Comparison of Lodox Whole Body Slit Beam Technology with Traditional Radiography for Evaluation of Radioprotective Lead Aprons

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Declaration

I, Kate Mahlako Mahango, declare that this research report is my own work. It is being submitted for the degree of MMed (RadD) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

DR KATE MAHLAKO MAHANGO

On this 30th day of July 2020.

To my Parents

"I am who I am today because you believed in me and I did not have the heart to let you down"

To Kami

My anchor. My constant. Best Father. Together we have grown. Thank you.

Publications and presentations

This work has never been published.

It has never been presented at a congress.

Abstract

INTRODUCTION: The Lodox Statscan is a digital low radiation dose X-ray unit. Its ability to also scan a full patient length in a few seconds with equivocal image quality to conventional radiography, has led to its use in multiple trauma units. We intended to extend the application of the Lodox Statscan in the Quality Assurance program of Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), by utilizing the device to evaluate the integrity of lead aprons.

AIM: This study aimed to compare Lodox Statscan with Fluoroscopic evaluation of radio-protective lead aprons with regard to the integrity of the lead shielding.

METHOD: 35 lead aprons from the Radiology department at Charlotte Maxeke Johannesburg Academic Hospital were collected and imaged using Fluoroscopy and Lodox Statscan. The digitally recorded images of the lead aprons were assessed to determine the presence, number and size of lead apron fractures. The Lodox Statscan findings and conventional radiography findings, including time taken to assess each apron, were compared.

RESULTS: Lodox Statscan, was faster in acquiring images, with an average procedure time of 1.43 minutes, compared to an average time of 5.72 minutes with Fluoroscopy.
In terms of identifying fractures, the two methods displayed no statistical difference (p-value: 0.33). No statistical difference was found in the fractures scores (total number of fractures detected) between the two imaging technologies (p-value: 0.79).

CONCLUSIONS: The findings of this study have shown that compared to the gold standard fluoroscopic examination, Lodox examination of lead aprons is a feasible option in determining the integrity of lead aprons.

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1. Introduction

The LODOX Statscan (Sandton, South Africa) is a South African product, representing X-ray fan beam technology, designed for **whole body imaging** in polytrauma patients. One of the major advantages of the design is the long scan range providing the ability to scan a full patient length in one image(1). The Lodox Statscan has not previously been considered for use in evaluating the integrity of lead aprons, even though the advantages of whole body imaging seems obvious for making evaluation of the topographic position of defects easier. This research aimed to compare Lodox Statscan evaluation of lead aprons against the gold standard for feasibility of use, detection of lead fractures and speed of the procedure.

1.1. Background

Radioprotection is an integral but often neglected part of radiology. Lead aprons form a major part of protective attire for radiation staff in clinical interventional and diagnostic fluoroscopy suites including new hybrid computed tomography interventional theatres, which generate high doses of radiation. Their use also extends to any medical personnel working with medical radiation during radiography or surgical procedures. The integrity of lead aprons ensures user protection from radiation and its evaluation forms an essential part of quality assurance (QA). This is a task, usually left to the radiographic technologist rather than the radiologist. It is possibly because of this, that new technology is not often considered for the evaluation of protection apparel.

Radiation exposure for medical imaging is considered a risk to both patients and staff, with its stochastic and deterministic effects well documented (2). There are risks associated with any radiation exposure; therefore, the fundamental principle of radiation safety is to keep exposure ALARA (as low as reasonably achievable) (3). The International Commission on Radiological Protection (ICRP) recommends occupational dose limits as well as radio-protective measures, which include radio-protective clothing and shields. These recommendations have been adopted by the South African department of Health as part of regulation and guidelines for radiation safety (4).

It is required that lead aprons be worn by any person who cannot remain behind a fixed protective barrier during radiographic examinations (4)(5). Conventional lead aprons are primarily composed of lead impregnated vinyl material. These:

- must have minimum lead equivalence attenuation of 0.25mm. When the X-ray machine is operated at tube voltages above 100KV,any person standing within 1 meter of the X-ray tube or patient when the radiographic examination is performed, should wear at least 0.35mm lead equivalence lead apron (4).

- should cover the anterior aspect of the body, from the level of the shoulders/throat to the knees; and posteriorly it should extend from the shoulder level to the knees(6).

The deterioration of the lead impregnated material manifests as cracks or defects in the shielding. In addition to physical examination, the integrity of lead aprons is assessed for occult fractures by X-ray techniques. These occult fractures can **only** be seen radiographically or fluoroscopically. Such defects in the apron are associated with an increased radiation dose to the wearer. It is, therefore, recommended that lead apron integrity be assessed at least on a yearly basis to detect, quantify and record these defects (7). Based on replacement costs of lead aprons and the estimated radiation dose received from defects, it is recommended that the lead aprons be replaced only when the sum of areas of defects exceeds 15 mm^2. Furthermore, defects **not in close proximity** of critical organs, namely, on the back of the lead apron, in overlapped areas and along the seams should be subject to less stringent rejection criteria. In such instances, it is therefore suggested that defective lead aprons be replaced only if the sum of areas of defects is greater than 670 mm^2 (7). An additional study by Stam W and Pillay M, has recommended rejection criteria according to length (cm) of the tears/ defects in the aprons in relation to the lead equivalence of the material (8).

Previously, the traditional mechanism of evaluating lead aprons at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), involved systematic X-ray imaging of segments of the front and back of the apron to detect defects or fractures in the lead. The dimensions of available cassette sizes limited these segments. The process, therefore, required intricate systematic recording of the topography imaged, to adequately correspond it to the defect location on the apron itself. Currently, CMJAH has adopted the use of fluoroscopy in the evaluation of lead aprons, which has decreased time and cost, but continues to be time consuming because, this process still requires systematic, segmental imaging of lead aprons due to the limited field of view. In addition, this is a task done yearly and is left to the radiographers assigned to quality assurance. These lead aprons are used daily in various departments of the hospital including surgical theatres, interventional radiology theatre, as well as all other departments where radiographic imaging is required; this daily use as well as poor handling leads to fractures in the lead impregnated apron, thus increasing radiation dose to the exposed personnel. These fractures may occur daily depending on handling; and based on findings by Stam and Pillay who reported a 270% increase in fracture lengths which were initially recorded as small defects in the lead apron within a period of 1 year, one can expect an increase in size of fractures that occur between periods of evaluation, and thus, increased radiation dose to the user (8). It then, becomes imperative that institutions should strive to continuously find ways to improve staff safety, in a manner that is cost effective, that requires minimal staff time, with tools that are easy to use.

1.2.LODOX Statscan

The LODOX Statscan is a digital low radiation dose X-ray unit originally manufactured for the diamond mining industry to detect smuggled diamonds by employees. This machine emits an X-ray fan-beam from a C-arm, which is mounted on its one end. The C-arm rapidly navigates along the length of the table in one direction, and provides a detailed whole body scan, with soft tissue and skeletal detail, in 13 seconds (1)(9). Acquired images can be enlarged and digitally enhanced (1). Radiation dose from the Lodox Statscan is significantly lower compared to conventional radiography. It has been reported that the Statscan can result in up to 75% less radiation compared to conventional radiography - this depends on the imaged body part (9). Its configuration minimizes scatter radiation with the mean dose to staff adjacent to the X-ray unit reported as 3% of that for conventional X-ray machines (10). These features result in significantly lower radiation doses to patients, staff and operators.

Lodox Statscan is reported to have the potential to replace conventional X-rays in acute trauma settings due to its ability to scan paediatric and adult patients in a single image, thus allowing rapid total-body exam and primary evaluation of patients with multiple injuries (11)(12). Images are acquired at a significantly lower radiation dose; with equivocal accuracy compared to conventional X-rays (1)(13)(14)(15). Other uses reported in the literature include: an ability to detect ingested radio-opaque foreign bodies, and rapid identification of bullets in multiple gunshot injuries (16)(17).

Its approval has led several trauma centres to incorporate the technology into their advanced life support protocols (18). A Lodox Statscan has been installed at the CMJAH trauma and emergency department, and is incorporated in the acute management and imaging of polytrauma patients. Studies have shown that, after tuition of about 30 minutes both radiographic and medical personnel were comfortable with the use of the machine, with satisfactory image retrieval and manipulation. The user interface, however, was felt to require simplification (19).

The cost of acquisition of the Lodox Statscan is comparable to other conventional radiographic equipment, and with a computerised software which is compatible to most conventional computer hardware, the material costs and running costs are low with no additional staff time, service or staff costs incurred in most institutions (18). The cost of the single full body image from a Lodox Statscan study is also lower than the sum of multiple X-rays, which will be required for full body conventional radiographic studies (12).

A picture of the Lodox Statscan used at CMJAH is included in figure 1 below.

Figure 1: Example of Lodox Statscan Machine

1.3.Radiation Protection and Quality Assurance

Regular Inspection of radio-protective wear should form part of Quality Assurance (QA) programs in radiology departments (19)(20). The Quality Assurance (QA) Program is a program designed by institutions to assure the quality of products or services (20). Quality control (QC) involves actions, which are designed to keep measurable aspects of the process involved in manufacturing a product or providing a service within specified limits. These actions typically involve measurement of a process variable, checking the measured value against a limit, and performing corrective action if the limit is exceeded. QC Program should allow facilities with limited resources and staff to monitor the basic components of the imaging processes through the use of basic tools with less time. The concept of quality assurance in medical imaging, especially, is rapidly evolving and facilities are encouraged to continually review and pursue course of actions to improve and expand these programs. One of the questions that should be considered during the review process of a quality assurance program is: “Do any QC procedures need to be changed or updated?” (20).

Since the benefits of the Lodox Statscan are its low dosage, ease of use and ability to provide a full-body image, with comparative accuracy, and the speed of image acquisition, a wide spectrum of new clinical and non-clinical indications is expected. For example, it has found use and proven to be invaluable in forensic medicine (21). The ultimate intention of this study is to extend the application of the Lodox Statscan, available at CMJAH, to include the Quality Assurance program of CMJAH, by utilizing the device to evaluate the integrity of lead aprons. This is because aprons can be imaged in one full-length pass, at low dose to the operator with speed. It remains that the accuracy of Lodox Statscan in identifying defects in lead aprons be proven.

1.4. Aim

This study aimed to compare Lodox Statscan with conventional radiographic evaluation of radio-protective lead aprons with regard to the integrity of the lead shielding.

1.5. Study Objectives

1. To evaluate the feasibility of use of the Lodox Statscan for evaluating the integrity of lead aprons, by using the Lodox Statscan technology to image lead aprons in one radiology department.
2. To determine the presence, number, position and size of fractures in radio-protective lead aprons with traditional radiography using fluoroscopy and with the LODOX technology
3. To compare quantification and positioning of fractures in the lead aprons seen on Lodox Statscan against conventional radiography
4. To compare the time taken to image the lead apron using the two methods

2. Methods

2.1. Research Paradigm

This was a prospective experimental comparative study of two techniques. Lead radio-protective aprons from the department of radiology at the Charlotte Maxeke Johannesburg Academic Hospital were collected by the principal investigator, and evaluated by the principal investigator and 2 additional evaluators.

2.2. Sample

35 lead aprons, which were available at the Charlotte Maxeke Johannesburg Academic Hospital, were collected and imaged by the primary investigator.

2.2.1. Inclusion Criteria

Available Lead aprons from sub-specialty areas in the radiology department at Charlotte Maxeke Johannesburg Academic Hospital, namely angiography, paediatric radiology, fluoroscopy, Computed tomography (CT), and casualty x-rays.

Available lead aprons that had been condemned or no longer in use were also included in the study.

2.2.2. Exclusion Criteria

Lead aprons which were not made available for the study due to use, or difficult to access after hours despite numerous attempts to access the aprons.

2.3.Materials and Methods

1. Imaging of all lead aprons as well as measurement of time taken for imaging with each modality was performed by the primary investigator. The images were analysed by 3 readers including the primary investigator.
2. 35 Lead aprons which included condemned lead aprons were collected from 5 sub-specialty areas in the radiology department at Charlotte Maxeke Johannesburg Academic Hospital that use lead aprons for radiation protection. The subspecialties from which aprons were obtained are the Casualty X-ray areas, the fluoroscopy suites, interventional radiology suite, computed tomography department and paediatric radiology. Condemned aprons, which were kept in a separate storage facility, were also included.

   The aprons were collected in a sequential manner so as not to disturb requirements of the department.

   The imaging of the aprons took place after normal working hours, so as to have minimal interference with daily duties. Aprons were imaged in groups of 6; the last group was made up of 5 aprons; these sample groups were made up of a mixed sample of aprons from the different subspecialty areas as well as condemned aprons. 3 aprons from this sample were imaged first using the Lodox Statscan, thereafter; the same aprons were imaged fluoroscopically. The next set of 3 aprons from the sample were be imaged fluoroscopically first, then using the Lodox Statscan thereafter. In the last group made up of 5 aprons, 3 were imaged first using the Lodox Statscan thereafter the same aprons were imaged fluoroscopically. The remaining set of 2 aprons from the sample were imaged fluoroscopically first then using the Lodox Statscan thereafter.

   After imaging, the aprons were returned to their respective departments

3. The lead aprons were tagged on the top front right corner with a permanent marker according to their origin for identification and labelled as per figure 2. A metallic marker was also placed next to the top right front corner during imaging for confirmation of front surface.

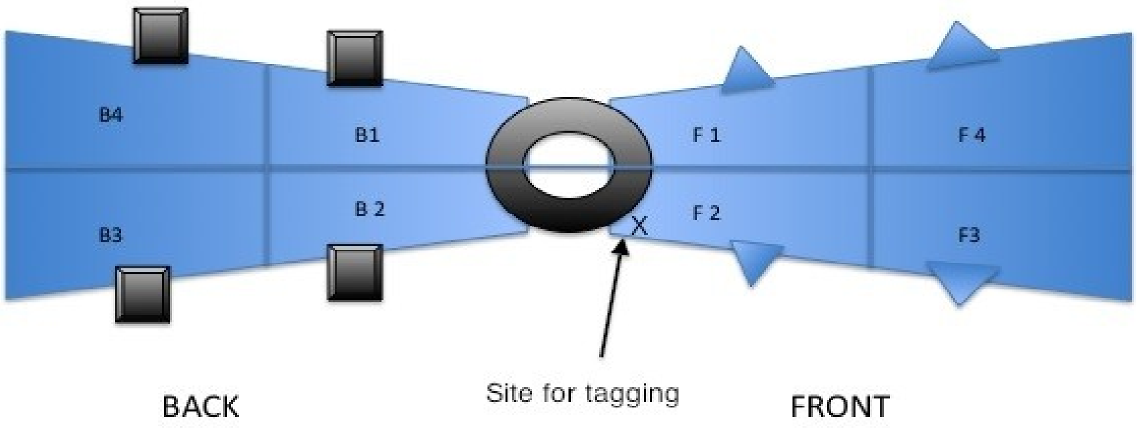


Figure 2:Schematic representation of tagged lead apron

The apron has been laid open, divided into four quadrants on each side: B1 – back left upper quadrant, B2- back right upper quadrant, B3- back right lower quadrant, B4-back left lower quadrant, F1- front left upper quadrant, F2- front right upper quadrant, F3 – front right lower quadrant, F4 – front left lower quadrant.

4. The lead aprons were imaged by the primary investigator using the Lodox Statscan available in the trauma department at the Charlotte Maxeke Johannesburg Academic Hospital according to a standardised system which was timed.

a. Technique

i) Lead apron was laid out 'open' and in full length onto the Lodox Statscan table.

ii) Imaging was performed using the fixed 'adult' setting, according to manufactures' specifications on the Lodox Statscan

iii) A metallic ruler was placed next to each apron in the imaging field to facilitate measuring detected fractures taking magnification into account.

iv) The images were stored on a USB flash drive and read at a later stage by 3 readers, including the primary investigator.

v) For assessment of the lead aprons for fractures, the images were transferred onto Apple MacBook Pro computers and viewed using Osirix DICOM (Digital Imaging and Communications in Medicine) software (Pixmeo, Geneva, Switzerland). Images viewed on Osirix are diagnostically accurate.

b. Timing – Time taken to image each apron was measured in minutes, from the moment the investigator began to lay out the apron onto the Lodox Statscan, to the end of the imaging process (i.e. once the image was acquired and seen on the viewing monitor).

5. The lead aprons were also imaged using the gold standard conventional radiographic method, which at Charlotte Maxeke Johannesburg Academic Hospital, is fluoroscopy. The primary investigator performed this task and the technique was also timed.
   a. Technique
      i) The apron was placed on the fluoroscopy table
      ii) Each apron was imaged systematically according to sequential quadrants as illustrated in Figure 2. (i.e. F1-F4 and B1 – B4 in order).
      iii) A metallic ruler was placed next to each apron in the imaging field to facilitate measuring any detected fractures taking magnification into account.
      iv) Each quadrant on the lead apron was imaged separately under pre-set settings used for acquiring fluoroscopic spot images of the stomach used at CMJAH with constant parameters of 80KV and 250mA. . The images were stored using the last image exposure function in a systematic fashion.
      v) The images were transferred to a DVD (digital versatile disc). The images were read at a later stage by 3 readers, including the primary investigator.
      vi) For assessment of the lead aprons for fractures, the images were transferred onto Apple MacBook Pro computers and viewed using Osirix DICOM (Digital Imaging and Communications in Medicine) software (Pixmeo, Geneva, Switzerland). Images viewed on Osirix are diagnostically accurate.

b. Timing – Time taken was measured in minutes, from the moment the investigator began to lay out the apron onto the fluoroscopy table to the end of the imaging process.

6. The primary investigator and 2 other readers (radiology registrars), reviewed the digitally recorded images at a later time, using Osirix DICOM software to determine the number and size of lead apron 'fractures' according to quadrants defined and labelled in figure 2. The sizes were measured in terms of surface area of fractures on the apron, in mm^2, in order to determine whether the fractures were significant or not, according to fracture significance criteria followed at CMJAH, where significant fractures are categorised as those with total surface area exceeding 15 mm^2 for the front surface of the apron and 670 mm^2 for the back surface of the apron. The fracture surface area of the acquired images was calculated using the Osirix DICOM software. Images acquired from the Lodox Statscan are calibrated to actual size and surface area was therefore calculated using the available rectangular ROI to cover the area of each fracture on the acquired images. Images acquired from Fluoroscopy are not calibrated, therefore, the images were recalibrated using the metallic ruler as a reference point of measurement, before measurement of surface area.

7. The reading of each method was performed independently and in a blinded fashion. (LODOX was read first after which a window period of a month was allowed before traditional fluoroscopic images were read)

8. The Lodox Statscan findings versus conventional radiography findings were compared with regard to presence, number and size of fractures (measured as total

surface area of fractures) overall, as well as time taken with each procedure to assess each apron.

9. Fractures were categorized as significant when (a) the sum of the areas of defects exceeded 15 mm^2 in the front surface of the apron (F 1 – 4 i.e. on the front) and (b) the sum of areas of defects exceeded 670 mm^2 in the back surface of the apron (B 1- 4 i.e. on the back).

10. The number of aprons with significant fractures was recorded for each modality.

2.4. Data Collection

Data was collected according to the data collection sheet Appendix A. To ensure reliability and consistency of the measurements, three readers were associated in the study. Each reader recorded their findings on the data collection sheet.

A fracture score was determined according to the overall number of fractures per apron and from this, a mean and range was developed for the sample for each method.

An apron segment score was determined based on the number of segments involved for each apron (maximum of 8) and a mean and range was determined for the sample for each method.

The following outcomes were measured or derived from measurements (the data type for each variable is given in brackets):

- Presence of fracture (yes/no)
- Presence of fracture for each quadrant
- Fracture score (Total number of fractures) (count)
- Total area of fractures for each quadrant, in mm^2 (continuous)
- Total area of fractures for front, in mm^2 (continuous)

- Total area of fractures for back, in mm^2 (continuous)
- Significant fractures in front (sum of areas of defects exceeding $15mm^2$) (yes/no)
- Significant fractures in back (sum of areas of defects exceeding $670mm^2$) (yes/no)
- Time taken to image aprons, in minutes (continuous)

Cohen's unweighted kappa was used to investigate reliability in the readings by the three readers. All derived outcomes recorded for each method, with the exception of time, were used to evaluate reliability between the readers. Lodox Statscan readings from the 3 readers were compared, and thereafter, conventional radiography readings from the three readers were compared. Statistical analysis was blinded to all readers. As detailed in the results below, no statistical difference was found in the measurements between the three readers; therefore, measurements taken by one reader, who was arbitrarily chosen, were relied on for further analysis.

2.5. Statistical analysis plan

Data was captured in Excel spread sheet and was imported into Stata (software for statistics and data science) for further management and analysis.

Frequency tables were used to describe categorical variables. These included presence of fracture, significant fracture in front and/or back and pie charts were used to portray the distribution of the aforementioned characteristics.

Continuous variables including fracture score, apron segment score (number of quadrant which have fractures), total area of fractures were described using mean and standard deviation. Although most of these continuous variables were not normally distributed, a parametric test was used (paired t-test) as the sample size was relatively high (n=35, i.e. >

30). Bar charts were used to portray differences in measurements obtained, using the two different imaging technologies.

Comparison of quantification and positioning of fractures in the lead aprons between the two technologies were obtained using the paired t-test for continuous variables and Pearson chi-square for categorical variables. All differences were tested at 5% level of significance, thus assuming a 95% confidence in the inference.

3. Results

3.1. Description of the study sample

This dissertation sought to compare Lodox Statscan with conventional radiographic (fluoroscopic) evaluation of radio-protective lead aprons with regard to the integrity of the lead shielding.

We collected a sample of 35 aprons available at Charlotte Maxeke Johannesburg Academic Hospital and imaged them using Fluoroscopy and Lodox Statscan.

This chapter presents results of the findings, followed by a discussion and a conclusion. Of the 35 aprons, most (23%) originated from the Casualty X-Ray department and from the fluoroscopy department (20%). A significant proportion of the sample (20%) was made up of condemned aprons (see figure 3).

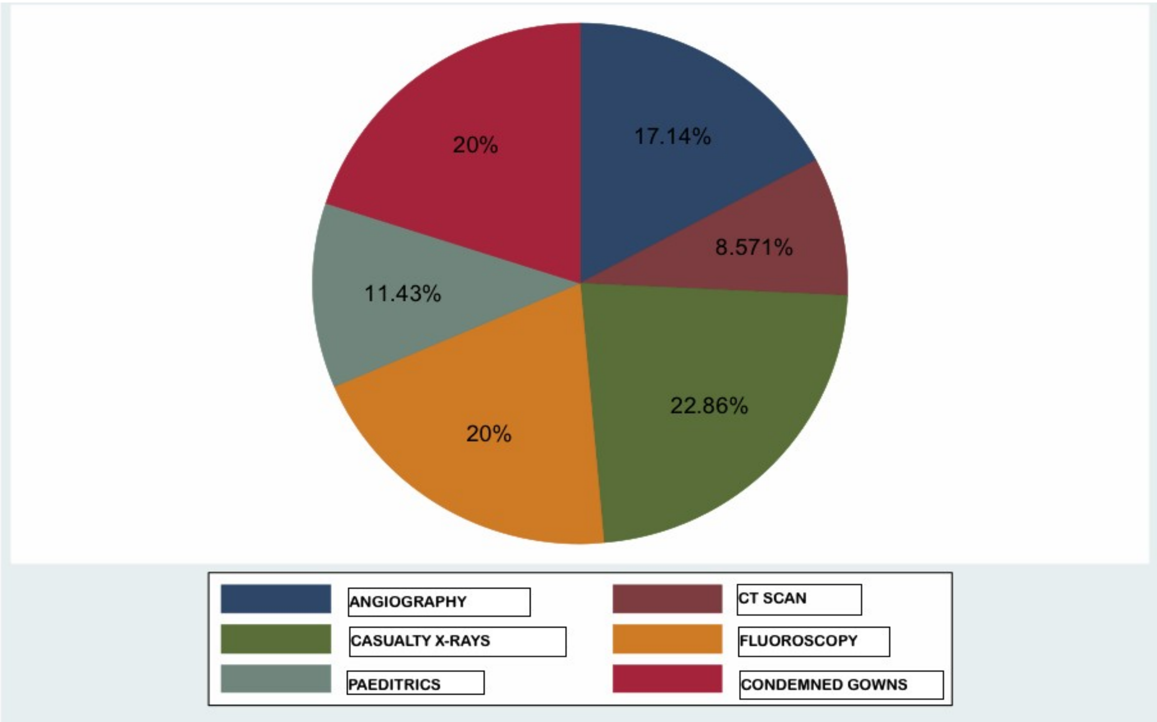


Figure 3: Distribution of Lead Aprons by Department

3.2. Agreement and consistency of measurements between readers

To ensure reliability of the measurements by the main investigator, two additional radiology registrars assessed the lead apron images. Table 3.1. below presents the results of the readings by the three readers and the extent to which they agreed.

A substantial agreement (kappa: 0.66, p- value: 0.001) between the readers was found regarding fracture scores, using conventional fluoroscopic imaging. Using the Lodox Statscan, measurements of fracture scores revealed a substantial agreement between the three readers (kappa: 0.76, p-value: 0.001).

However, the three readers displayed a fair agreement with regard to the size and position of the fractures using conventional imaging (fluoroscopy). For instance, in terms of the total surface area of fractures, a fair agreement (kappa: 0.37, p-value: 0.001) between the three readers was found on the conventional imaging. There was a moderate agreement between the three readers concerning the assessment of back surface of the aprons with regard to surface area (Kappa: 0.44 and 0.43).

Table 3.1.Measurement agreement between the three readers

Characteristics	Conventional Radiography			Agreement (Kappa)	LODOX Stat-scan			Agreement (Kappa)
	Reader 1	*Reader 2*	*Reader 3*		*Reader 1*	*Reader 2*	*Reader 3*	
Presence of fracture								
No	23 (65.71)	25 (71.43)	24 (68.57)	0.91	19 (54.29)	19 (54.29)	19 (54.29)	1.00
Yes	12 (34.29)	10 (28.57)	11 (31.43)		16 (45.71)	16 (45.71)	16 (45.71)	
Fracture score (mean, std)	6.2 (19.96)	6.22 (18.65)	7.17 (21.16)	0.66	6.97 (22.38)	8.03 (22.71)	7.83 (21.86)	0.76
Total surface area of fractures (mm^2)	6477.03 (26765.91)	6873.77 (28685.64)	5360 (20578.21)	0.37	9001.57 (37528.32)	8699.51 (35668.76)	8502.06 (34873.82)	0.37
Front Surface area(mm^2)	2850.09 (9884.48)	3047.143 (11333.73)	2634.46 (8930.80)	0.39	3831.51 (12992.76)	3805.06 (12963.54)	3853.83 (13333.21)	0.40
Significant Front Fracture								
No	26 (74.29)	28 (80.00)	27 (77.14)	0.89	25 (71.43)	24 (68.57)	24 (68.57)	0.95
Yes	9 (25.71)	7 (20.00)	8 (22.86)		10 (28.57)	11 (31.43)	12 (31.43)	
Back Surface area (mm^2)	3626.943 (18872.06)	3826.63 (19846.13)	2726.29 (13747.53)	0.44	5170.06 (27339.5)	4894.46 (25148.72)	4648.23 (24030.81)	0.43
Significant Back Fracture								
No	31 (88.57)	31 (88.57)	31 (88.57)	1.00	30 (85.71)	30 (85.71)	30 (85.71)	1.00
Yes	4 (11.43)	4 (11.43)	4 (11.43)		5 (14.29)	5 (14.29)	5 (14.29)	

Although the three readers displayed fair agreement on some measurements, substantial and perfect agreements were found on the main measurements. For instance, there was a perfect agreement between the three readers regarding the presence of fractures on the leads aprons (kappa: 0.91 using the conventional radiography, and kappa: 1 using the Lodox Statscan).

Hence, measurements taken by the main investigator (reader 1) were relied on for further analysis.

3.3. Measurement comparison between the conventional radiography (Fluoroscopy) and LODOX Stat-scan

Objective two of this study sought to compare quantification and positioning (back vs front fractures) of radio-protective lead apron between the two imaging technologies. This section presents results of the comparisons made, with the statistical tests.

These results are portrayed in Table 3.2:

Table 3.2. Quantification and positioning of fractures, by type of imaging technology

Fracture Characteristics	Type of Imaging Technology		p-value
	Fluoroscopy	LODOX Stat-scan	
Presence of fracture			
No	23 (65.71)	19 (54.29)	0.33
Yes	12 (34.29)	16 (45.71)	
Fracture score (mean, std)	6.2 (19.96)	6.97 (22.38)	0.79
Total surface area (mm^2) (mean, std)	6477 (26765.91)	9001.57 (37528.32)	0.18
Front Surface area (mm^2) (mean, std)	2850.09 (9884.48)	3831.51 (12992.76)	0.29
Significant Front Fracture			
No	26 (74.29)	25 (71.43)	0.79
Yes	9 (25.71)	10 (28.57)	
Back Surface area (mm^2)	3626.94 (18872.06)	5170.06 (27.34)	0.08
Significant Back Fracture			
No	31 (88.57)	30 (85.71)	0.72
Yes	4 (11.43)	5 (14.29)	
Time taken to image aprons in minutes: mean(SD)	5.72(2.12)	1.43 (0.5)	0.001*
Position F1			
No Fracture detected	32 (91.43)	33 (94.29)	0.64
Fracture detected	3 (8.57)	2 (5.71)	
Position B1			
No Fracture detected	31 (88.57)	31 (88.57)	1.00
Fracture detected	4 (11.43)	4 (11.43)	
Position F2			
No Fracture detected	30 (85.71)	25 (71.43)	0.15
Fracture detected	5 (14.29)	10 (28.57)	

Position B2			
No Fracture detected	31 (88.57)	29 (82.86)	0.50
Fracture detected	4 (11.43)	6 (17.14)	
Position F3			
No Fracture detected	29 (82.86)	29 (82.86)	1.00
Fracture detected	6 (17.14)	6 (17.14)	
Position B3			
No Fracture detected	32 (91.43)	28 (80.00)	0.17
Fracture detected	3 (8.57)	7 (20.00)	
Position F4			
No Fracture detected	32 (91.43)	32 (91.43)	1.00
Fracture detected	3 (8.57)	3 (8.57)	
Position B4			
No Fracture detected	32 (91.43)	28 (80.00)	1.00
Fracture detected	3 (8.57)	7 (20.00)	

Note: p-values in the table refer to paired t-test for numerical variables and Pearson chi square test for categorical variables

Results of comparison in table 3.2 above, show that with the exception of the time taken for imaging, the two technologies displayed no significant statistical difference in most aspects of measurements.

In both imaging technologies, the time taken to image the aprons varied in the study sample, with a median measurement time 5.12 minutes and an inter quartile range of 4.37 – 6,4 minutes for the conventional radiographic fluoroscopic technology and a median measurement time of 1.35 minutes, with an inter quartile range of 1.27 – 1.48 minutes for the Lodox Statscan.

Lodox Statscan, was faster in acquiring images of the entire apron, with an average time of 1.43 minutes and a standard deviation of 0.5 minutes, compared to an average speed of 5.72 minutes and standard deviation of 2.12 with Fluoroscopy. Figure 4 below depicts this distribution.

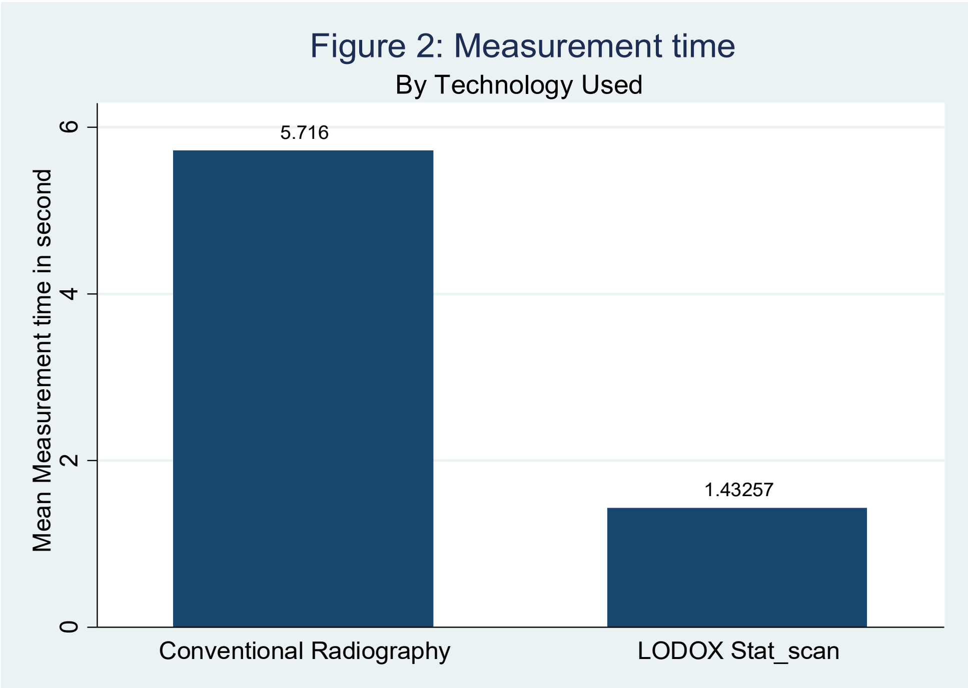


Figure 4: Average Time by Type of Imaging Technology (minutes)

Of the 35 aprons analysed with Lodox, 46% had fractures, whereas the conventional fluoroscopic radiography identified fractures on 34% of the aprons (see figure 5), and in terms of identifying the fractures, the two methods displayed no statistical difference in the proportions of fractures identified (p-value: 0.33).

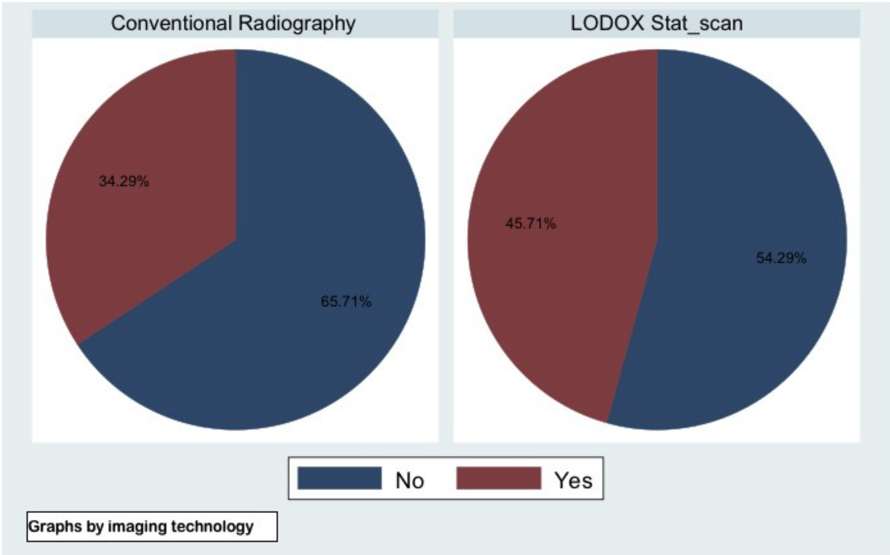


Figure 5: Identification Of Fractures By Technology Used

Fractures scores between the two imaging technologies were not statistically different (p-value: 0.79).

With regard to the position of fractures, the two technologies detected the same proportions of fractures. Although on some positions F2 and F3, marginal association was found (p-value: 0.15 and 0.17 respectively). For the remaining positions, the two technologies performed quite well in detecting fractures, with high p-values.

In terms of size of the fracture, no statistical difference was found in the total surface area measured by the two methods (p-value: 0.18) as well as the front surface area (p –value 0.29). A near marginal difference was observed between the two methods as far as the quantification of the back surface was concerned, this difference, however is not statistically significant at a p value of 0.08. This is depicted in figure 6.

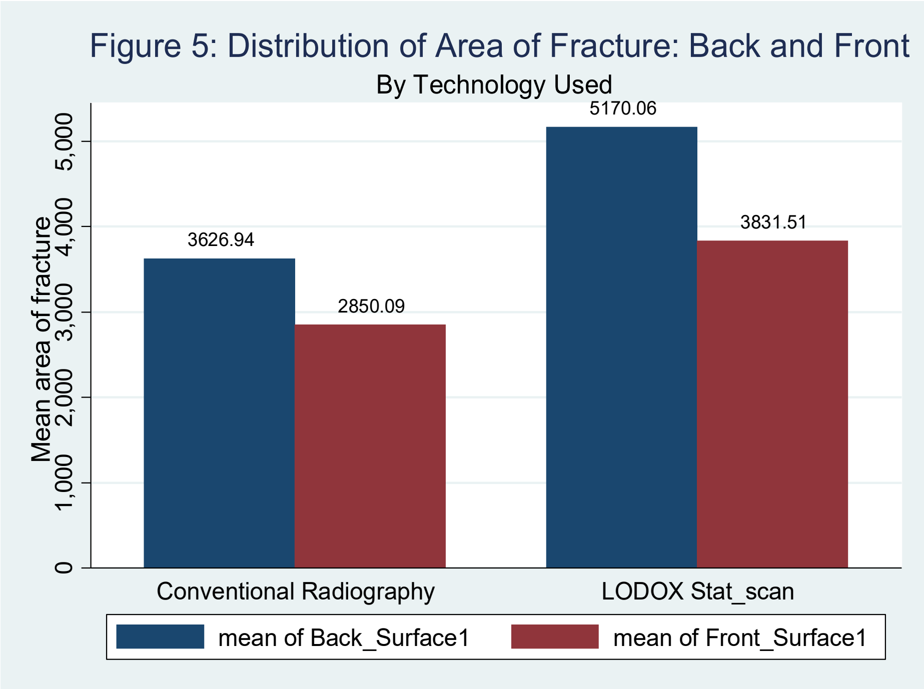


Figure 6: Distribution of Area of Fracture: Back and Front (by technology used) (mm^2)

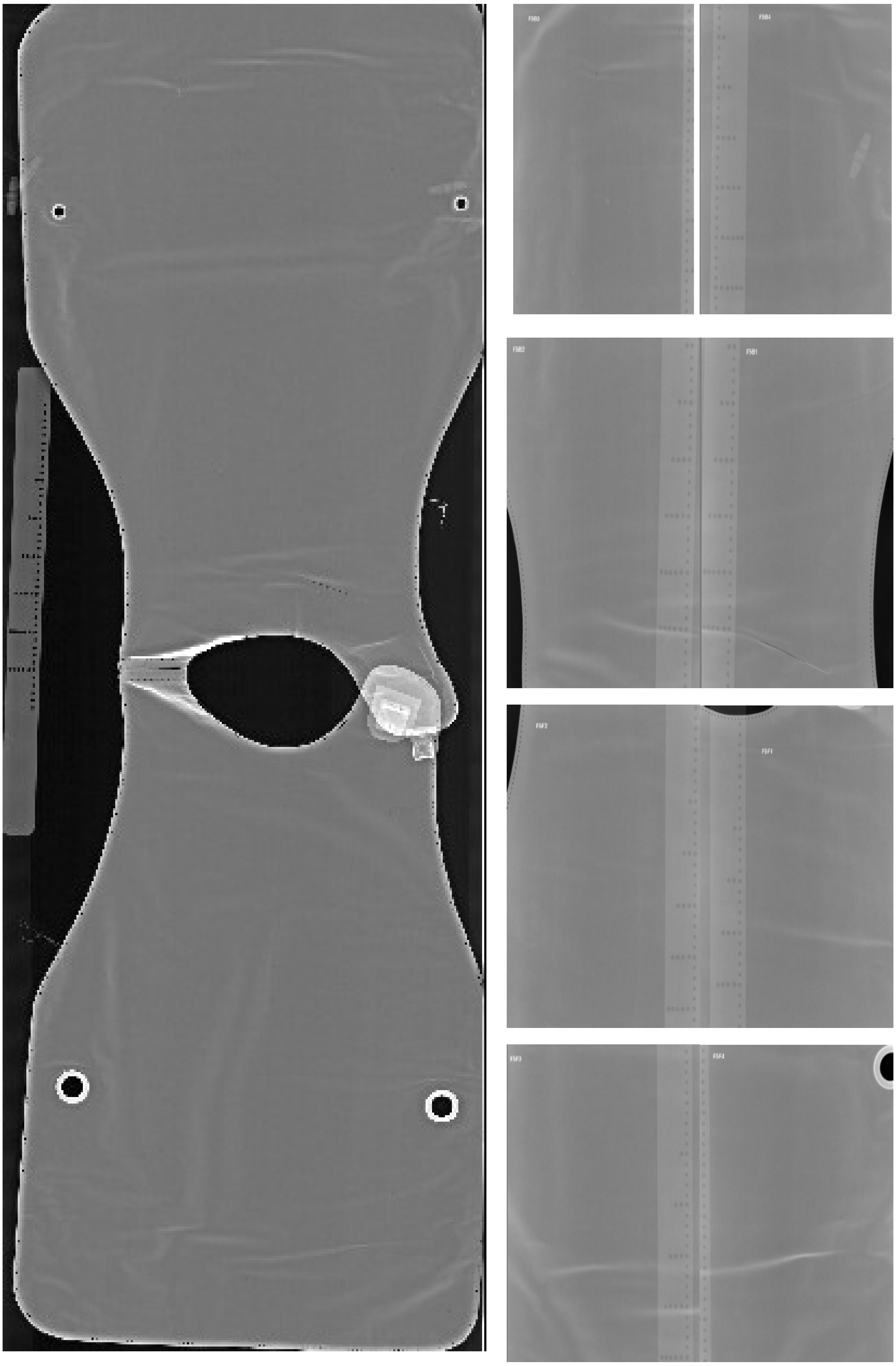
4. Discussion

The primary aim of this study was to assess whether the Lodox Statscan was a feasible means of accurately assessing the integrity of radioprotective wear (lead aprons) compared to the conventional gold standard (fluoroscopy) as used at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH).

The results in this study show that Lodox Statscan is not only feasible, having successfully imaged all aprons with relative ease, but it is also faster in imaging of lead aprons with a mean imaging time of 1.43 minutes as opposed to 5.72 minutes with Fluoroscopy. This evidence is comparable to other reports and to the study by Exadaktylos (2008) where average total scanning time for full body imaging in two planes was 3.5minutes with Lodox Statscan as opposed to 25.7minutes for conventional radiographic imaging (11).

One disadvantage of conventional imaging of lead aprons using fluoroscopy is that the fluoroscopy field of view is much smaller than the actual apron sizes. This mismatch between the fluoroscopic field of view and the actual apron size necessitates imaging of the apron in a segmental fashion. Furthermore, due to calibration and scaling mismatch, the fluoroscopic images do not correspond to actual apron size, thus necessitating a further step of rescaling and calibrating in order to obtain accurate measurement of fracture surface areas - this is done by means of a reference metallic ruler which is included in the field of view and transferring of images to an approved DICOM software where they can be recalibrated. In contrast, images from the Lodox Statscan machine are calibrated to actual size, which makes it possible for measurements, especially lengths, to be calculated from the images as viewed on the monitors of the machine itself. This is significantly advantageous in time-constrained environments such as CMJAH.

Although no statistical difference was obtained in terms of overall fracture detection, between the two methods (p-value:0.33), it was observed that the number / percentage of fractures detected by the Lodox Statscan was slightly higher than that of the current gold standard (fluoroscopy). It is postulated that this near marginal difference in fracture detection may be as a result of limited field of view of fluoroscopic imaging warranting segmental imaging of aprons. The aprons were divided into quadrants (4 at the back and 4 at the front) in order to facilitate fluoroscopic imaging, each quadrant on the lead apron was imaged separately in a sequential manner, systematically moving over the apron to image each quadrant. This raises the possibility of a small number of fractures being missed between apron quadrants resulting in slightly lower number of detected fractures. This possibility is however eliminated with the Lodox Statscan as the whole length of the apron was captured in a single image. This is also illustrated in figure 7 below.



A B

Figure 7: Lead apron images taken from (A) Lodox Statscan and 8 segmental fluroscopic images of the same apron (B) . The fluoroscopic images have been positioned in a manner comparable to the orientation of the Lodox image for comparison.

Furthermore, the study showed that there was no significant statistical difference in the number, proportions and positions of fractures detected by the two methods, with high statistical p- values for all the measured variables, proving that the Lodox Statscan detects defects in the lead aprons with comparable accuracy to Fluoroscopy. Figure 8 below is an example of images that were taken and depicts images of an apron segment acquired with fluoroscopy and Lodox Statscan. Similarities in lead apron fractures detection are evident in these images.

The inclusion of condemned aprons in this study ensured there would be adequate number of fractures detected.

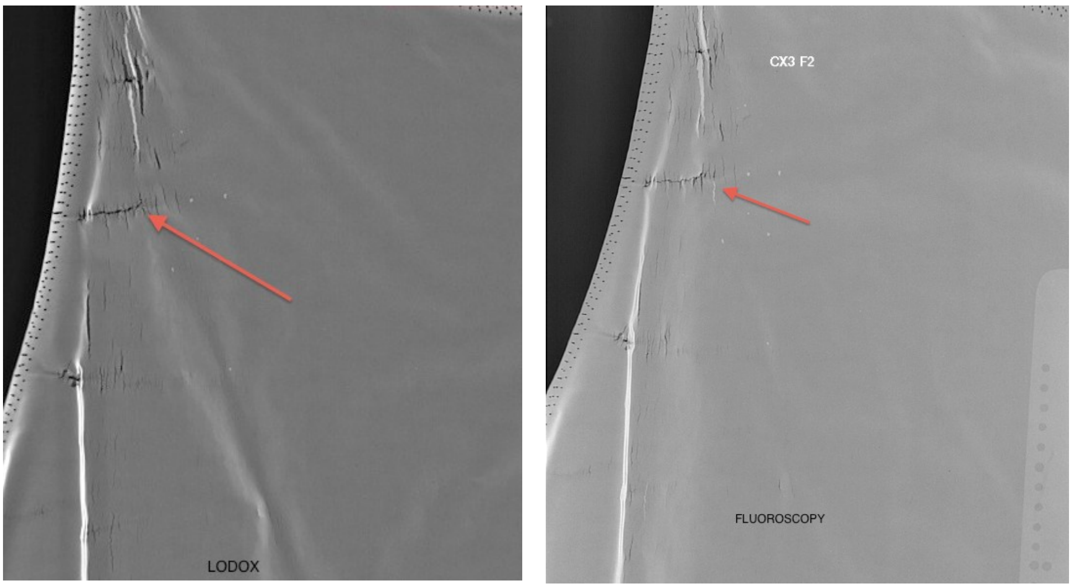


Figure 8: Example of an imaged lead apron imaged with Lodox Stascan (image cropped to demonstrate only the relevant part) and Fluoroscopy, depicting corresponding lead apron fractures (arrows).

To obtain comparable measurable variables, the significance of fractures utilising the total surface area was measured, with significant fractures categorised as those with total surface area exceeding 15 mm^2 for the front surface of the apron and 670 mm^2 for the back surface of the apron. The guidelines followed at CMJAH were incorporated, which subject fractures along the seams and in overlapping areas to less stringent measures. The surface areas of these fractures were incorporated and included into the total measurement of their corresponding location (back or front of apron). No statistical difference was found in the total surface area measured by the two methods.

The exposure to radiation whilst utilising either method was negligible in this study as the primary investigator was positioned behind protective screens in the protected area where monitors for both machines are placed. This however may not be the case in some institutions depending on the type of fluoroscopic machine that is used. Some machines may require the operator to manually operate the fluoroscopic over-couch detector by hand with no protective barrier, thus exposing the operator to radiation. The Lodox technology was originally developed by De Beers to identify locations of stolen diamonds in workers (21). Its added advantage of significantly low radiation dose to the operator and persons being imaged is one of the factors that has lead to the extension of the technology to hospital trauma units.

By Law in South Africa, any equipment which emits radiation and is used for medical diagnostic purposes should be operated by registered radiation workers; this limits the operation of the Lodox Statscan in our setting to radiographers and radiologists, with radiographers being those responsible for quality control of lead aprons. Depending on the laws governing a particular health institution, the ease of use of the Lodox Statscan will make it possible for any personnel to evaluate their lead aprons before use.

In addition to the published advantages of Lodox imaging such as low radiation and ease of use (1,7), the demonstrated better acquisition times and comparable apron defect detection rates on Lodox makes it possible for:

i. More frequent apron inspections to be conducted.

ii. Redirection of staff (radiographers) time to other core functions.

iii. Providing a quick effective method in addition to visual and tactile assessment.

iv. An easier and more user-friendly QC/QA system.

v. Psychological reassurance amongst staff on safety matters.

4.1.Current Applications and Future Applications

The study will be made available to the radiographer in charge of quality assurance program, to discuss with relevant stakeholders to include Lodox Statscan in the assessment of radio protective wear. This will not only decrease imaging time significantly, but also provide measurable surface areas or lengths of fractures which will help in determining significance of fractures.

Additionally, in comparison to the fluoroscopy machine available at CMJAH, these measurements can be calculated directly from the monitors of the Lodox machine eliminating the time consuming transfer of recorded images into approved DICOM software for analysis. This reliability will eliminate the number of aprons which are erroneously discarded on the basis of visualisation of fractures alone regardless of size.

The ultimate cost saving benefits of this intervention will be greatly valued by the institution.

4.2. Limitations of the current study

This study was limited to one institution. Our study sample was also limited by difficulty in accessing certain areas of the sub-specialities after hours.

5. Conclusion

The ultimate objective of this research is determining the feasibility of utilising and incorporating Lodox Statscan in the radiation protection and quality control programs of institutions in which it is available and in use.

The findings of this study have shown that compared to the traditional gold standard fluoroscopic examination, Lodox examination of lead aprons is a feasible option in determining the integrity of lead aprons. The study also demonstrated that the Lodox detects defects in the lead aprons with comparable accuracy to the fluoroscopy. Furthermore Lodox is an attractive alternative in that it is quicker to utilise but doesn't compromise the reliability of the results and fulfils radiation safety requirements.

These findings necessitate that institution in which the device is available strongly consider updating their quality control procedures to include the use Lodox Statscan in the evaluation of their lead aprons.

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Appendix A: Data collection sheets

LODOX STAT-SCAN DATA COLLECTION SHEET

APRON		TIME (Sec)	FRACTURE Yes or No	LOCATION AND NUMBER OF FRACTURES and size							
No	Department			F1	F2	F3	F4	B1	B2	B3	B4
1											
2											
3											
4											
5											
6											
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10											

LODOX STAT-SCAN DATA COLLECTION SHEET

APRON		TIME (Sec)	FRACTURE Yes or No	LOCATION AND NUMBER OF FRACTURES and size							
No	**Department**			**F1**	**F2**	**F3**	**F4**	**B1**	**B2**	**B3**	**B4**
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LODOX STAT-SCAN DATA COLLECTION SHEET

APRON		TIME (Sec)	FRACTURE Yes or No	LOCATION AND NUMBER OF FRACTURES and size							
No	Department			F1	F2	F3	F4	B1	B2	B3	B4
21											
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LODOX STAT-SCAN DATA COLLECTION SHEET

APRON		TIME (Sec)	FRACTURE Yes or No	LOCATION AND NUMBER OF FRACTURES and size							
No	Department			F1	F2	F3	F4	B1	B2	B3	B4
31											
32											
33											
34											
35											

CONVENTIONAL RADIOGRAPHY DATA COLLECTION SHEET

APRON		**TIME (Sec)**	**FRACTURE Yes or No**	**LOCATION AND NUMBER OF FRACTURES and size**							
No	**Department**			**F1**	**F2**	**F3**	**F4**	**B1**	**B2**	**B3**	**B4**
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CONVENTIONAL RADIOGRAPHY DATA COLLECTION SHEET

APRON		TIME (Sec)	FRACTURE Yes or No	LOCATION AND NUMBER OF FRACTURES and size							
No	Department			F1	F2	F3	F4	B1	B2	B3	B4
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CONVENTIONAL RADIOGRAPHY DATA COLLECTION SHEET

APRON		TIME (Sec)	FRACTURE Yes or No	LOCATION AND NUMBER OF FRACTURES and size							
No	Department			F1	F2	F3	F4	B1	B2	B3	B4
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CONVENTIONAL RADIOGRAPHY DATA COLLECTION SHEET

APRON		TIME (Sec)	FRACTURE Yes or No	LOCATION AND NUMBER OF FRACTURES and size							
No	**Department**			**F1**	**F2**	**F3**	**F4**	**B1**	**B2**	**B3**	**B4**
31											
32											
33											
34											
35											

Appendix B: Ethics Clearance Certificate

Human Research Ethics Committee (Medical)

Research Office Secretariat: Senate House Room SH 10005, 10th floor. Tel +27 (0)11-717-1252
Medical School Secretariat: Medical School Room 10M07, 10th Floor. Tel +27 (0)11-717-2700
Private Bag 3, Wits 2050, www.wits.ac.za. Fax +27 (0)11-717-1265

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

Ref: W-CJ-131027-1 27/10/2013

TO WHOM IT MAY CONCERN:

Waiver: This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical).

Investigator: **Dr K M Mahango.**

Project title: **Comparison of Lodox whole body slit bean technology with traditional radiography for evaluation of lead aprons.**

Reason: This is a laboratory-type study in which protective lead aprons will be systematically imaged by the applicant using fluoroscopy and Lodox Statscan to identify apron defects. There are no human participants.

UNIVERSITY OF THE WITWATERSRAND
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Professor Peter Cleaton-Jones

Chair: Human Research Ethics Committee (Medical)

Copy - HREC(Medical) Secretariat: Anisa Keshav, Zanele Ndlovu.