Radiation risk from fluoroscopically-assisted anterior cruciate ligament reconstruction

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ABSTRACT

INTRODUCTION Precise tunnel positioning is crucial for success in anterior cruciate ligament (ACL) reconstruction. The use of intra-operative fluoroscopy has been shown to improve the accuracy of tunnel placement. Although radiation exposure is a concern, we lack information on the radiation risk to patients undergoing fluoroscopically-assisted ACL reconstruction with a standard C-arm. The aim of our study was to determine the mean radiation doses received by our patients.

PATIENTS AND METHODS Radiation doses were recorded for 18 months between 1 April 2007 and 30 September 2008 for 58 consecutive patients undergoing ACL reconstruction assisted by intra-operative fluoroscopy. Dose area product (DAP) values were used to calculate the entrance skin dose (ESD), an indicator of potential skin damage and the effective dose (ED), an indicator of long-term cancer risk, for each patient.

RESULTS The median age of 58 patients included in data analysis was 28 years (range, 14–52 years), of whom 44 were male (76%). The mean ESD during intra-operative fluoroscopy was 0.0015 ± 0.0029 Gy. The mean ED was 0.001 ± 0.002 mSv. No results exceeded the threshold of 2 Gy for skin damage, and the life-time risk of developing new cancer due to intra-operative fluoroscopy is less than 0.0001%.

CONCLUSIONS Radiation doses administered during fluoroscopically-assisted ACL reconstruction were safe and do not represent a contra-indication to the procedure.

KEYWORDS

Anterior cruciate ligament – Reconstruction – Intra-operative fluoroscopy – Radiation dose – Radiation risk

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Anterior cruciate ligament (ACL) reconstruction using an arthroscopically-assisted technique is commonly undertaken world-wide. Over 100,000 are performed annually in the US alone.¹ The procedure can be exacting, however, with a failure rate of up to 13%.² If surgeons place the femoral or tibial tunnels incorrectly, stiffness or recurrent instability may arise in the operated knee.^{3,4} Indeed, despite the use of drill guides and jigs, the commonest cause of failure in ACL reconstruction is tunnel malposition. To diminish error, some surgeons use image intensifiers during surgery to confirm anteroposterior location of the footprints of their ACL reconstruction.⁵

To our knowledge, the intra-operative radiation dose incurred by patients with the use of standard image intensifiers for ACL reconstruction has not been determined. Evidence suggests radiation exposure to surgeons using

standard C-arm fluoroscopy is safe.⁶ Recently, Larson and DeLange⁷ reported that levels of radiation delivered to patients in fluoroscopically-assisted ACL reconstruction was safe when using devices with miniaturised C-arm units. However, such devices deliver narrower beams of radiation than the more commonly available standard C-arm units familiar to orthopaedic surgeons. In an experimental cadaveric study focusing on ankle surgery, Giordano *et al.*⁸ reported that patient and surgeon exposure with standard C-arms was safe. However, there is a lack of specific information on the safety of intra-operative fluoroscopy using standard C-arms in knee surgery.

Radiation exposure may cause skin damage in the short term and increased cancer risk in the long term.⁹ The aim of our study, therefore, was to quantify the actual radiation exposure to patients sustained during anterior cruciate ligament

reconstruction. Since May 2007, the senior author (JC) has used image intensifier control for primary ACL reconstruction. A repeatable technique assisted by fluoroscopy has been developed.

The present study is a retrospective review of cases undertaken to determine how much radiation was delivered by the procedure. The authors had not planned to undertake the review when the senior author (JC) began using image intensifiers for ACL reconstruction.

Patients and Methods

All patients undergoing primary ACL reconstruction using image intensifier guidance between April 2007 and October 2008 were included in the study. Patients undergoing secondary repair of previously failed surgery were excluded. Radiation dose data such as duration of exposure and dose area product (DAP) were obtained from the hospital Computed Radiology Information System database (CRIS; Healthcare Software Systems, Derby, UK). Entrance skin dose (ESD) and effective dose (ED) were calculated as described below. Radiographic exposure was under the control of the operating surgeon (JC).

Surgical and fluoroscopic technique

Following graft harvest (patella ligament or hamstring tendons), an arthroscopy and notch clearance was performed. The standard C-arm of the image intensifier (Siemens Siremobil Compact L; Siemens UK, Camberley, UK), was positioned above the knee to provide a true lateral view of the distal femur. Using the quadrant method,¹⁰ an angled awl (Linvatec, Florida, USA) was used to mark the femoral entry point (see Fig. 1). The femoral tunnel was drilled in full flexion using a 4.5-mm solid drill. The tunnel was expanded to the diameter of the prepared graft using a femoral router (Smith and Nephew; London, UK) channelled over a long 3-mm guide wire. A true lateral view of the proximal tibia was then obtained. Using an Acufex guide (Smith and Nephew) and the image intensifier, a guide wire was located in the posterior third of the ACL footprint on the tibia, as recommended by Pinczewski *et al.*^{11,12} (see Figs 1 and 2) The tibial tunnel was expanded to accommodate the graft using the tibial router of appropriate size channelled over the tibial guide wire. Following graft passage and fixation using round-headed cannulated interference screws (Smith and Nephew), a lateral view of the knee was obtained to confirm satisfactory screw position prior to wound closure.

Procedures were performed in an operating theatre using the same model of C-arm device (Siemens Siremobil Compact L), with image intensifier sizes of 17 cm and 23 cm, and filtration of 3 mmAl. The distance between the X-ray tube focus and the patient was estimated to be some-

Figure 1 (A) Diagram showing lateral femoral condyle divided into quadrants. (B) Intra-operative fluoroscopy showing tip of bone awl situated in ideal quadrant and guide pin in tibial footprint. (C) Intra-operative fluoroscopy showing position of interference fit screws postoperatively.

Figure 2 Intra-operative photograph showing standard C-arm located above operating table providing true lateral image of extended knee.

where between 30–50 cm, for the purpose of calculating skin dose it was taken as 40 cm. Radiation doses were measured by the dose area product (DAP) in $\text{cGy}\cdot\text{cm}^2$, using an in-built ionisation chamber. The DAP is the absorbed dose to air averaged over the area of the X-ray beam in a plane perpendicular to the beam axis, multiplied by the area of the beam in that plane. Measurement of DAP thus gives an indication of the total radiation energy received by the patient. With a knowledge of the organs and tissues irradiated, conversion factors can be used to convert the DAP into an effective dose (ED) of radiation. The installed DAP-meter was calibrated by means of an independent DAP-meter (VacuDAP 2000; VacuTec Messtechnik, Dresden, Germany) with traceable calibration. The DAP values were entered manually into an online database at the time of the procedure. The equipment was also regularly audited and subjected to 6-monthly servicing by the manufacturer.

Exposure calculations

The DAP values from the C-arm were used to calculate the ED. The entrance skin dose (ESD) reflects the amount of radiation absorbed at any given point on the skin and corresponds to the risk of skin damage. The incidence of skin damage increases significantly once a threshold of 2 Gy is exceeded. The ESD was calculated from the DAP based on an X-ray beam size of 25 cm diameter at the image intensifier and, therefore, approximately a 9 cm $\times$ 9 cm beam at the patient's skin. To account for the fact that the X-ray field is not always sited at the same place on the patient's skin, but may cover an area approximately three times the instantaneous beam area, the calculation was repeated using an area of 243 cm^2 . The ED is an indicator of the risk of radiation-induced malignancy later in life following exposure to a given level of radiation.

The ED was derived from the DAP data by the PCXMC 1.5 computer program (STUK [Radiation and Nuclear Safety Authority], Helsinki, Finland). These calculations assumed a tube voltage of 90 kVp.

Results

Radiation dose data were recorded for 18 months between 1 April 2007 and 30 September 2008 for 63 consecutive patients undergoing primary ACL reconstruction with intra-operative fluoroscopy. Data from 5 patients were incomplete, so these patients were excluded. The median age of the remaining 58 patients included in data analysis was 28 years (range, 14–52 years), of whom 44 were male (76%).

During the same study period, a further four patients underwent planned cruciate ligament reconstruction without fluoroscopy. These four were, therefore, excluded from the study. Revision ACL reconstruction operations were also excluded from the study. Of the 58 patients studied, 47 underwent primary hamstring autograft ACL reconstruction, seven patients had patella tendon ACL reconstructions and four had patella tendon ACL reconstruction with meniscal repairs.

Based on an irradiation area of 243 cm^2 , a mean dose area product of $0.29 \pm 0.55 \text{ Gy}\cdot\text{cm}^2$ and screening time 0.33 min (SD 0.32), the mean ESD during intra-operative fluoroscopy was $0.0016 \pm 0.0029 \text{ Gy}$. This represents a very low ESD, with no results approaching the threshold of 2 Gy for skin damage. The mean ED for intra-operative fluoroscopy was $0.001 \pm 0.002 \text{ mSv}$. Based on epidemiological studies suggesting a 5% risk of developing lethal cancer per Sv of radiation exposure,¹⁵ the life-time risk of developing new cancer due to fluoroscopy equates to less than 0.0001%.

Discussion

Though intra-operative fluoroscopy is common, there are no published studies on the radiation exposure to patients having ACL reconstruction with standard C-arms. As reflected in our sample, many patients undergoing these procedures are young, including women of child-bearing age. Therefore, a consideration of actual patient radiation exposure levels during intra-operative fluoroscopy in clinical practice is important.

In addition to increasing the risk of cancer, radiation exposure causes skin damage through a deterministic mechanism. Skin damage is seen after radiation exposure exceeds a threshold dose that kills a critical number of cells.¹⁴ A 2-Gy radiation dose may cause transient damage to skin, clinically manifesting as erythema. Doses of 3 Gy may lead to transient hair loss and, therefore, 2 Gy is considered a safe threshold for radiation dose to skin.¹⁵ Radiation dose has a stochastic effect on the development of malignancy. Although the probability of malignancy increases with the

Figure 3 Sequential analysis of radiation dose in 58 cases of anterior cruciate ligament reconstruction.

total dose of administered radiation, ultimate severity is independent of the total dose administered.¹⁵

Long-term epidemiological studies suggest a 5% risk of developing lethal cancer per Sv of radiation exposure (with a mean latency of 10–20 years post-exposure).¹⁵ Based on our estimated effective dose, the life-time risk of developing new cancer due to fluoroscopic ACL reconstruction, therefore, equates to less than 0.0001%. Deterministic effects such as skin damage have a well-defined threshold: approximately 2 Gy for any skin damage (erythema) as reinforced

by the latest guidelines of the International Committee on Radiation Protection (ICRP).¹⁵

The maximum ESD of our cohort was 0.044 Gy, well below the threshold of 2.5 Gy thought to induce sterility in reproductive tissue.¹⁵ Sequential case analysis (Fig. 3) did not reveal clear evidence of a 'learning curve' for the surgeon or the variety of radiographers also involved in learning the technique. Detailed retrospective analysis of the highest doses recorded revealed no intra-operative problems to explain the higher doses received by cases 41, 44

Table 1 Mean radiation dose during common radiological procedures

	DAP (Gy.cm ²)	ESD (Gy)	ED (mSv)	Screening time (min)
ACL fluoroscopy	0.29	0.0015	0.001	0.33
Radiograph limbs and extremities ¹⁶	0.04–1.62	–	0.01	0.2–1.4
Radiograph hips and spine ¹⁶	0.4–10.2	–	1	0.2–1.4
Endovascular aneurysm repair (EVAR) ¹⁷	150.5	0.59	28.3	21.5
Therapeutic endoscopic retrograde cholangiopancreatography (ERCP) ^{17,18}	66.8	0.08	–	10.5
Operative cholangiography ¹⁹	1.67	0.0069	0.18	0.53
Coronary stent ²⁰	82.1	0.182	14.9	13.1
Intracranial aneurysm neuro-embolisation ^{21,22}	283	–	–	75
Dynamic hip screw ¹⁶	2.58			
Cannulated hip screw ¹⁶	2.65			
MUA wrist ¹⁶	0.04			
ORIF wrist ¹⁶	0.09			
ORIF ankle ¹⁶	0.39			

and 47. Indeed, the mean DAP observed in this study is amongst the lowest of all fluoroscopic procedures and is less than that associated with common imaging such as plain limb radiographs or other common orthopaedic procedures (Table 1).¹⁶

Concerns persist regarding radiation doses in a range of surgical specialities. For example, high exposures are entailed in endovascular repair of aortic aneurysms (EVAR).¹⁷ However, compared with EVAR, the calculated effective dose and DAP recorded in our study were over 100 times lower (Table 1). This correlates with the relatively short mean screening time observed for ACL fluoroscopy (0.33 min). The DAP in our cohort is 200 times lower than that seen in endoscopic retrograde cholangiopancreatography (ERCP).^{17,18} This finding suggests that intra-operative fluoroscopy imparts significantly less radiation dose than that received by patients undergoing an ERCP, a common diagnostic and therapeutic intervention.

The method used to calculate radiation exposure has been previously validated,^{17,19} and the DAP in our series is five times lower than that received in intra-operative fluoroscopy in a recent study.¹⁹

The main advantage of fluoroscopic assistance for ACL reconstruction is more accurate and reproducible tunnel positioning. Prior to using fluoroscopy, the senior author (JC) had greater variation in positioning both femoral and tibial tunnels. A tendency to place the femoral tunnel anteriorly and to place the tibial tunnel posteriorly existed. Fluoroscopic assistance has also enabled more rapid surgery for two main reasons. First, there is less doubt about the best position for the tunnels. Second, there is less need to undertake extensive soft tissue debridement in the femoral notch. Potential disadvantages of using fluoroscopy include radiation and cost. However, by using the C-arm to obtain lateral and anteroposterior views the requirement for postoperative radiographs is obviated. This study confirms that the levels of radiation delivered during ACL reconstruction with intra-operative fluoroscopy are safe and are much lower than those received in other fluoroscopically-assisted operations.

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