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Novel Radiation Dose Reduction Fluoroscopic Technology Facilitates Chronic Total Occlusion Percutaneous Coronary Interventions

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Short Title: Dose-Reducing Fluoroscope Facilitates CTO-PCI

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ABSTRACT

Aims – Radiation exposure and prolonged procedure time continue to limit the complexity of CTO-PCI procedures attempted. This study aimed assess the impact of radiation-dose-limiting equipment on radiation dosage and fluoroscopic time in chronic total occlusion (CTO) percutaneous coronary interventions (PCI).

Methods and Results – Retrospective clinical and dosimetric data from diagnostic catheterizations (DXC) and CTO-PCI procedures performed on one of three variants of interventional fluoroscopic equipment were collected. Fluoroscopic time, air kerma, kerma area product and contrast utilization were stratified by procedure type and compared between equipment types. To standardize comparisons between equipment configurations, an Efficiency Index (EI) was calculated.

In total, 2947 DXC and 276 CTO-PCI procedures were studied. For DXC, radiation dose (AK) decreased by 45% (despite modest increases in fluoroscopic time (FT)) between the reference (REF) and moderately dose-optimized (ECO) machines. A further 20% decrease in AK was observed on the highly dose-optimized machine (CLA). For CTO-PCI, AK declined by almost half (43%), despite a 76% increase in FT and higher procedural success rates (69.8% versus 83.0%) between REF and CLA.

Conclusions – Novel dose-optimized fluoroscopic equipment allows longer FT with a decrease in radiation dose to both patient and operator. This should allow operators to undertake increasingly longer and more complex procedures and reduce operators' lifetime irradiation.

Key Words: Chronic coronary total occlusion, Clinical research, Innovation, Multiple vessel disease, Radiation protection

CONFLICT OF INTEREST DISCLOSURES

Dr. Stephen Balter: No relevant disclosures

Mr. Matthew Brinkman: No relevant disclosures

Dr. Sanjog Kalra: Speaker's bureau: Abiomed, Servier Canada

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ABBREVIATIONS LIST

AK	Air Kerma
BSA	Body Surface Area
BMI	Body Mass Index
CLA	Allura Clarity FD 20 system
CTO	Chronic Total Occlusion
CVOL	Contrast Volume
DXC	Diagnostic Cardiac Catheterization
ECO	Allura Xper FD 20 system
EI	Efficiency Index
FT	Fluoroscopic Time
Gy	Gray
KAP	Kerma Area Product
mGy	Milligray
PCI	Percutaneous Coronary Intervention
REF	Allura Xper FD 10 system
RSI	Radiation-induced Skin Injury

CONDENSED ABSTRACT

Chronic total occlusions percutaneous interventions are technically challenging procedures that require comparatively longer procedural times and higher radiation exposures. Herein, we studied radiation use, fluoroscopic time, and contrast volume delivered during 2947 diagnostic cardiac catheterizations (DXC) and 247 chronic total occlusion percutaneous coronary interventions (CTO-PCI) performed on one of three fluoroscopic imaging machines. We observed a decrease in radiation dose during both DXC and CTO-PCI (45% and 43%, $p<0.0001$) respectively, between procedures performed on a "2005 reference" system and those performed on a novel dose-optimized system, despite marked increases in fluoroscopic time and no change in contrast use. Our results indicate that radiation-optimizing fluoroscopic equipment may allow the safe undertaking of increasingly complex procedures, and reduce operators' lifetime irradiation.

IMPACT ON DAILY PRACTICE

Dose-optimizing fluoroscopic equipment reduces patient and operator radiation during both diagnostic and complex/CTO-PCI procedures with no change in contrast utilization despite longer fluoroscopic times. This has the potential to change practice by allowing operators to attempt highly complex procedures without the limitation of excessive patient or operator radiation exposure. Such equipment also has the potential to reduce the overall radiation burden borne by operators throughout their careers in Interventional Cardiology**.**

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INTRODUCTION

Percutaneous coronary intervention (PCI) in chronic total occlusions (CTOs) is associated with longer fluoroscopic times and increasing radiation dosage to both the patient and operator (1). Though fluoroscopic time, contrast use, and radiation exposure in CTO interventions decrease with commensurate increases in operator experience (2), prolonged procedure time and radiation exposure remain salient issues.

Accurate assessment of radiation use transcends fluoroscopic time (FT), which fails to consider cine-acquisition imaging, patient size, X-ray-beam filter use, collimation and table/image receptor positioning. Two standard radiation dosage parameters are kerma area product (KAP) and air kerma (AK). KAP monitors the potential for patient stochastic radiation effects and is a surrogate for operator radiation exposure (3). AK monitors overall cumulative X-ray energy delivery to an interventional reference point and estimates the likelihood of radiation-induced skin injury (RSI) (4). Below 5Gy, clinically significant RSI is unlikely whereas at exposures greater than 10Gy, surgical intervention may be necessary (5).

Optimizing radiation management requires continuous attention to operator education, fluoroscopic maintenance, system configuration, and technological advances. One such advance is the Philips AlluraClarity FD20 (CLA), a novel imaging platform utilizing advanced image processing hardware that may allow substantial patient and operator dose reduction.

This paper examines fluoroscopic radiation-dose variation and contrast media utilization during Diagnostic Cardiac Catheterizations (DXC) and CTO-PCI performed on three fluoroscopic equipment configurations at a high volume, quaternary care PCI center.

METHODS

Clinical and dosimetric data for DXC and CTO procedures, performed between 2012 and 2014 on three different fluoroscopic configurations, were retrospectively reviewed. Key equipment parameters are outlined in Table 1.

All systems were manufactured and maintained by Philips Healthcare (Andover, MA, United States) to as close to "state-of-the-art performance" as possible. The REF (FD10) system was state of the art when it was installed in 2005. In 2012, the installation of ECO (FD20) allowed progressively lower procedural fluoroscopic and cine dose rates than those possible on the FD10. The FD20 image processor was upgraded two years later (with generator reprogramming) to create a third configuration, Allura Clarity (CLA).

Operators were free to select any clinically available dose rate and frame rate before or during any procedure (default frame-rate for CTO-PCI of 7.5 frames/second was used). Integrated dosimeters monitored AK and KAP, calibrated biannually (correction factors 0.89-1.08 over the study). All rooms were equipped with standard operator scatter-reduction technologies.

Operator and procedural scheduling was determined by laboratory workflow and physician preference. Effectively, DXCs were randomly distributed between all procedure rooms and operators. As operators became aware of inter-equipment differences, CTO-PCI procedures were scheduled almost exclusively in labs with dose-efficient equipment.

The Japanese Chronic Total Occlusion score (J-CTO score) predicts the probability of wiring a given CTO within 30 minutes (6). High J-CTO scores and the use of retrograde recanalization techniques predict longer procedure times and indicate complex lesion subsets (7); these factors were used herein to denote procedural complexity. Procedural success was defined as successful CTO recanalization with TIMI 3 flow in the target vessel at the conclusion of the procedure.

Statistical Analyses

Descriptive data are presented as frequencies and percentages for categorical variables or as median and interquartile value ranges and median +/- standard deviations (SD) for continuous variables. Statistical significance was set at $p<0.05$.

Normality of distributions was established using the Shapiro-Wilks test. For normally distributed data, the ANOVA F test for multiple comparisons was used to detect differences between group means. For non-normally distributed data, the Mann-Whitney U test or the Kruskal-Wallis test was used to detect differences between group medians. Finally, a post-hoc Tukey's Test on the log-transformed outcome was utilized for pairwise comparisons. The median difference and the median percent change of pairwise configurations were calculated for each outcome. The Kruskal Wallis Test was then used to determine whether a significant difference exists between pairwise configurations. Using the Bonferroni Correction method, the significant level of comparisons between configuration medians was set at $p<0.05/3=0.017$.

Efficiency Indices (EI) and the mean differences of pairwise configurations were calculated for each procedure. The Student's T-test was used to detect differences between pairwise configurations.

All statistical analyses were conducted using SAS software (version 9.3; SAS Institute, Cary, North Carolina).

Ethics and Funding

This study was approved by the local Institutional Review Board. The study was funded in part by Philips Healthcare. However, the evaluation protocol, investigation, data analysis, and preparation of the manuscript were entirely performed by the authors with no input from the study sponsor.

RESULTS

Data from 2947 diagnostic coronary angiograms and 276 CTO-PCI procedures were analyzed. Forty-eight percent of DXCs were performed using one of the two radiation dose-optimizing configurations (ECO or CLA). Eighty-one percent of CTOs were performed using an optimizing configuration (Table 2). For CTO cases, demographic characteristics (including age and BMI) were similar, regardless of equipment configuration (Table 3).

Diagnostic Coronary Angiograms

Summary statistics for DXCs are shown in Table 4. Radiation use, expressed as median AK, declined by 45% when going from REF to ECO. There was a further decline of 20% between ECO and CLA. The overall decline (REF to CLA) was 56%. All of these differences were highly significant ($p<0.0001$). Median KAP also declined as follows: REF to ECO 34%, ECO to CLA 15%, and REF to CLA 44% ($p<0.0001$ for all comparisons). Median FT increased significantly, by 7% between REF and ECO ($p<0.001$) and by 19% between REF and CLA ($p=.002$).

Contrast use increased by 7% going from REF to ECO ($p<0.001$), was unchanged for REF to CLA ($p=0.46$) and actually declined by 6% from ECO to CLA ($p<0.001$). Of note, contrast use decreased from ECO to CLA despite an increase in FT between these configurations.

Chronic Total Occlusions

Summary statistics for CTOs are shown in Table 5 and Figure 1. Radiation use (median AK) declined 43% between REF and ECO ($p<0.001$), an additional 9% between ECO and CLA ($p = 0.2$) and 48% between REF and CLA ($p<0.001$). Corresponding KAP declines were: REF to ECO 23% ($p=.01$), ECO to CLA 6% (p.43) and REF to CLA 28% ($p=.01$).

With respect to FT, despite an increase of 21 minutes between REF and CLA ($p<0.001$), a highly significant decrease of 48% in AK was observed. When comparing FT to cine run time (FT/CR) between the equipment modes, a significant difference between mean FT/CR was also noted. Mean FT/CR ranks for CLA and ECO were 139.1 and 140.9 versus only 108.1 for REF ($H=7.48$, df 2, $p=0.02$), indicating relatively higher use of fluoroscopy versus cine acquisition in both dose-optimized rooms.

No significant difference in contrast use between any of the three configurations was observed.

Procedural complexity was higher in CLA cases; retrograde techniques were used in 36% of CLA cases compared to only 12% in ECO and 0% in REF. Significantly higher J-CTO scores in CLA and ECO cases were also observed (see Table 6 for details). Despite higher complexity, there was a trend towards higher procedural success, going from REF (69.8%) or ECO (68.5%) to CLA (83%) (p=0.05) and a decrease in cases with total AK over 5Gy (15% for REF versus 7% for ECO and only 4% for CLA, p=0.08).

Efficiency Index

An Efficiency Index (EI) was calculated using clinical data from each procedure. This metric is the fluoroscopic time used for a complete procedure divided by the total procedural AK (fluoro + cine). Thus, the EI is defined as:

(Figure 2)

It is the analog of computing the average "miles-per-gallon" after a trip. A higher EI indicates equipment that highly optimizes radiation dosage and thus, maximizes safe procedural time. EIs for the three equipment configurations, stratified by procedure class, are shown in Table 7.

DISCUSSION

Our study evaluated the effect of radiation-dose-reducing fluoroscopic technologies on key parameters during diagnostic coronary angiography and coronary chronic total occlusion interventional procedures. The results of our study suggest that this technology successfully lowers radiation dose, despite longer FT.

Diagnostic coronary angiograms are amongst the most common procedures performed in today's catheterization labs, capturing similar information regardless of the site at which they are performed. As such, the DXC is used to determine national and international radiation reference levels (4,8-16). In DXCs, we demonstrated highly significant AK and KAP reductions of 45% and 34% respectively between the REF and ECO configurations and additional 20% and 15% reductions between ECO and CLA ($p<0.001$). The reductions with ECO and CLA occurred despite slightly longer fluoroscopic times, confirming that FT is not a reliable indicator of the radiation dose delivered during DXC. Further, though FT was somewhat longer using ECO and CLA versus REF, only minimal variation in contrast use was observed. Hence, it is possible that although DXC procedure times may be slightly longer with the use of dose-optimized fluoroscopic equipment (total increase in FT of 1.0 minutes between REF and CLA), the additional FT may be due to other aspects of the procedure (i.e. arterial access, wire navigation, catheter manipulation, etc) and note from poor coronary visualization.

CTOs are identified in up to 30% of all patients with coronary artery disease (17). Still, despite the body of evidence suggesting the clinical benefits of successful CTO-PCI (18-21), these procedures represent only 3.8% of the total PCI volume performed in the United States (22) with national success rates of only 58%. Contemporary data from expert US centers (23,24) have shown success rates of 80-90% with acceptable complication rates (1-3%) (24,25). CTO-PCI procedures are longer, require more contrast than standard PCI and utilize specialized equipment that can take considerable time to deliver. Herein, we confirmed previous work, demonstrating longer procedure times and overall radiation exposure during CTO-PCI (1,26). A significant decrease in AK of nearly 50% was seen in CTO-PCI procedures performed on the ECO and CLA systems versus the standard REF system. Notably, this decrease occurred despite important increases in FT (75% between REF and CLA), without significant increases in contrast usage, despite higher procedural complexity (Table 6) and without overt concerns regarding image quality by the operators. As such, even in the hands of highly-experienced/senior CTO operators, whose skills may facilitate efficient progress through procedures, important decreases in AK are achievable using dose-optimized equipment. Further, given the improvement in procedural success rates achieved on the CLA system despite higher procedural complexity, our data suggest that radiation-optimized equipment may facilitate procedural success by allowing longer procedural duration without the risk of excessive patient and operator radiation exposure.

The Efficiency Index (EI) is a clinical indicator of imaging equipment performance. The EI may be thought of as a measure of the fluoroscopy time available to an operator within a given total (fluoro+cine) radiation limit. A higher EI indicates better radiation optimized equipment for a given procedure type. As shown in Table 7, EI increased significantly from REF to ECO to CLA ($p<0.001$ for all comparisons) for both DXC and CTO procedures. Comparisons of EI between DXC and CTO were not significant for any equipment mode (REF $p=0.931$; ECO $p=0.203$; CLA $p=0.074$) indicating good internal consistency of the EI measure and that technology improvements were equally beneficial across procedure types.

Many studies over the past decade have examined the issue of radiation exposure during DXC and PCI (12-16,27-36). Overall, our results are in agreement with the literature, demonstrating an important decrease in overall radiation dose delivered with use of radiation dose-optimizing equipment. The results of our study also underscore the lack of utility of FT alone as a true measure of radiation exposure.

LIMITATIONS

Several study limitations warrant mention. Firstly, though all operators were highly experienced and employed radiation limiting strategies, differences in operator radiation setting preferences and speed/skill may have ultimately influenced the final radiation dose delivered in each room independent of fluoroscopic technology. Secondly, differences in operator skill and case selection may have influenced success rates due to reasons other than radiation limits and procedural time. Finally, though EI is an intuitive measure, the most appropriate usage of this parameter requires prospective study and further validation.

CONCLUSIONS

Both the feasibility and success of CTO-PCI has increased substantially over the past 10 years. Limitations to procedural success are now more focused on the limitations of the angiographic equipment and fluoroscopic imaging technologies.

Herein, we have shown that improved fluoroscopic generator technology (ECO) and a novel image processor (CLA) can reduce overall radiation dose (AK) by approximately 50% in both DXC and CTO-PCI. Significant radiation reductions were achieved despite increases in fluoroscopy time and contrast use, suggesting that these novel imaging-technologies may facilitate the performance of increasingly complex procedures without encountering radiation dosage limitations. Further, this study failed to document an important increase in contrast usage due to longer procedures or low-dose images. In view of these findings, the workflow in our catheterization laboratories has changed to preferentially place complex procedures in rooms with dose-optimized fluoroscopic equipment. This will likely become the standard as radiation limiting technologies become mainstream.

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FIGURE LEGEND

1. **Figure 1 –** Graphical representation of mean, median, and percentile values for AK, FT and CVOL between all three fluoroscopic machines for CTO-PCI

   REF – Allura Xper FD 10 system**; ECO** – Allura Xper FD 20 system;

   CLA - Allura Clarity FD 20 system

2. **Figure 2 –** Equation for the Efficiency Index (EI).

TABLE 1: Fluoroscopic configuration outline

Configuration	Base System	Installed	Generator Type	Image Receptor Size	Image Processor Type	Main Display Size
REF	Allura Xper FD10	2005	A	25 cm (Diagonal)	I	30X30 cm
ECO*	Allura Xper FD20	2012	B	50 cm (Diagonal)	I	60X60 cm
CLA*	Allura Clarity FD20	2014	B	50 cm (Diagonal)	II	60X60 cm

* A new type of image processor was installed in the FD20 in 2014. The original generator, Image receptor and display were retained. The X-ray generator was then reprogrammed to optimize the system's performance.

CLA - Allura Clarity FD 20 system; **ECO** – Allura Xper FD 20 system; **REF** – Allura Xper FD 10 system

TABLE 2: Procedural classes with distributions within equipment modes

Procedure Class	Class		Equipment Mode		
			REF	**ECO**	**CLA**
		n (column %)	**n (row %)**	**n (row %)**	**n (row %)**
Diagnostic coronary angiogram	**DXC**	2947 (91)	1539 (52)	1101 (37)	307 (11)
Chronic Total Occlusion	**CTO**	276 (9)	53 (19)	152 (55)	71 (26)
	ALL	**3223 (100)**	**1592 (49)**	**1253 (39)**	**378 (12)**

* **CLA** - Allura Clarity FD 20 system; **CTO** – Chronic total occlusion; **DXC** – diagnostic cardiac catheterization; **ECO** – Allura Xper FD 20 system; **REF** – Allura Xper FD 10 system

TABLE 3: Baseline demographics for all patients who underwent CTO PCI

Equipment Configuration	Mean Age (years)	Mean BMI (kg/m^2)	Mean Procedure Time (minutes)
REF [A] (n=53)	64+12	30+6	109+36^{C}
ECO [B] (n=152)	64+11	30+6	121+56^{C}
CLA [C] (n=71)	65+10	28+5	167+75$^{A, B}$
p-value	0.87	0.06	<0.0001

CLA - Allura Clarity FD 20 system; **ECO** – Allura Xper FD 20 system; **REF** – Allura Xper FD 10 system; **BMI** – Body Mass Index

Superscript letter denotes statistically significant difference between comparisons at p<0.05

TABLE 4: Radiation dose, fluoroscopic time and contrast utilization in diagnostic angiograms stratified by equipment configuration

Configuration n=2947		AK mGy	KAP Gycm2	FT min	CVOL ml
REF [A] (n=1539)	**median**	800[B,C] (550, 1120)	61[B,C] (42, 87)	5.4[B,C] (3.4, 8.9)	75[B] (55, 100)
ECO [B] (n=1101)	**median**	440[A,C] (330, 650)	40[A,C] (27, 63)	5.8[A] (3.7, 10.6)	80[A,C] (60, 110)
CLA [C] (n=307)	**median**	350[A,B] (230, 540)	34[A,B] (23, 54)	6.4[A] (3.8, 10.5)	75[B] (50, 100)
p-value		<0.0001	<0.0001	<0.0001	0.0009

CLA - Allura Clarity FD 20 system; **ECO** – Allura Xper FD 20 system; **REF** – Allura Xper FD 10 system; **SD** – standard deviation; **AK** – Air Kerma; **CVOL –** Contrast volume; **FT** – Flourscopic time; **KAP** – Kerma area product

Superscript letter denotes statistically significant difference between group medians at p<0.05 (First used Kruskal Wallis Test for multiple comparisons and then used a post-hoc Tukey's Test on the log-transformed response variables to see the differences between groups)

TABLE 5: Radiation dose, fluoroscopic time and contrast utilization in chronic total occlusion PCI stratified by equipment configuration

Configuration n=276		AK mGy	KAP Gycm2	FT Min	CVOL ml
REF [A] (n=53)	**median**	341^{B,C} (253, 413)	235^{B,C} (178, 301)	30.3^{C} (21.2, 36.8)	260 (180, 350)
ECO [B] (n=152)	**median**	193^{A} (131, 301)	180^{A} (110, 277)	32.0^{C} (23.8, 47.3)	260 (200, 360)
CLA[C] (n=71)	**median**	176^{A} (108, 294)	169^{A} (88, 279)	53.3^{A,B} (29.3, 88.1)	305 (195, 450)
p-value		<0.0001	0.02	<0.0001	0.27

CLA - Allura Clarity FD 20 system; **ECO** – Allura Xper FD 20 system; **REF** – Allura Xper FD 10 system; **SD** – standard deviation; **AK** – Air Kerma; **CVOL –** Contrast volume; **FT** – Flourscopic time; **KAP** – Kerma area product

Superscript letter denotes statistically significant difference between group medians at p<0.05 (First used Kruskal Wallis Test for multiple comparisons and then used a post-hoc Tukey's Test on the log-transformed response variables to see the differences between groups)

TABLE 6: Comparison of Procedural Complexity

Comparison	Group	N	Mean J-CTO Score	Mann Whitney U	P value
CLA vs ECO	CLA	66	1.47±1.11	3421	0.42
	ECO	102	1.43±1.10		
CLA vs REF	CLA	66	1.47±1.11	653.5	0.02*
	REF	27	0.93±0.87		
ECO vs REF	ECO	102	1.43±1.10	1032.5	0.02*
	REF	27	0.93±0.87		

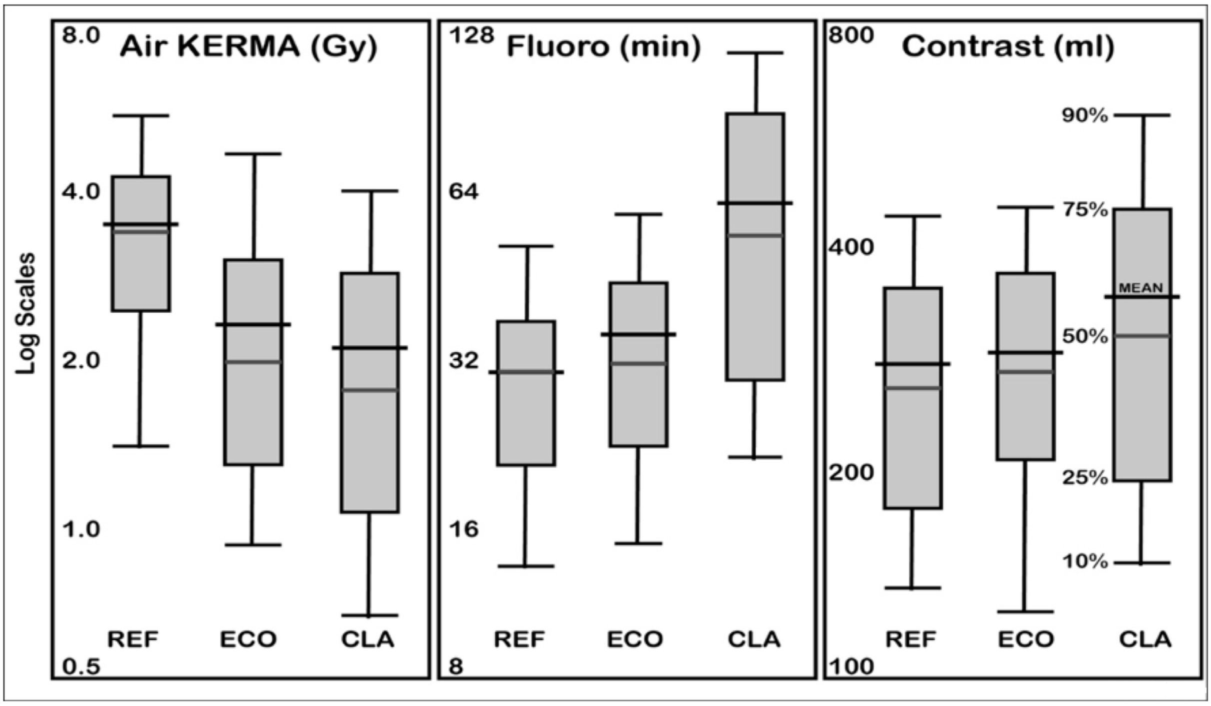
CLA - Allura Clarity FD 20 system; **ECO** – Allura Xper FD 20 system; **REF** – Allura Xper FD 10 system. * Statistical significance at p<0.05.

TABLE 7: Efficiency Indices for all equipment configurations stratified by procedure type

Configuration	DXC		CTO	
	Mean	**SD**	**Mean**	**SD**
REF	9.1	11.8	9.2	3.6
ECO	17.0	12.2	18.4	13.0
CLA	26.3	34.3	33.8	16.4
Comparison	**EI Difference**	**P-value**	**EI Difference**	**P-value**
REF to ECO	7.9	>0.001	9.2	>0.001
ECO to CLA	9.3	>0.001	15.4	>0.001
REF to CLA	17.2	>0.001	24.6	>0.001

CLA – Allura Clarity FD 20 system; **ECO** – Allura Xper FD 20 system; **REF** – Allura Xper FD 10 system; **EI** – Efficiency Index; **SD** – standard deviation; **DXC** – Diagnostic Angiogram; **CTO** – Chronic Total Occlusion. Significance set at p<0.05

Figure 1 – Graphical representation of mean, median, and percentile values for AK, FT and CVOL between all three fluoroscopic machines for CTO-PCI



REF – Allura Xper FD 10 system; **ECO** – Allura Xper FD 20 system; **CLA** - Allura Clarity FD 20 system

Figure 2 – Efficiency Index Equation

$$\textbf{EI} = \frac{\textbf{Total Fluoroscopy Time}}{\textbf{Total Air KERMA (fluoroscopy and cine)}}$$