for biometry. Thus, for the above mentioned reasons, the role of ultrasound

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will remain there despite emerging technologies in optical biometry. The studies which have compared PCI to AUS for measuring the ocular parameters to calculate IOL power have used the older IOL power calculation formulas which can induce error in IOL power calculation in comparison to 4^{th} generation formulas.[11,12] In this study we have compared the PCI and AUS in terms of axial lengths, IOL power, and post cataract surgery refraction using the 4^{th} generation IOL power calculation formula (Universal Barrett II formula). To our knowledge, this comparison has not been done in the Indian population yet.

The study hypothesis is that the measurement of the axial length of the eye and the IOL power calculated for eyes undergoing cataract surgery using Partial Coherence Interferometry (PCI) and Applanation Ultrasound Biometry (AUS) are comparable when Intra Ocular Lens power is calculated using the Universal Barrett II formula.

Methods

This was a prospective double blind randomized clinical trial involving patients presenting in the department of ophthalmology at a tertiary care teaching hospital with visually significant senile cataract.Subjects were screened for inclusion and exclusion criteria (Table 1) and included in the study after taking informed consent. The study was approved by theInstitutional Ethics Committee and conducted following the tenets of the Declaration of Helsinki.

After the subjects were included in the study, they were randomized into two groups, Group PCI (partial coherence interferometry biometry using IOL master 500 (Carl Zeiss Meditec, Bengaluru, India)) and Group AUS (Applanation ultrasound biometry using A-scan Biometer (Echorule PRO Biomedix Optotechnik & Devices Private Limited, Bengaluru, India).

Intra Ocular Lens power was calculated using the Universal Barrett II formula (UB II)suiteavailable at the APACRS site[13] for all the subjects using axial lengths measured by PCI & AUS. The UB II formula allows the input of lens thickness as an optional parameter, which is not measured by PCI (IOL master 500) so the lens thickness was used only with axial length obtained AUS group when calculating the IOL powers. The first myopic IOL power was selected for implantation during the cataract surgery as per the UB II formula. The subjects allotted to the respective groups were implanted with the IOL power as per the designated group (PCI or AUS). A preloaded hydrophobic Monofocal IOL was implanted (Supraphob, Appasamy associates, Chennai, India) after 2.8 mm Clear corneal phacoemulsification as described by Sanjiv et al.[14] The final refractive status at 6 weeks after the surgery was evaluated in terms of spherical equivalent power in diopter, the residual refractive error (postop spherical equivalent power minus predicted spherical power), and absolute residual refractive error were compared between the two groups and analyzed.

A sample size of ~100 subjects was reached upon considering a confidence level of 95%, confidence interval of 10, and population of 4000 (the total number of patients operated in the hospital unit in a year). Thus, we planned to screen 150 subjects assuming a 20% dropout rate. As is known that PCI is unable to measure the axial length in mature cataracts and dense PSC (Posterior Subcapsular Cataract) we shifted these patients to Group B and used the axial length as measured by the AUS for the IOL power calculation.

The statistical analysis was done to compare the axial lengths between the two groups using the **Bland Altman** (B & A) **plot** and mountain plot. The agreement between the predicted refraction and the final refraction in both groups was compared using paired student T test or Mann Whitney test. The Chi square test was used to compare the grades of post op refractive errors between the groups.

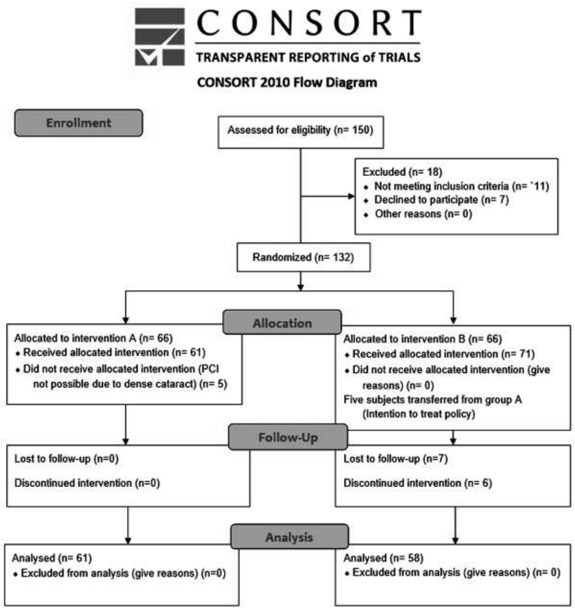
Results

A total of 150 subjects were screened against the exclusion criteria (Table 1)

Table 1: Exclusion criteria for screening subjects.

Exclusion Criteria
Intraoperative and postoperative complications.
Pre-existing astigmatism >2.5D
History of previous ocular surgery.
Presence of associated ocular pathologies (such as uveitis, zonular dialysis, corneal disease or dystrophy, glaucoma).
Diabetic retinopathy.
Uncooperative for PCI (IOL master)
Uncooperative for phacoemulsification under topical anesthesia

and 132 subjects were randomized into Group PCI and group AUS. Five subjects had to be shifted from group PCI to group AUS due to a very dense cataract which precluded axial length measurement using PCI. Thirteen subjects were lost to follow up due to various reasons and thus finally, 119 subjects were analyzed with 61 and 58 subjects in the Group PCI and AUS respectively (Figure 1. CONSORT flow chart).



The demographic features of the study group have been presented in Table 2.

Table 2: Demographic details of the study population and the groups. (PCI-Partial Coherence Interferometry, AUS-Applanation Ultrasound).

	Group PCI	Group AUS	Total	
Gender				
Females	31	30	61	P=0.93
Male	30	28	58	
Laterality				
Right	28	29	62	P=0.79
Left	33	29	57	
Age (Years) Median	58	58		P=0.64

The two groups (PCI and AUS) were symmetrical regarding the age, gender, and eye planned for the surgery. The clinical characteristics of the two groups are depicted in Table 3, which shows a significant difference in the pre-op visual acuity between the two study groups (p<0.0001). The frequency of the types of cataracts was also significantly different between the groups (p=0.008). This difference in the visual acuity and the types of cataracts was different because of mature cataracts being exclusively allotted to the AUS group. Once we excluded mature cataracts (10, 8.4%), which were exclusively allotted the AUS group, the frequency of the types of cataracts between the groups was symmetrical (p=0.91).

Table 3: Preop clinical data of the subjects in the two groups.

	Visual aquity (Log MAR)		Cataract Type					Average Keratometry		Axial lengths (mm)			IOL power		
	Preop (Avg, SD, Range)	P value (Mann-Whitney test)	IMSC	Mature cataract	Posteri or polar catara ct	PSC	P value (Chi-squared test)	Median (Average, Range)		Average (SD, Range)	Median	P value (Student t test)	Average (SD, Range)	Median	P value (Mann-Whitney test)
Group PCI (n=61)	1.0 (0.78, 0.18-1.0)	p<0.0001	55	0	1	5	p=0.0087	44.7 (44.47, 40.84-47.67)	p=0.60	23.27 (1.2, 19.59-27.16)	23.3	0.4	20.85 (2.95, 11.5-29.5)	21	0.59
Group AUS (n=58)	1.4 (1.51, 0.18-3.0)		44	10	1	3		44.29 (44.26, 33.02-48.88)		23.13 (1.25, 19.65-27.3)	23.2		21.0 (2.96, 12-29.5)	21	

Average keratometry was similar between the groups (p=0.6).The average axial length measured using PCI (107) and AUS (119) were statistically similar when compared using the studentt-test (p=0.4) (Table 3). The axial lengths as measured by PCI and AUS had a correlation coefficient of 0.99 (p<0.0001), indicating excellent agreement between the two methods (Figure 2).

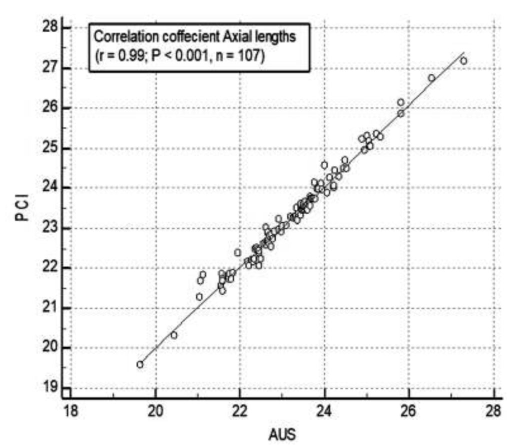


Fig. 2: Scatter diagrtam showing correlation between the axial lengths as measured using AUS (Applanation Ultrasound) Vs PCI (Partial Chorerence Interferometry).

We classified the eyes as short (<22mm) 22 eyes (18.5%), Medium (22.1-24mm) 83 eyes (69.7%), long (24.1-26) 12 eyes (10.1%), and very long (>26mm) 2 eyes (1.7%) based on AUS as there were few eyes where PCI failed to measure axial length. The distribution of these types of eyes was statistically similar between the groups (p=0.12).

The regression analysis showed the following relation between the axial lengths measured using AUS and PCI as per the givenequation for the range 19.65-26.3 mm (Figure 3).

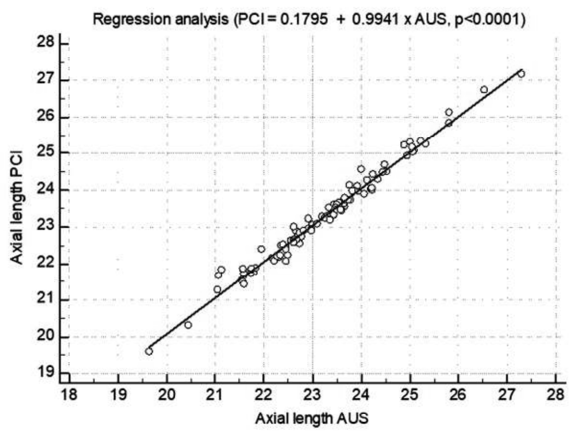


Fig. 3: Regression analysis showing relation between axial lengths as measured using PCI and AUS and equation repesenting the relationship.

PCI = 0.1795 + 0.9941xAUS ($p<0.0001$)

The Bland-Altman plot and the mountain plot to compare the agreement between the PCI and AUS in measuring the axial length is shown in Figure 4a & 4b, where it is showingthat 95.8% cases were within the limits of agreement which is considered an adequate agreement between the two diagnostic modalities.[15]

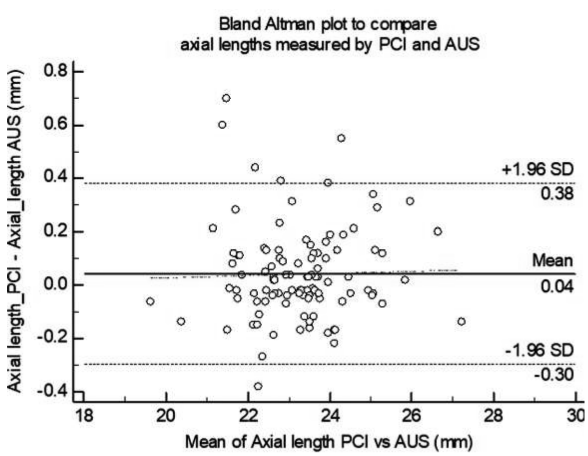


Fig. 4a: Bland Altman Plot comparing axial length as measured by PCI & AUS.

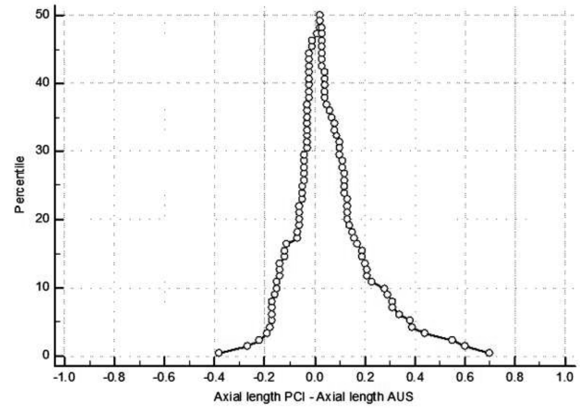


Fig. 4b: Mountain plot comparing axial length measured by PCI & AUS.

The average IOL power as calculated using axial lengths measured using PCI and AUS were 20.85D (SD 2.95, range 11.5-29.5D) and 21.0 D (SD 2.96, range 12.0-29.5 D)respectively (Table 3). This was statistically similar in both the groups with a pvalue of 0.59 (Mann-Whitney test). There was a statistically significant correlation (Correlation coefficient 0.98, $p<0.0001$) between the IOL power calculated by using axial lengths measured using PCI and AUS.

As is known, a change of 1 mm in the axial length may result in a change of 2.5 diopters in the IOL power calculation. When the IOL power-induced error is translated to the error in the refraction it is known that half of this error is reflected as the change in the refraction of the eye. Thus, an error of 1 mm in the measurement of axial length will result in induced refraction of ~1.25 D.[17] Considering that the residual refractive error of more than 0.75 may not be an acceptable outcome, we identified the cases where the disagreement between PCI and AUS was more than 0.5mm.

There were 6 such cases, 3 cases in each of the two groups. Bland-Altman plot to compare the two diagnostic techniques also revealed that there were 6 (4.2%) cases out of 119 cases that lay outside the limits of agreement (0.68 mm) when comparing the axial lengths measured by PCI and AUS (Bland Altman plot, Figure 4a). when comparing the IOL power calculated using the axial lengths measured using PCI and AUS there were 6 (5.0%) cases that lay outside the limits of agreement (Bland Altman plot, Figure 5).

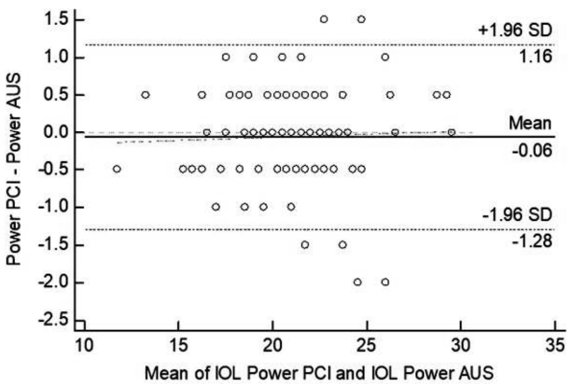


Fig. 5: Bland-Altman plot comparing the IOL power calculated using PCI & AUS.

The refractive outcomes at 6 weeks after the surgery is presented in Table 4.

Theaverage target post op refraction was -0.26 D as the target refraction was minimum myopia among all the subjects. For subjects having preexisting myopia since an early age,it was 2nd or 3rd myopic IOL power as it is desirable to leave them myopic as per their convenience and habit.[18] The average refraction at the end of 6 weeks was -0.51 D for all the subjects and -0.59 D and -0.43 D for the groups PCI and AUS respectively (P=0.44). It may be worth mentioning that though the post-op refraction was targeted to be myopic in all the subjects, however, there were 3 (4%) and 9 (15%) subjects in the PCI group and AUS group who ended up with hypermetropic refraction more than 1.0 D. Residual refractive error (Post-op refraction minus Target refraction) was similar in both the groups and the difference was statistically insignificant (p=0.68).

Table 4: Post-op refractive outcomes and comparison between the group PCI and Group AUS `showing statistical similarity between the two groups.

	Average All subjects (119) (SD, Range)	**Average PCI (61) Group (SD, range)**	**Average AUS group (58) (SD, Range)**	**p value**
Target refraction	-0.26 (0.36, -1.2 to 0.8)	-0.3 (0.33, -1.0 to 0.7 D)	-0.22 (0.39, -1.2 to 0.8 D)	0.27
Post-op refraction	-0.51 (1.09, -3.5 to 2.0)	-0.59 (1.01, -3.5 to 1.5 D)	-0.43 (1.17, -2.75 to 2.0 D)	0.44
Residual refractive error	-0.24 (1.13, -2.7 to 2.3)	-0.28 (1.07, -2.7 to 2.1 D)	-0.20 (1.20, -2.3 to 2.3)	0.68
Absolute residual refractive error	0.93 (0.68, 0 to 2.7)	0.84 (0.71, 0.0 to 2.7)	1.03 (0.63, 0.1 to 2.35)	0.12
	Number of subjects (%)	**n (%)**	**n (%)**	
Absolute residual refractive error <1.0	72 (60.5%)	41 (67.2%)	31 (53.4%)	0.17
Absolute residual refractive error>1.0	47 (39.5%)	20 (32.8%)	27 (46.6%)	

The absolute residual refractive error was greater in the AUS group when compared to the PCI group but this difference was statistically insignificant (p=0.12). The data distribution comparing the absolute residual refractive errors is presented in figure 6.

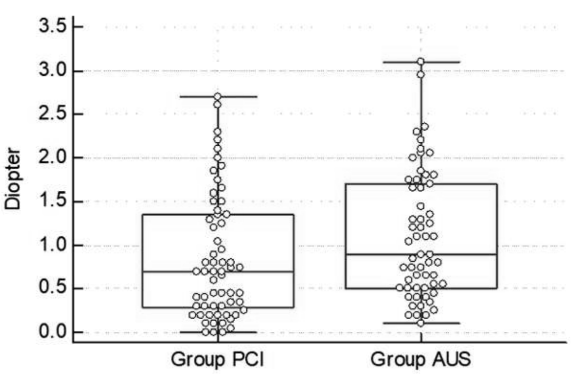


Fig. 6: Box & Whisker plot comparing Absolute residual refractive errors between the two groups. (Mann-Whitney test, p=0.05).

The number of subjects within 1 Diopter of absolute residual refractive error was 41 (67.2%) and 31 (53.4%) within the PCI and AUS groups respectively (p=0.08). There were 47 subjects with absolute residual refractive error >1.0D (20 (32.7%) in PCI group and 27 (46.5%) in AUS group, p=0.41). Thus,the PCI group had a greater percentage of subjects within +/- 1.0 D of the desired refraction butit was statistically insignificant.There were 2 cases with absolute residual refractive error of more than 2.5 D, both the cases in the PCI group.

Discussion

The subjects in the groups PCI and AUS were comparable in terms of gender, age, and laterality establishing the congruency between the two study groups. The distribution of the types and maturity of the cataracts were not comparable as the subjects with mature and dense cataracts were shifted to the ultrasound group because of the inability of the IOL Master 500 to measure the axial lengths in eyes with dense media opacity. This also caused lower pre-operative visual acuity in the AUS groups when compared to the PCI group.

Axial lengths measured using PCI and AUS were comparable with reasonable agreeability in our study (p=0.4). This has been seen in other studies as well.[19,20,21,22] A study by Nakhli FR[21] has estimated a linear equation establishing a relation between axial lengths measured using PCI and AUS, which is very similar to the relation derived in our study. The mountain plot and Bland-Altman plot are used to compare diagnostic tests against each other to visualize the agreement between the measurements done by two different methods. Agreement of more than 95% of the readings within 2 standard deviations from the mean of the differences measured by the methods in question validates the compared methods when tested by the Bland-Altman plot.[15] In our study we had 95% of the axial lengths falling between the defined limits demonstrating good agreement between PCI and AUS techniquesand this has been seen in the studies by other authors as well.[5, 21,23]

The IOL power calculation was done for all the patients using both the techniques except for the subjects in which PCI failed to measure the axial lengths due to media opacity(Group PCI =107, Group AUS =119). The average IOL power calculated for the subjects using axial lengths measured using PCI and AUS was 20.85D and 21.0D respectively and was statistically similar (P=0.59). The IOL power calculation was done using the UB II formula and the parameters as provided by the IOL master 500 except for the axial length and ACD which was derived using PCI or AUS. As the axial lengths were in good agreement between the two groups hence it was reasonable that the IOL power between the two groups will also in agreement as seen in other studies as well.[9,24] The similarity between the IOL powers between the two groups was also tested using the Bland Altman plot which also confirmed the good agreement between the two groups (95% cases between the limits of agreement).

The post op refractive status of the patients can be considered to be the litmus test for the accuracy of biometry done by the two techniques. The post op refractive status is illustrated in table 4.As mentioned, the target refraction was not emmetropia so we did our analysis on the residual refractive error (post op refraction target refraction) and absolute residual refractive error. The results showed that the average residual refractive errors in both the groups PCI and AUS were comparable with the average being -0.28D and -0.20 respectively (p=0.68). The absolute residual refractive error was 0.84D and 1.03D in the respective groups (p=0.12). Table 4 illustrates the absolute residual refractive error in the two groups as per the categories of <1.0D and more than 1D. It can be seen that the subjects with absolute residual refractive error with >1D were more in the group AUS but this difference was statistically insignificant (p=0.17). Thisindicates that the PCI provides better accuracy in IOL power calculation but the difference is statistically insignificant when compared to AUS. It has been observed and recommended in various studies that nearly 70% to 85% of cases fall within +/- 1.0D of refraction after cataract surgery.[25,26,27] In our study we had 60.5% of cases within +/-1.0D of refraction at the end of the observation period.

Conclusion

The PCI and AUS are comparable for the measurement of axial lengths and can be used interchangeably without inducing significant error. The axial lengths measured by AUS are marginally smaller when compared to PCI and this can be corrected by using the given equation.

The IOL powers predicted for a given target post-op refraction using axial lengths provided by PCI and AUS using the UBII formula are in good agreement for the axial lengths between 19.5-27.16 mm as seen in the study.

The post op residual refractive error (Post op refraction-target refraction) and absolute residual refractive error are statistically similar when comparing the PCI and AUS provided axial lengths.

Thus, the AUS and PCI can be considered as a reliable replacement for each other and considering the cost difference between the two techniques the health care provider can invest in any of the technique looking at the other relevant issues like cost, convenience, patient turnover, and sterilization without compromising the clinical and refractive outcomes.

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