

A study investigating the effects of a personalized Ceiling suspension shield-sensor system on minimizing radiation exposure in cath lab interventional procedures

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Abstract

Aim: To develop and evaluate a sensor system that can alert cardiologists when the ceiling suspension shield (CSS) is not positioned correctly during cath lab procedures.

Methodology: This study was carried out in our cath lab room which was equipped with the MAVIG ® OT90001 CSS model. A Ray Safe ® X2 detector was used to measure the dose rate with and without CSS to study the efficacy of CSS. A CSS sensor system was designed using basic electronic components and ultrasonic sensor module. The impact of the CSS sensor system in the cath lab was analysed by comparing the cardiologist's dose and the total dose during an angioplasty procedure.

Result: The CSS sensor system successfully detected any misalignment of CSS within a 50cm range. Analysis showed an 82.38% reduction in cardiologist's radiation exposure while using this new system

Conclusion: The implementation of a radiation safety sensor system in the cath lab is a novel step toward ensuring the well-being of healthcare professionals and enhances the overall radiation safety standards in the cath lab.

Background

Technological advancements have made it easier for humans to carry out numerous intricate tasks. The use of state-of-the-art medical equipment has notably increased the quantity and quality of treatments conducted in the field of medicine, particularly in cath lab interventional procedures. A global survey by UNSCEAR(United Nations Scientific Committee on the Effects of Atomic Radiation) released in 2022 revealed a six-fold increase in annual interventional operations, totalling 24 million, compared to their previous study¹. Data from the American Heart Association 2023 indicates that 481780 Percutaneous interventional procedures were performed in the United States during 2018². According to the Atomic Energy Regulatory Board, there are currently 3031 licensed interventional units operating in India³. The information presented above points to the possibility of raising the occupational dose to Cath lab workers. In a busy practice, an interventional cardiologist may complete around 300 procedures annually, leading to an occupational exposure of about 0.6 mSv⁴. A case study involving 31 physicians who carried out such interventions revealed that among them,23 had different types of brain tumors, especially malignancies on the left side^{5,6}. Other studies have also observed higher MN(micronucleus) values among interventional cardiologists, indicating elevated levels of somatic DNA damage^{7,8}. Furthermore, these heart specialists also exhibit a notable number of eye abnormalities, which may be connected to their prolonged exposure to radiation in cardiac catheterization labs^{9,10}. A variety of protective gear and protocols are accessible for mitigating occupational radiation exposure among cath lab staff ¹¹⁻¹⁴. The Ceiling Suspension Shield(CSS) is deemed essential as it covers the major part of cardiologist's body from scattered radiation¹⁵. Due to the hectic nature of Cath-lab procedures, there is often an oversight in properly positioning the CSS, resulting in reduced protection¹⁶. This research aims to develop a sensor system that can alert cardiologists when the CSS is not correctly positioned during

procedures. Additionally, this study assesses the impact of this sensor system on radiation protection during Cath lab procedures.

Material and Methods

The study was conducted in our cath lab room which was equipped with the Siemens Artis dFC Cath-Lab unit by Siemens Medical Solutions USA. A Ceiling Suspension Shield (CSS) is a lead acrylic transparent sheet of 0.5mm lead equivalence suspended on an independent handle, and it was mounted on a longitudinal ceiling rail system on the right side of the patient table, which can easily be adjustable during the procedure. CSS is intended to protect the upper half region of the cardiologist from scattered radiation emerging from the patient's body¹⁷. Various models of CSS are available in the market. The CSS model installed in our cath lab was OT90001 (Fig-1) manufactured by MAVIG GmbH X-Ray Protection and Medical Suspension Systems, Germany.

The dose rate at the cardiologist's location was assessed using a calibrated RaySafe X2 base unit with a survey sensor across different projections of the X-ray tube. RaySafe X2 systems are specially designed dosimeters for diagnostic QA (Quality Assurance). The system was manufactured by Unfors RaySafe AB, Sweden and marketed in India through Fluke Biomedical, USA. It can measure the dose ranges from 1nGy to 999Gy with 5% uncertainty. The radiation dose to the cardiologist during the procedure was measured using an analog pocket dosimeter (W-500) manufactured by Arrow-Tech, Inc.

The efficacy of CSS was checked by measuring the dose rate at the cardiologist position with and without CSS. A water equivalent phantom with 20 cm thickness was utilized to replicate the patient, resulting in realistic scattering of X-rays. The dose rate was measured using the Survey sensor of the RaySafe X2 system positioned at a reference point that is 1 meter away from the Patient entrance reference point¹⁹. This location is typically where the cardiologist stands during the procedure; hence, the dose can be considered an approximation of the cardiologist's dose. To enhance the visualization of different blood vessels, the cardiologist employed various projections of the X-ray tube. The common projections²⁰ are Right Anterior Oblique –Cranial (RAO-CRA), Right Anterior Oblique –Caudal (RAO-CAU), Left Anterior Oblique –Cranial (LAO-CRA), and Left Anterior Oblique –Caudal (LAO-CAU) (Fig-2). For every angle of projection, the dose rate at the reference point was measured using the RaySafe X2 system. To evaluate the effect of CSS, the reading was taken in three conditions-(i) without CSS (ii) With CSS (normal position) (iii) with CSS in a customised positions. The customised position means the position of CSS rearrange to a more covered position on scattered radiation in the selected projection. The dose to the cardiologist was measured using the pocket dosimeter that was affixed to the left side of their collar²¹. The dose at this level may be taken as the estimated dose to the eyes. All cardiologists wear lead aprons as a routine process during cath lab procedures. But most of them are not interested in wearing lead goggles, lead caps, or lead face shields due to their inconvenience. Therefore, the dose measurement at this level is significant. The most common cath lab treatments were percutaneous transluminal coronary angioplasty (PTCA)²² and coronary angiography (CAG)²³. Coronary angioplasty is known to be the most

time-consuming and radiation-intensive procedure among these. Hence, the average dose to the cardiologist is calculated using the readings taken from ten angioplasty procedures. The total radiation dose exposed to the patient is recorded from the machine-generated radiation dose structured report (RDSR).

In a busy cath lab schedule it was noticed that the staff kept the CSS at a single position throughout the procedure or forgot to position the CSS in between the field of view and the cardiologist (Fig-3). They may be exposed to a higher occupational dosage as a result of this potentially severe mistake. Fig-4 shows an incidental image taken during a cath lab procedure, adding context to the situation. In order to prevent such occurrences in our facility, we have designed and implemented a CSS sensor system that is affixed to the side of the flat detector. This system serves as an alert mechanism for cardiologists, reminding them to maintain proper positioning of the CSS during procedures.

The major component of the sensor system is an ultrasonic sensor²⁴ module, which produces ultrasonic sound signals (USS) and detects the reflected USS signals. The electronic components utilized for constructing the alert system are detailed in Table 1, while Fig. 5 illustrates the circuit diagram. The ultrasonic sensor module comprises a transmitter and receiver responsible for transmitting and receiving ultrasonic sound signals. The IC 555²⁵ was wired as an astable multivibrator for producing continuous square pulses to trigger the ultrasonic transmitter to produce USS. When the CSS was placed in front of the sensor, it reflected the signals. The ultrasonic receiver picked up these reflected signals and generated output pulses. The inverter circuit receives these output signals, which power the green LED. The red LED and buzzer may be turned on if the ultrasonic module is not sending out any signals. An analysis was conducted to assess the effects of the CSS sensor system in the cath lab by examining the radiation exposure for cardiologists and total air kerma during ten angioplasty procedures for LAD artery lesions.

Table – 1 Component list used for the CSS Sensor System

| No | Component | Specification | Quantity |
|----|-------------------------|--------------------------|----------|
| 1 | IC1 | NE555 | 1 |
| 2 | IC2 | SN7404 | 1 |
| 3 | Ultrasonic Module | HC-SR-04 | 1 |
| 4 | LED | 3V Red | 1 |
| 5 | LED | 3V Green | 1 |
| 6 | Piezo buzzer | 5V | 1 |
| 7 | Resistor | 1K | 1 |
| 8 | Resistor | 10 variable | 1 |
| 9 | Capacitor | 100 μ F | 1 |
| 10 | Capacitor | 10 μ F | 1 |
| 11 | Battery charging module | TP4056 | 1 |
| 12 | Rechargeable Battery | 3.2V | 2 |
| 13 | Switch | 2pin SPST | 2 |
| 14 | Plastic case | (11X8X3) cm ³ | 1 |

Result

The dose rate at the reference point in various projections is shown in Fig-6, comparing with and without CSS. The dark blue bar represents the dose rate without CSS, while the white bar demonstrates the reduction of dose when using CSS in a customised position with respect to the projection of the X-ray tube. This finding demonstrates the importance of CSS in a position that is sufficiently covered, which highlights the need for a CSS sensor system. The CSS sensor system was calibrated to detect CSS within a 50cm range, and it did so appropriately. When the sensor does not detect the CSS in front of it, it triggers alert signals by activating a red LED indicator and a beeping buzzer sound. At this point, a technologist or other assisting staff member takes responsibility for repositioning the CSS to provide better protection from scattered doses for the cardiologist. The sensor is powered by two rechargeable batteries, providing continuous operation for up to 8 hours. It transmits signals in the form of ultrasonic sound and functions as a wireless device, eliminating concerns about compromising the sterile conditions in the cath lab. The schematic diagram depicting the sensor's operation can be observed in Fig-7, while an image captured during an angioplasty procedure with the sensor in place is available in Fig-8.

The average exposure to the cardiologist for an angioplasty procedure with and without the sensor was calculated. The exposure determined from ten procedures before the use of the CSS sensor was 19.3mR;

following the sensor installation, it was 3.4mR. The measured exposure is given in Table 2 and the data indicates that, there is an 82.38% reduction in cardiologist's doses while using the CSS sensor system.

Table-2 Dose to the cardiologist without and with CSS sensor system in angioplasty procedures for LAD Cases.

| SL.NO | Measurements without CSS Sensor System | | Measurements with CSS Sensor System | |
|---------|---|-------------------------------------|--|-------------------------------------|
| | Total air kerma from RDSR (mGy) | Pocket Dosimeter Reading (mR) | Total air kerma from RDSR (mGy) | Pocket Dosimeter Reading (mR) |
| | 1 | 3898 | 29 | 2656 |
| 2 | 1098 | 10 | 1503 | 3 |
| 3 | 1168 | 11 | 2472 | 4 |
| 4 | 2751 | 26 | 2671 | 5 |
| 5 | 901.7 | 10 | 1282 | 2 |
| 6 | 2537 | 23 | 1888 | 3 |
| 7 | 1712 | 19 | 2229 | 3 |
| 8 | 2207 | 25 | 1022 | 1 |
| 9 | 3608 | 28 | 3048 | 6 |
| 10 | 1198 | 12 | 1398 | 2 |
| Average | 2107.87 | 19.3 | 2016.9 | 3.4 |

Discussion

It was well studied that the proper usage of CSS¹⁷ is significant during cath lab procedures. The criticality of the illness and the experience of the cardiologist²⁶ affect the procedural time in the cath lab. Unlike other radiological procedures, mainly X-ray and CT, the Cath lab operator (cardiologist) does not have an option to take a maximum distance from the X-ray tube. Because they want to do the procedure through a radial artery or femoral artery approach²⁷. So, the most applicable process for the reduction of occupational radiation exposure in the cath lab was the efficient usage of Shielding devices²⁸. The lead apron and thyroid shield may provide the major protection from scattered radiation, but they will not cover the head region. The CSS takes that role not only for the cardiologist but also for the supporting staff standing near the cardiologist¹⁰. However, more than 55% of cardiologists²⁹ ignore this crucial device or do not correctly use it. Figure 6 indicates the effect of CSS in a fixed position and the

repositioning of CSS according to the projection used during the procedure. Additionally, the graph indicates that the dose rate at the cardiologist's position is higher in the RAO-CRA and LAO-CAU projections; hence, it is advised to minimize the usage of these projections during the procedure. The basic awareness of radiation protection^{12,30} is normally acquired by all staff who are dealing with radiation, but its implementation is crucial. The CSS sensor played an important role in alerting the cardiologist to use the CSS in our cath lab. In a busy cath lab, it also acts as a mental alert system to the cardiologist and other staff by hearing the buzzer sound. By adopting these kinds of systems, the occupational dosage to cath lab workers can be reduced to a significant level³¹. It is advised that these kinds of sensors be included in the machine by the manufacturers while installing the equipment. The sensor system in this study was designed using less expensive, basic electronic components. Therefore, the sensor system may be readily assembled and used in the department by anyone with a basic understanding of electronics. Similar to radiotherapy installations, the competent authority for radiation safety may mandate that all institutions put this additional safety measures in place as a necessary condition of operating a cath lab facility. All these new modifications will improve the radiation safety standards in cath lab and, thus reducing the occupational radiation dose. In the future, we can add more possibilities to the device by modifying the circuit with the assistance of an expert in the field of electronics.

Conclusion

The implementation of a radiation safety sensor system in the cath lab is a novel step toward ensuring the well-being of both healthcare professionals and patients. These types of radiation protection alert systems serve as a crucial tool to warn healthcare professionals when protective measures are not used. The installation of radiation safety sensors enhances the overall safety standards in the cath lab, contributing to a safer and more secure healthcare environment for all stakeholders involved.

Declarations

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Author contribution: Conceptualization, methodology, validation, writing –original draft, and editing: Sajeesh S Nair, Supervision: Dr Saral Kumar Gupta & Dr Shine N S, Formal analysis, Writing–review: Prof. K.T Thomas All authors have read and agreed to the submitted version of the manuscript.

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Ethical consideration-The whole study was carried out with the approval of the institution's ethical committee (IEC/2020/29). All the procedures were performed according to the current standard of care and after receiving the patient's informed consent.

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Figures



Figure 1

The MAVIG ® OT90001 Ceiling Suspension Shield¹⁸

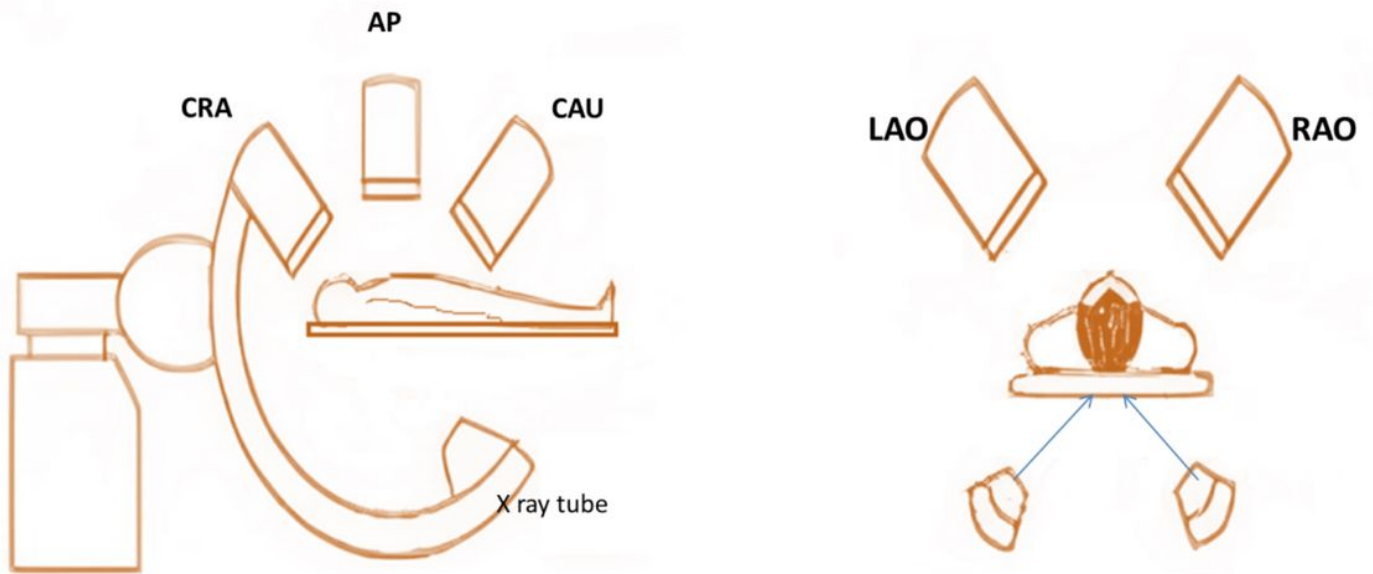


Figure 2

Schamatic representation of common Projections in Cath lab

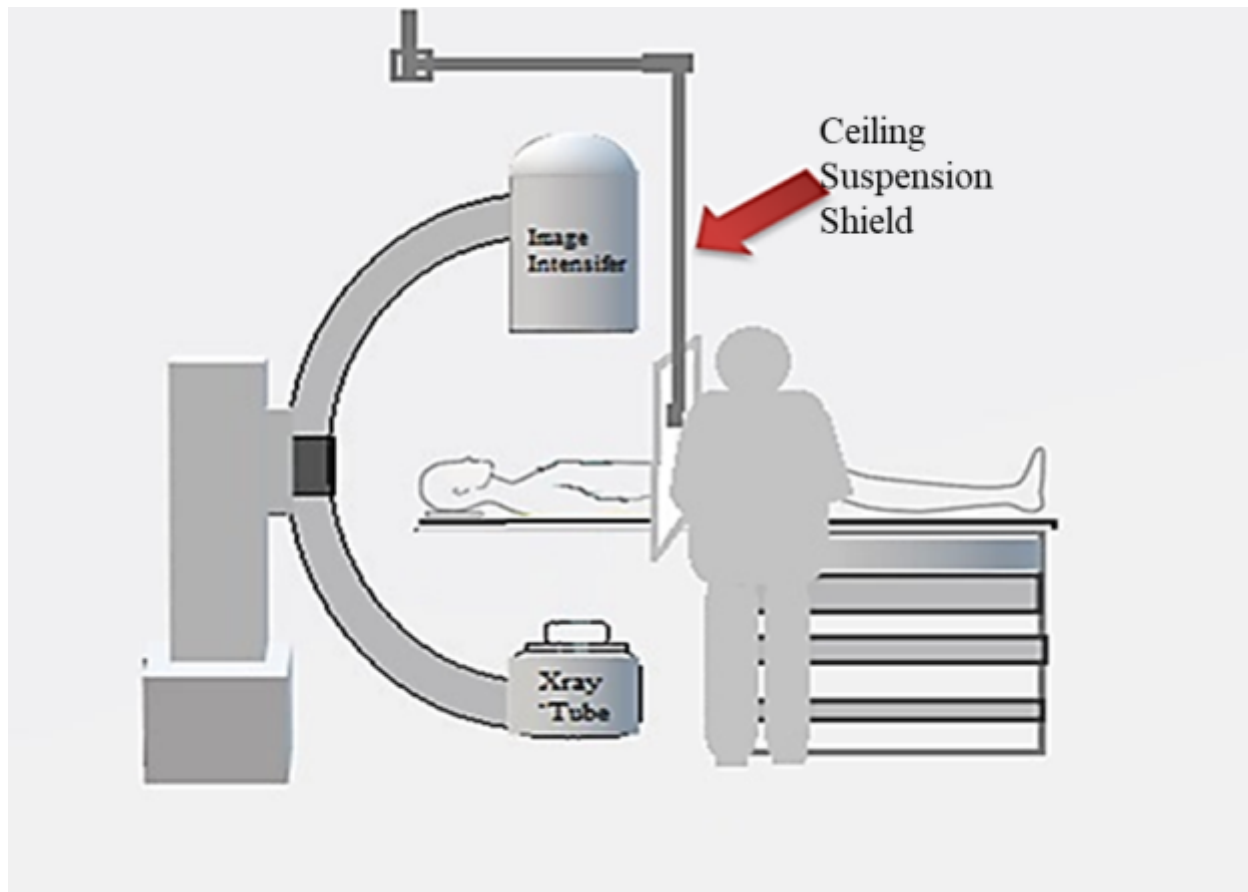


Figure 3

The normal position of the Ceiling Suspension Shield in the Cath lab



Figure 4

The incorrect use of the Ceiling Suspension Shield in the Cath Lab

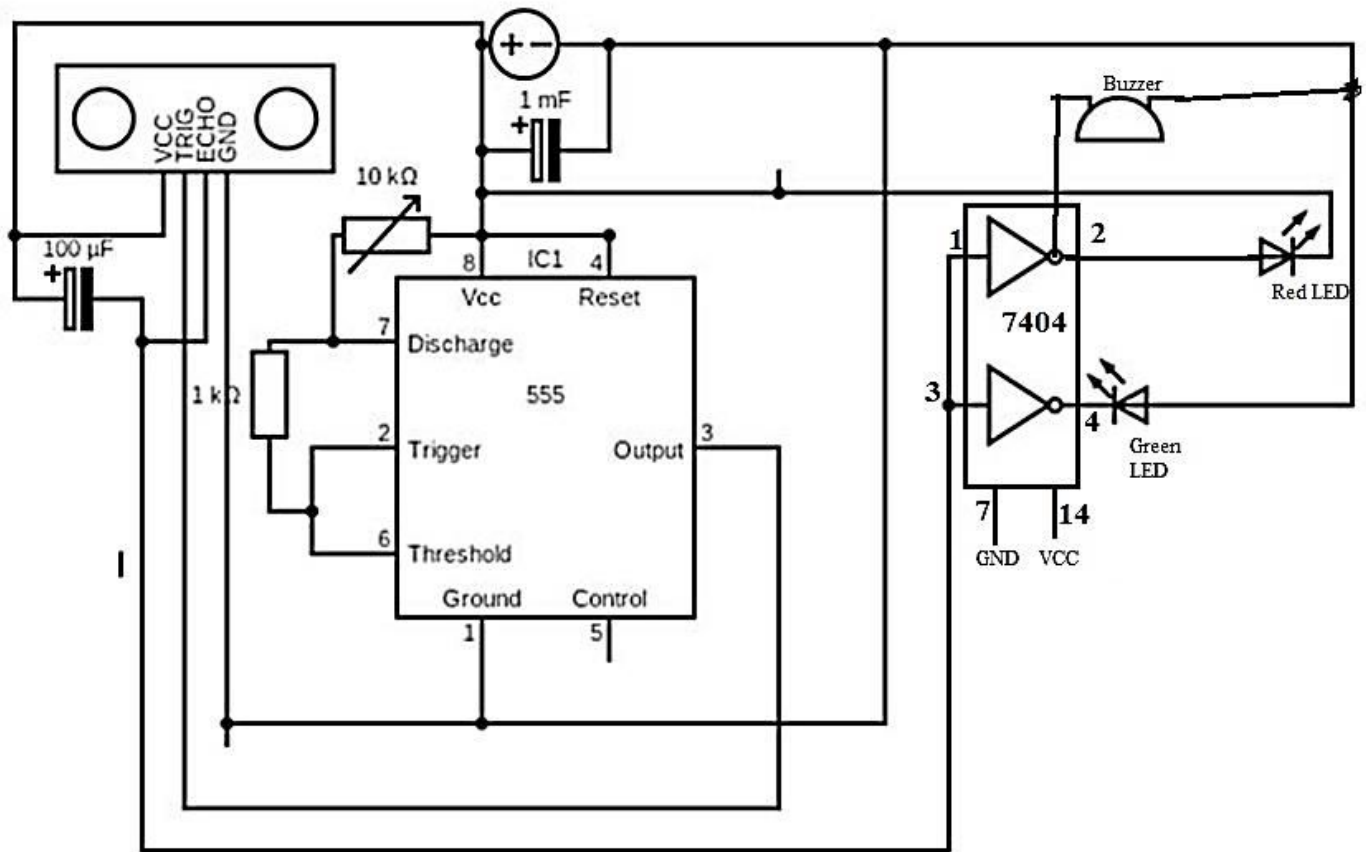


Figure 5

Circuit Diagram of CSS Sensor System

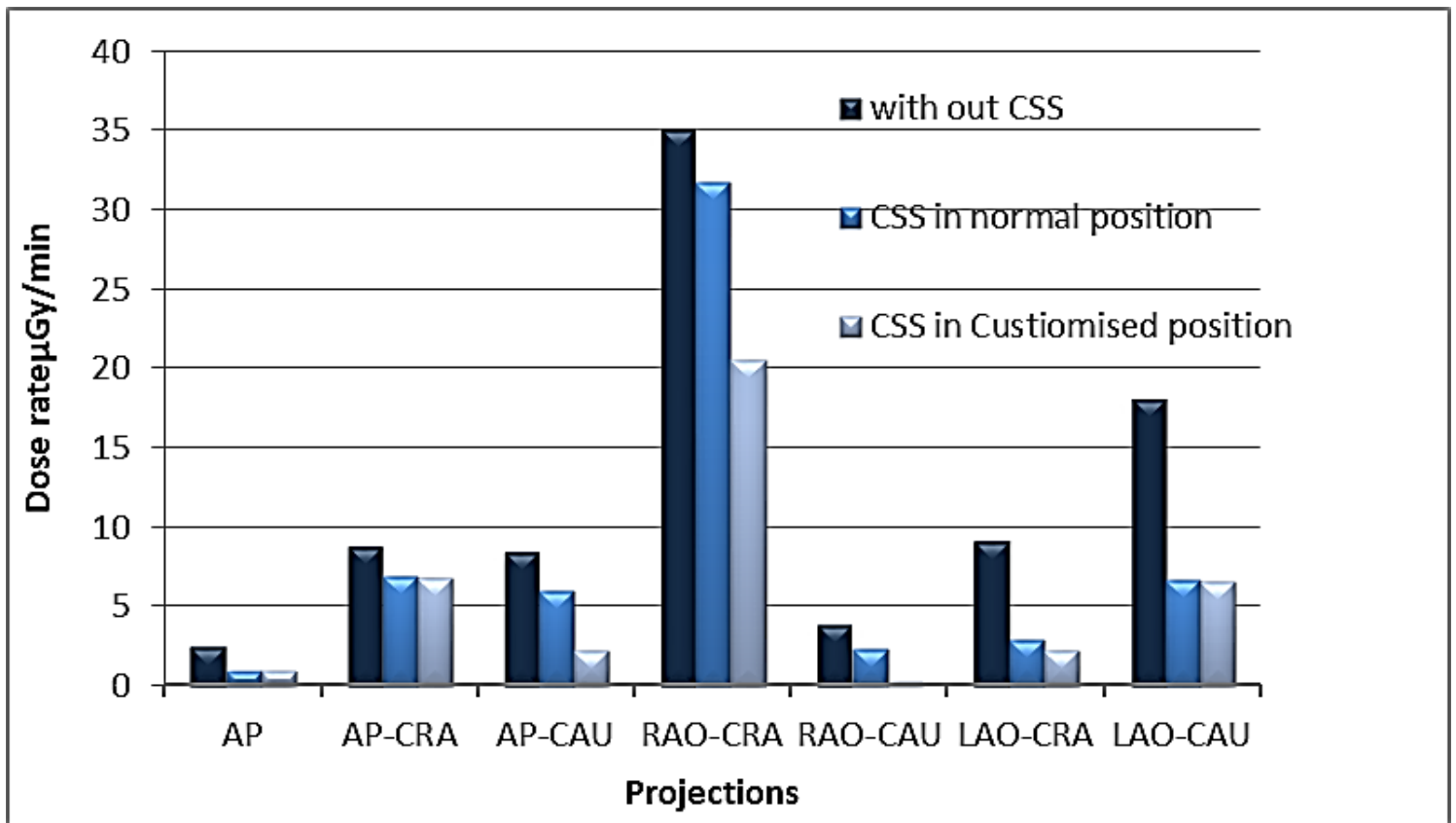


Figure 6

The effect of CSS on dose rate in various projections



Figure 7

Schematic diagram of CSS sensor system working. A- shows no reflection of signals in the absence of CSS. B- shows the detector senses the CSS by reflecting the signals.



Figure 8

Cathlab procedure with the CSS sensor attached to the Flat Detector