# FactSheet Fluoroscopy in Research

Fluoroscopy is an imaging procedure that uses a continuous x-ray beam to create real-time images viewed on a monitor. It enables physicians to view internal organs and vessels in motion and can be used in both diagnostic and therapeutic procedures.

The long term risk associated with fluoroscopy is cancer, however, more immediate risks of skin injury due to high doses are possible. The typical fluoroscopic entrance exposure rate for a medium-sized adult is approximately 30 mGy/min (3 rad/min), but is typically higher in image-recording modes. Table 1 on the next page illustrates skin injury per fluoroscopy dose and time of onset.

For physicians/researchers, it is not often clear when the use of fluoroscopy is considered Standard of Care versus research.

Standard of Care (SOC) is about clinical judgement, decision flexibility, whereas research needs to adhere strictly to protocols. The following assessments assist the physician/researcher in determining whether use of fluoroscopy is for research purposes:

- Would the subject receive this care absent of the clinical trial?
- Can you back yourself up in the literature?
- Does local SOC differ from national standards/ guidelines?
- Are protocol deviations documented?

For any "NO" answer to the above, use of fluoroscopy may be for research purposes. If so, then it is necessary to educate the patient on risks associated with fluoroscopy in order for him/her to provide an informed consent.

Appropriate consent language would need to be drafted to underscore the risks of augmented x-ray exposure (above routine diagnostic x-ray exposures) namely, the potential for skin reddening (erythema), cancer, and other deleterious effects.

The doctor performing the study would need to carefully explain the risks and how it relates to the patient's overall health.

## What I need to know...

Dose Reduction Techniques

- Use ultrasound imaging when possible.
- Position the image intensifier as close to the patient as practicable.
- Maximize the distance from the radiation source.
- Remove Grids. Grids improve the image quality, however, they increase the dose to the patient and staff by a factor of two or more.
- Use pulsed rather than continuous fluoroscopy when possible, and with as low a pulse as possible.

***References***


U.S. Food and Drug Administration (FDA)
Medical X-ray Imaging - Fluoroscopy
http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115354.htm



USC Environmental Health & Safety

University Park Campus
3434 South Grand Ave, CAL 120
Los Angeles, CA 90089-2815

Health Sciences Campus
2001 N Soto St, SBA 329
Los Angeles, CA 90032

**323.442.2200**
radsafety@usc.edu
http://adminopsnet.usc.edu


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| Skin Injury and Time to Onset | | | | | |
|---|---|---|---|---|---|
| Listed in order of time of initial onset | | | | | |
| Effect | Time of Initial Occurrence | Approximate Threshold Dose (Gy) | Note | Minutes of fluoroscopy at typical normal dose rate of 20 mGy/min) | Minutes of fluoroscopy at typical high dose rate of 200 mGy/min |
| Early transient erythema | 2-24 hours | 2 | Inflammation of the skin caused by activation of a proteolytic enzyme that increases the permeability of the capillaries | 100 | 10 |
| Main erythema | 1.5 weeks | 6 | Inflammation of the skin caused by hyperemia of the basal cells and subsequent epidermal hypoplasia | 300 | 30 |
| Temporary epilation | 3 weeks | 3 | Temporary hair loss caused by the depletion of matrix cells in the hair follicles | 150 | 15 |
| Permanent epilation | 3 weeks | 7 | Permanent hair loss caused by the depletion of matrix cells in the hair follicles | 350 | 35 |
| Dry desquamation | 4 weeks | 14 | Atypical keratinization of the skin caused by the reduction of the number of clonogenic cells within the basal layer of the epidermis | 700 | 70 |
| Moist desquamation | 4 weeks | 18 | Loss of the epidermis caused by sterilization of a high proportion of clonogenic cells within the basal layer of the epidermis | 900 | 90 |
| Secondary ulceration | >6 weeks | 24 | Secondary damage to the dermis as a consequence of dehydration and infection when moist desquamation is severe and protracted | 1200 | 120 |
| Late erythema | 8 to 10 weeks | 15 | Inflammation of the skin caused by injury of the blood vessels; edema and impaired lymphatic clearance precede a reduction in blood flow. | 750 | 75 |
| Ischemic dermal necrosis | >10 weeks | 18 | Necrosis of the dermal tissues as a consequence of vascular insufficiency | 900 | 90 |
| Dermal atrophy | >52 weeks | 10 | Thinning of the dermal tissues associated with the contraction of the previously irradiated area | 500 | 50 |
| Telangiectasia | >52 weeks | 10 | Chronic dilation of the capillaries and other small blood vessels | 500 | 50 |
| Dermal necrosis (delayed) | >52 weeks | >12 | Necrosis of the dermal tissues as a consequence of vascular insufficiency | 750 | 75 |
| Skin cancer | >15 years | None known | | N/A | N/A |

**Table 1. Skin injury per fluoroscopic dose and time of onset.**