X-Ray Intensive Medical Procedures Using a Standard Fluoroscope and its Lowest Automated Radiation Settings

Karikari IO, Brown CR, Anderson DG

Introduction:
The deleterious effects of ionizing radiation are well established, with its cumulative impact having known health risks both for healthcare providers1-5 and patients6-9. This is of particular concern with respect to fluoroscopically guided medical procedures, as these rely on constant exposure to radiation throughout the procedure. While fluoroscopically guided procedures enhance surgical accuracy and reduce surgical morbidity, they do so at the cost of increased radiation exposure.

Altering the dose settings and pulse rate on a conventional fluoroscope are simple measures that can radically minimize this exposure to ionizing radiation. These techniques, advocated by the American College of Radiology10 and the FDA11, can reduce radiation usage more than 90% as compared to conventional fluoroscopy12. Unfortunately, the image quality is often compromised with these techniques, rendering them ineffective.13 Despite this fact, the FDA has clearly stated that “medical imaging examinations should use techniques that are adjusted to administer the lowest radiation dose that yields an image quality adequate for diagnosis or intervention (i.e., radiation doses should be “As Low as Reasonably Achievable”)11” – or ALARA. Therefore physicians require technology that allows greater utility of low radiation imaging.

LessRay® is a computer display system that can interface with a standard fluoroscope to enhance image resolution, allowing for a greater ability to use the pulse and low dose settings on a fluoroscope. It therefore offers a physician the opportunity to use significantly reduced radiation imaging in any procedure that requires a fluoroscope, and potentially better abide by the principles of ALARA.

In this study, we assess the ability to use the lowest automatic radiation settings on a standard fluoroscope throughout the entirety of a radiation intensive surgical procedure when used in conjunction with LessRay. Typically, the image quality of pulsed and low dose images are not adequate to safely perform a surgical intervention. Hence, we are attempting to identify if poor quality images could be improved by LessRay® to a level considered adequate to perform the procedure safely.

Methods
A prospective, randomized cadaveric study was undertaken to compare the utility and radiation exposure experienced during a fluoroscopically intensive medical procedure. Physicians with experience in performing kyphoplasties were asked to duplicate the procedure in cadaveric specimens, imitating precisely their routine when performing a kyphoplasty in their daily practice. Each surgeon repeated the procedure at one spinal level using LessRay® enhanced imaging and another using conventional fluoroscopy unaided by enhancement. These were performed at adjacent spinal levels, randomly starting with conventional or reduced radiation imaging. In the reduced radiation case, though, the fluoroscope was set to the 1 pulse and low dose settings, the lowest automated setting on a GE OEC 9900 fluoroscope. As well, the physicians were blinded to the fluoroscope screen and only allowed to use the LessRay® enhanced images as long as they remained viable. At any point, if the image clarity was not sufficient to perform the procedure safely, the physicians were allowed to increase the radiation or look at the fluoroscope screen.

The number of images taken prior to cement injection, seconds of fluoroscopy for the entire procedure, and the amount of radiation in mGy for the entire procedure were recorded for each surgeon, as was the need to convert to conventional imaging. The amount of radiation reduction was quantified as the percent reduction. The chi-square test was used to determine statistical significance. A p value <0.05 was considered statistically significant.

Results:
Seven spine surgeons performed fourteen (14) kyphoplasties throughout the thoracolumbar spines of 2 human cadavers. In no case did any of the physicians abandon the LessRay® enhanced images. The average duration of fluoroscopy for the entire procedure was 11.0s and 65.6s in the LessRay® enhanced and conventional fluoroscopy groups respectively (p<0.001). Despite statistically similar number of images with both methods prior to cement injection (24 Conventional vs. 21 LessRay®-assisted, p=0.30), the pulsed/low dose procedures achieved an overall 88.8% radiation reduction over conventional imaging (36.1mGy vs. 4mGy, p<0.001).

The Technology
LessRay® is a computer display system that interfaces directly with the fluoroscope. The captured images produced by the fluoroscope are transmitted in real time to the LessRay® computer where the images are enhanced and then displayed on the LessRay® monitor.

LessRay® uses proprietary image processing algorithms to post-process low-dose / pulsed images, improving resolution and contrast to provide a clinically valuable image to the physician. This allows for greater utility of low dose imaging. As the radiation needed to obtain the image dictates the radiation exposure to the patient and physician, using low radiation images should strongly impact this exposure.

When a pulsed and/or low dose image of this shot is taken, they appear on the C-Arm monitor as washed-out and grainy, but the general form of the anatomy is faintly apparent through the noise. LessRay® embellishes this grainy image to make it appear more like the original image taken (see Figure 1). As long as the image is of the same anatomy in a similar orientation, LessRay® will, in most cases, improve the poor quality precursor from the C-Arm monitor to a useable quality image on the LessRay® monitor. This works for both static images and continuous fluoroscopy, which is key for a procedure like a kyphoplasty which requires both.

Discussion:
Across nearly all surgical subspecialties, minimally invasive (MIS) procedures are becoming increasingly commonplace. While the benefits have been lauded in numerous studies14-18 they often require increased radiation exposure due to the extensive

Figure 1: A lateral view of the spine, taken during the study at 1 pulse and low dose settings, prior to (upper) and after (lower) enhancement by LessRay®. Note the clarity of the anatomy only once LessRay® improves the image.

Note: In clinical practice, the amount of patient dose reduction achieved when a Pulse and/or Low Dose is improved with LessRay is dependent on the clinical task, patient size, anatomical location and clinical technique. The dose should only be lowered to the level to which the physician is able to achieve the adequate image quality needed for the particular clinical task. A consultation with a radiologist and a physicist may aid in determining the appropriate dose settings.
imaging needed to make up for what is not directly visualized at the time of surgery. The cumulative impact of this radiation exposure can quickly result in a physician exceeding their yearly or lifetime limits set by the National Council on Radiation Protection.

As dozens of the most common medical procedures performed in the United States are fluoroscopically dependent, the concern for radiation over-exposure is most acute in these procedures. Kyphoplasty is a common surgical procedure that is totally dependent on fluoroscopic guidance, making it an ideal radiation intensive procedure for investigating radiation reduction strategies. In their practice guideline for the performance of vertebral augmentation, the American College of Radiology (ACR) press the physician to use imaging during these procedures in a manner “consistent with the ALARA radiation safety guidelines.”

The options available for minimizing radiation exposure include pulse and low-dose imaging. They can be employed with standard fluoroscopy to reduce radiation over 90%. When acquiring an image with pulsed radiation, an 8 pulse image uses essentially 8 times the radiation of a 1 pulse image, and roughly 1/4 the radiation of standard imaging settings. While this technique is lauded by the ACR as one of the most effective ways to decrease radiation, it often cannot be fully utilized in medical procedures. Image clarity is negatively affected by decreasing the radiation settings. Each drop in pulse also causes a drop in image quality. Therefore, lower pulse settings often do not produce adequate image quality needed to safely perform a procedure.

In this study, all of the LessRay® procedures were performed exclusively using one pulse and low-dose imaging (ie, the lowest setting on a conventional C-arm) without the need to supplement these low quality images with additional lower dose images to ensure safety or efficacy. The effectiveness of the LessRay® technology was demonstrated by the observation that no additional imaging was needed when LessRay® was utilized. Moreover there was no compromise in surgical accuracy and no procedure was aborted due to poor image quality.

The technique of lowering the ionizing radiation emitted by the fluoroscope by altering the pulse rate is not unique to this study. Decreasing the pulse rate is strongly advocated by the ACR and the Society for Pediatric Radiology in their Image Gently and Image Wisely campaigns. It has been employed in numerous studies, both preclinical and clinical, to address radiation exposure. Although some neonatal and pediatric studies have shown the ability to lower the pulse rate down to less than 6pps (pulses per second), no study focusing on adults or adult anatomy has gone lower than 0.5pps. Further, no study has gone to 1pps, and they typically do not include the addition of low dose imaging. The reason for this is probably best articulated in a recent study of minimally invasive spine fusions which sought to decrease radiation using 8pps in combination with low dose imaging wherever image clarity allowed that decrement in radiation. Unfortunately, “for fine detail,” when required to perform the procedure accurately, because the “detail of the pedicle is lost with the low-dose pulsed fluoroscopy,” they “aborted the procedure and steering away from that technique.” It should be noted that identifying accurately the borders of the pedicle is required in exactly the same fashion in performing the surgical intervention used in this paper, yet image enhancement allowed our physicians to continue to perform the procedures throughout a lower radiation setting than their 8pps and not abandon it when anatomic detail was required.

Conclusions:

By digitally improving low radiation images, this study demonstrates that LessRay® allows entire procedures to safely be performed using the lowest automated radiation settings on a fluoroscope. The procedure can progress as the physician desires without altering the steps or the number of images. Setting the C-arm to one pulse and a low dose radiation emitted by an order of magnitude. LessRay® makes these images useful. Together, they are a powerful combination resulting in a safer environment for everyone in the operating room.