THE EFFECT OF THE INTRODUCTION OF PICTURE ARCHIVE AND COMMUNICATION SYSTEMS (PACS) ON PATIENT RADIATION DOSES AND PATIENT MANAGEMENT

A thesis submitted for the degree of Doctor of Philosophy

by

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ABSTRACT

This thesis considers the effects of Picture Archive and Communications Systems (PACS), on both patient radiation doses and patient management. PACS is a relatively new technology which acquires, transmits, and stores radiological images digitally. This thesis investigates the doses which are required to produce radiographic images which are acceptable to radiologists and referring clinicians, and compares these doses with those required for the film/screen systems which they are replacing. A review of the literature shows that despite claims of dose reductions, very little good evidence exists about dose changes with the introduction of PACS.

A comparison of images of test objects indicates that the images are comparable under limited conditions, that PACS has a much wider latitude than film (>250 mAs), and that contrast detail improves with increase in exposure. Two original observational studies are described in which PACS and film doses are compared for examinations of two groups of adult patients. The results indicate that the doses for PACS equate to those used with a 300 speed film/screen system thus necessitating dose increases of around 30% for the majority of adult patients in the UK. The issue of whether the number of images which are repeated, with additional patient doses, due to unsatisfactory images (rejected images), or unavailability of the images when clinically required (lost images), is addressed and indicates that PACS may allow a dose saving of 1.1% and 1.4% respectively. The overall result of these studies indicates that the widespread introduction of PACS is likely to increase population doses. Two original studies which consider patients within the Accident and Emergency department are described. These studies aim to produce evidence to justify the introduction of the new technology, despite higher radiation doses, by identifying improvements in patient management which might improve patient outcomes. The results of these studies provide little evidence of such benefits to patients.

This thesis concludes that the use of current PAC systems produces an increase in the radiation dose to the adult population in the UK, without demonstrable improvements in patient management.

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FOREWORD: BACKGROUND TO THE WORK REPORTED IN THIS THESIS

The quantitative studies which have been described in this thesis were undertaken at two hospitals: the majority of the work being undertaken at the Hammersmith Hospital in West London and the remainder at Glan Clwyd Hospital in North Wales. The studies at the Hammersmith formed part of a comprehensive exercise to identify and measure both the benefits and the costs of the introduction of a hospital-wide Picture Archive and Communications System (PACS) [Bryan et al 1998a, Bryan et al 1999a]. The evaluation was undertaken on behalf of, and funded by, the Department of Health, which had financed the Hammersmith PACS installation on condition that an independent evaluation was undertaken. This evaluation was commissioned to the Health Economics Research Group (HERG) at Brunel University and was undertaken by a small multidisciplinary team of researchers, including myself, with expertise in Health Economics, Health Services Research and Medical Imaging. (A summary of the scope of the HERG evaluation is provided as an addendum to this section). The work at Glan Clwyd Hospital was carried out on behalf of the Wales Office of Research and Development for Health and Social Care and was a collaborative study led by HERG, involving the Departments of Radiology and Intensive Care at Glan Clwyd and the Institute of Health Studies at Wrexham. As the only member of the HERG PACS evaluation team with a professional background in medical imaging, I took the lead on several studies within the radiology departments including those which related to patient radiation doses. It is these studies, for which I had responsibility, which are discussed in this thesis. In each of these studies, I designed and developed the methodology, collated the data, analysed or instructed the analysis of the data, and interpreted the results of the analysis.

The PACS at Hammersmith Hospital

The Hammersmith Hospital is a teaching hospital and tertiary referral centre situated in West London and at the time of the study had around 400 beds. At this hospital

a large General Electric PACS was installed and was operational hospital-wide by March 1996. The hospital is now virtually 'film less' although film continues to be used for dental examinations, and films are printed for patients who attend other hospitals (no mammography examinations are undertaken). Images of general radiographic examinations are acquired by phosphor plate computed radiography technology and processed in plate readers from which digital images are produced automatically and hard copies are printed if required. All other images are produced in a digital format and incorporated into the PACS. All images are viewed and reported in soft copy format on workstations which have image manipulation facilities, transmitted around the hospital via a dedicated fibre-optic network, and stored in digital format in a central archive. There are approximately 150 workstations within the hospital and users can view any images on any workstation.

The PACS at Glan Clwyd Hospital

The PACS at Glan Clwyd Hospital in North Wales was installed in January 1994 and was a 'mini' system which linked the radiology department with the Intensive Therapy Unit (ITU). Glan Clwyd Hospital is a district general hospital with approximately 550 beds which served a resident population of 175,000 and an additional tourist population during the summer. The Intensive Therapy Unit had a maximum of 8 beds. At the time of the study the PACS linked the radiology department on the ground floor of the hospital with ITU on the first floor via an ethernet network. The images were acquired on phosphor computed radiography plates in ITU and processed in the Kodak Ektascan Storage Phosphor Reader (KESPR) which was situated in a room within ITU adjacent to the clinical area. The processed images could be viewed by clinicians in soft copy format in ITU on workstations which were situated in the clinical area. The workstations had facilities for the manipulation of the images. The images could also be viewed on workstations in the radiology department, but the radiologists chose to report from hard copy images which were printed by the laser printers in the department. Throughout the rest of the hospital a conventional film/screen imaging system was used which could also be used in ITU if the KESPR failed.

Practical issues relating to the evaluation methodology

The focus of the work was on radiological examinations of real patients and since the Hammersmith has an Accident and Emergency (A&E) department, data was required seven days a week and for 24 hours each day. The ITU patient examinations at Glan Clwyd Hospital could also occur at any time. It was therefore not possible for one person to collect all the data, and therefore for some parts of the study it was appropriate that the data were recorded by the staff working in the hospital who were on duty at the time of the examination. Where it was possible, I personally collected the data. Otherwise, I organised and supervised the data collection activities.

It is important to note that both evaluations utilised the data from patients undergoing radiological investigations in the hospitals. No additional images of patients were produced for the purposes of these studies, and thus the research did not necessitate any additional radiation doses to patients.

Addendum: Components of the HERG Evaluation of the Hammersmith PACS.

The evaluation was complex and consisted of seven broad areas, outlined below, and they contained discrete sub-studies (shown as bullet points). Each sub-study contributed to the analysis of costs and benefits. The sub-studies shown in bold are related to the work discussed in this thesis.

1. An Assessment of Implementation Costs and the Impact of PACS on Running Costs

2. The Technical Performance of PACS at Hammersmith Hospital

3. Impact on Radiology Service Delivery
- Preparation of clinico-radiological meetings
- **The availability of images for outpatient clinics**
- **Reject rates at Hammersmith Hospital**
- The time from patient presentation to image production and report availability
- Radiology reporting times
- The work of research radiographers
- The preparation of radiology research projects

4. Impact on Clinical Practice
- Image availability on the Intensive Care Unit
- **'Diagnostic performance' in the Accident and Emergency department**
- **The visualisation of the lateral cervical spine and the proposed management of patients presenting with trauma**
- Time of clinical staff in Respiratory Medicine and Orthopaedics
- Length of consultations in an outpatient fracture clinic
- Length of stay for patients with total hip and total knee replacements
- **The effect of PACS on patient radiation doses for examination of the lateral lumbar spine**

5. The Views of Users and Providers of Radiology Services With and Without PACS
- **A survey of clinical users of radiology services**
- A survey of General Practitioner users of radiology services
- A survey of providers of radiology services
- A qualitative study of users' views of PACS

6. An Analysis of the Process of Implementation of PACS at Hammersmith Hospital

7. The Provision of Radiological Services
- How the radiology service at Hammersmith Hospital changed with the introduction of PACS
- A comparative analysis of Hammersmith Hospital and five comparator sites

GLOSSARY OF ABBREVIATIONS

ALARA	as low as reasonably achievable
ALARP	as low as reasonably practical
BIR	British Institute of Radiology
BMI	Body Mass Index
CARS	Computer Assisted Radiology and Surgery
CT	Computed Tomography
DAP	Dose area product
Dmax	Maximum (film) density
DSA	Digital Subtraction Angiography
FFD	(x-ray tube) focus to film distance
Fgd	Focus to grid distance
FSD	(x-ray tube) focus to skin distance
HERG	Health Economics Research Group
ICRP	International Radiological Protection Board
IPEM	Institute of Physics and Engineering in Medicine
ISU	Information Storage Unit
JWP	Joint Working Party
KESPR	Kodak Ektascan Storage Phoshor Reader
kVp	peak kilovoltage
lp/mm	line pairs per millimetre
mAs	milliampere seconds
MRI	Magnetic Resonance Imaging
NRPB	National Radiological Protection Board
PACS	Picture Archiving and Communications System
PRIEF	Pattern Recognizer for Iris of Exposure Field
QA	Quality Assurance
RCR	Royal College of Radiologists
RIS	Radiology Information System
SPIE	The International Society for Optical Engineering
TLD	Thermoluminescent dosimeter
WSU	Working Storage Unit

JOURNAL PUBLICATIONS BASED ON THE WORK IN THIS THESIS

Seven papers have been accepted for publication in peer reviewed journals which relate to the work reported in this thesis. These publications are:

- Weatherburn GC & Davies JG (1999) Comparison of film, hard copy Computed Radiography (CR) and soft copy picture archive and communications (PACS) systems using a contrast-detail test object, British Journal of Radiology 72: 856-863

This paper relates to some of the work reported in chapter 3

- Weatherburn G, Bryan S (1999) The effect of a picture archive and communication system (PACS) on patient radiation doses for examination of the lateral lumbar spine, British Journal of Radiology 72: 534-545

This paper is based on the work described in chapter 4.

- Weatherburn G, Bryan S, Davies JG (in press) Comparison of doses for portable examinations of the chest when Film and CR are used: results of a randomised controlled trial. Radiology

This paper is based on the work described in chapter 5

- Weatherburn G, Bryan S, West M (1999) A comparison of image reject rates when Film, hard copy Computed Radiography (CR) and soft copy images on Picture Archive and Communication Systems (PACS) workstations are used, British Journal of Radiology 72: 653-660

This paper is based on the study described in chapter 6.

- Bryan S, Weatherburn G, Watkins J, Buxton M (1999b) The benefits of hospital-wide picture archiving and communication systems: a survey of clinical users of radiology services, British Journal of Radiology 72: 469-478

This paper describes the results of a questionnaire survey of clinicians which was used to elicit their views of the service they received from the radiology department. Part of this survey asked about issues relating to 'lost' radiographic images and this part of the paper relates to chapter 7.

- Weatherburn G, Watkins J, Bryan S and Cocks R (1997) The effect of PACS on the visualization of the lateral cervical spine and the management of patients presenting with trauma, Medical Informatics; 22 (4) :359-368

This paper is based on the study which is described in chapter 8.

- Weatherburn G, Bryan S, Nicholas A, Cocks R (2000) The effect of a Picture Archiving and Communications System (PACS) on diagnostic performance in the accident and emergency department. Journal of Accident and Emergency Medicine 17 (3): 180-184

This paper is based on the study described in chapter 9.

Copies of these publications are included at the end of this thesis.

This thesis is dedicated to my parents Fred and Jean Jones

CHAPTER 1

INTRODUCTION

1.1 INTRODUCTION

This thesis focuses on issues related to patient radiation doses and a relatively new technology known as Picture Archiving and Communications Systems (PACS). The issue of balancing patient doses and image quality is one of the factors which are fundamental to the basis on which decisions about the purchase of radiographic equipment should be made. UK Health Service Guidelines [NHS Executive, 1991] recommend that health authorities and clinicians consider the minimisation of patient dose when selecting equipment for purchase. The NHS Executive [NHS Executive, 1995] has recommended that purchasers of radiology equipment use quality targets for service providers who should achieve doses below the NRPB reference doses [NRPB, 1990], and that these criteria are considered when making decisions about which equipment is purchased.

The Medical Exposure Directive [Commission of the European Communities, 1997] which was incorporated into UK legislation on 13 May 2000, states: *'All new practices must be justified before being adopted (article 3.1 (a)). This implies that a new procedure or the use of a new technology has to be critically reviewed before it can be introduced in practice. All aspects of the proposed technique, including*

patient dose, would have to be considered.' Thus the issue of balancing patient doses and image quality is one of the important fundamental bases on which the new technology, PACS, should be assessed.

1.2 HISTORICAL CONTEXT

The first x-ray image was produced by Wilhelm Conrad Roentgen in 1895 [Kotzur, 1994]. He produced an image of his wife's hand using a glass plate coated with silver salts and a single intensifying screen [Schuster 1896, Editorial, 1896] The use of x-rays for both diagnostic and therapeutic procedures spread rapidly and within a year the harmful effects of x-rays were seen. In 1896 skin erythema, epilation and desquamation were noted on the skin of x-ray workers [Webster, 1995] The hands of the operators which were in the x-ray beam began to show erythema, then tumours and ulcerations, and fatalities due to cancer occurred amongst the pioneers. In 1898 the Roentgen Society set up a committee 'to report on the alleged injurious effects of x-rays' and their first Code of Practice was produced in December 1915 entitled Recommendations for the Protection of X-ray operators [Oliver, 1973]. In 1928 the International Commission on Radiological Protection (ICRP) was established under the name of International X-ray and Radium Protection Commission [Schibilla, 1995].

Some of the effects of radiation, known as 'deterministic' [ICRP, 1990], require a threshold dose before they can occur e.g. cataract. Others are termed 'stochastic' and have no threshold but occur randomly and can be due to very low exposures e.g. genetic mutation and cancers. March reviewed the cause of death of radiologists in the period 1929-1943 and concluded that 4.57% died from leukaemia, a highly significant rate ten times that of other clinicians [March, 1944].

1.3 ATTEMPTS TO CONTROL RADIATION DOSES

In order to reduce the effects of radiation, a Code of Practice for the Protection of Persons against Ionising Radiations arising from Medical and Dental Use was published in 1957 [Department of Education and Science et al, 1957]. This was

intended primarily for the protection of staff exposed to ionising radiations in National Health Service Hospitals. It was not until later that the issue of patient doses was explicitly addressed. The Ionising Radiation (Protection of Persons Undergoing Medical Examination or Treatment) Regulations were published in 1988 [Great Britain Parliament, 1988], and Guidance Notes for the Protection of Persons against Ionising Radiations arising from Medical and Dental Use were published in 1988 to provide general guidance on good practice and to replace the previous Code of Practice [NRPB et al, 1988].

When radiological examinations are appropriate, it is important to obtain the relevant image information while exposing the patient to as little radiation as possible. There have been developments over the last century which have aimed to reduce patient doses. By 1919 two intensifying screens with double sided films were introduced [Patterson, 1944]. The speed[1] of both films and intensifying screens have increased over the years, making them more efficient at producing density on the processed film, thus allowing the incident radiation to be reduced. However, the quality of the images produced by fast film/screen combinations is not as good as for slower combinations [Gifford, 1984]. Thus a compromise has had to be reached to achieve a balance between patient dose and image quality. For some examinations where the primary diagnosis of small detail objects is required e.g. the detection of micro calcification in mammography, very fine detail is required. However, for scoliosis examinations of adolescents where the curvature of the spine has to be monitored over several years and where fine detail is not required, less detail is acceptable in order to allow lower patient doses [Jonsson et al,1995]. Thus the primary aim of radiographic imaging is the achievement of the required image quality at the lowest possible patient doses and is based on the ALARA (as low as reasonably achievable) [ICRP, 1990] or ALARP (as low as reasonably practical) principles [Department of Health, 1988].

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[1] 'speed' in the case of film is taken to be the reciprocal of the exposure required to produce unit density above fog [Gifford, 1984].

In order to reduce the number of inappropriate requests for radiological investigations with the associated unnecessary radiation doses, in 1989 the Royal College of Radiologists produced a booklet of guidance notes for doctors [RCR, 1989]. The following year The World Health Organisation published a comprehensive guide [World Health Organisation, 1990]. Both publications aimed to advise referring doctors which radiological investigations were, and were not, appropriate for specific conditions. The Guidelines also suggest that where possible, alternative investigations should be used, which do not involve ionising radiation, for example, ultrasound scans to demonstrate the gall bladder and MRI scans instead of CT scans.

European Guidelines have been produced for the diagnostic quality of the radiographic image and to provide criteria for radiation dose to the patient and choice of radiographic technique [Commission of the European Communities, 1996a, 1996b, 1997]. The European Commission aims to achieve

- adequate image quality, comparable throughout Europe,
- reasonably low radiation dose per radiograph or procedure [Busch and Jaschke, 1998].

1.4 GUIDELINES AND RECOMMENDATIONS RELATING TO PURCHASING RADIOGRAPHIC EQUIPMENT

The ideal situation is that any new equipment relating to radiology departments should produce more information with lower patient doses. If the new technology requires higher patient doses, its use can be justified if it can be shown that it provides additional information which is advantageous to the management of the patient's treatment. If doses are higher and no benefit to the patient is found, it is difficult to justify the use of the technology.

In 1990 the Joint Working Party of the Royal College of Radiologists and the National Radiological Protection Board [NRPB, 1990] advocated the use of the most sensitive rare-earth screens, compatible with retaining adequate image quality for

all radiographic examinations and referred to two studies which suggested that if these screens were used more widely in the UK, the population dose could be reduced by 3000 ManSv (25%) while maintaining adequate image quality [Shrimpton et al, 1986, Russell, 1986] .

The same Joint Working Party also recommended that:

> *'Radiologists should be aware of a number of new imaging systems that are just becoming available in this country, that all promise considerable reductions in patient dose as well as improvements in image quality. Although many of them involve substantial capital outlay, they may well prove to be more cost effective in comparison with conventional equipment when the time comes to replace existing systems. In particular, recent developments in digital imaging, such as computed radiography (Fuji, Toshiba, Philips, Siemens) ... offer digitally-enhanced images at a fraction of the patient dose required by conventional film-screen .. systems.'*

The Working Party neither provided nor cited any evidence to support this statement.

The proposed new Regulations from the Council of the European Union [Commission of the European Communities, 1997] includes Article 4 which states: *'All doses due to medical exposure for radiological purposes except radiotherapeutic procedures ..... shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information, taking into account economic and social factors',* and Article 8 which states: *'If new radiodiagnostical equipment is used, it shall have, where practicable, a device informing the practitioner of the quantity of radiation produced by the equipment during the radiological procedure.'*

1.5 PICTURE ARCHIVE AND COMMUNICATIONS SYSTEMS (PACS)

Picture Archive and Communications System[2] (PACS) is a relatively new technology whereby plain radiological images are currently acquired predominantly by computed radiography (also known as phosphor plate technology), (CR), and transmitted and stored in digital format, thus eliminating the use of x-ray film. A 'film less', digital hospital is seen as a desirable and inevitable ultimate goal by many radiologists [Stewart, 1999]. The first PACS equipment was introduced in the mid 1980s and it was predicted that 'a limited-scale PACS will be implemented in teaching hospitals by the turn of the century' [Fraser et al, 1989]. If a hospital has a hospital-wide PACS, there need be no films, no darkrooms and none of the disadvantages associated with the use of x-film, such as image unavailability and the cost of films and chemicals. Unlike the development of fast films and screens, PACS has not been developed specifically in order to reduce patient doses, but to facilitate storage and transport of images.

1.6 THE CLAIMED ADVANTAGES OF PACS

The advantages of PACS which have been claimed by its proponents and equipment manufacturers during presentations at conferences, advertising literature and in the published literature are :

- Images are available more rapidly [Gell 1998, Strickland 1998]
- No lost images [Lindhardt 1996, Sullivan 1998]
- Reduced length of stay in hospital [Straub 1990, Mosser et al 1994, Strickland 1997, Smeeton, 1999]
- Shorter reporting times [Strickland, 1997]
- Clinicians like it [Strickland, 1998]
- Reduced image reject rates [Murphey 1992, Siegel 1998, Smeeton 1999]
- Reduced patient doses [Smeeton 1999, Sweeney 1999, BT 2000]
- It is cheaper [Siegel 1998, Flagle 1999]

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[2]A PACS consists, at least, of one or multiple imaging modalities (acquisition devices),a communication network, an intermediate and/or long term storage device, and an image review and/or post processing workstation [Greinacher & Bach, 1990].

Indeed in 1992 the Hammersmith PACS Project Manager said

> *'PACS is a hospital management system. It is not a toy for radiologists, but benefits all departments'* [Glass, 1992].

This statement was made before any large PACS were installed or operational and so was not based on empirical evidence, but was a statement about the anticipated benefits of PACS. It is interesting to note that Glass did not include 'benefits to patients' as one of the ultimate goals of using PACS, since patients should benefit from images being available more rapidly, no lost images, less time as hospital in-patients, fewer rejected images and lower patient doses.

1.7 THE POTENTIAL BENEFITS OF PACS FOR PATIENTS

As indicated earlier in this chapter, *'Radiology involves a balance between benefit and risk for the patient. On one side many kinds of diseases can be detected and controlled by X-ray examinations. The benefit for the patient is a successful treatment of disease to prolong life and /or to increase the quality of life. On the other hand, X-rays are associated with a risk of clinically observable deleterious effects to the individual'* [Busch, 1998]. It is often very difficult to identify the role of radiological investigations in the management of patients and the outcome of treatment decisions because there are so many other factors which have to be considered which affect outcomes, making it difficult to extricate the contribution of the information provided by the radiological examination, and this is also true for PACS [Banta, 1992].

1.7.1 Benefits to patients associated with the speed of availability of radiographic images

There have always been problems about films being unavailable when required by the referring clinician. At first delayed access to images was due to the long processing times which took about an hour for the production of dry films. When films were processed manually if any clinicians wished to view images urgently soon after they were produced, they asked to see the 'wet plates' or 'wet films'. The relevant images had to be located in the processing tanks and if they had reached the final wash stage, the films, still fixed to the frames, were hung in a carrier,

beneath which was a tray to catch the dripping water, and taken to the clinician in the clinic. Alternatively the clinicians went to the viewing room to see the wet films. Automatic processors, introduced in the 1960s, eliminated the viewing of wet films and have accelerated the processing cycle so that dry films can now be available within 45 seconds. When PACS with central image storage and distribution is used, new soft copy images can be viewed at any workstation connected to the PACS within 3 seconds if the image is in the short term store [Bryan et al 1998a].

Studies have been undertaken at several sites to determine whether images are available more quickly in the Intensive Care and Intensive Therapy Units when PACS is used [Kundel et al 1996, Bryan et al 1998, Watkins et al forthcoming] and whether improved access to images affects the speed at which clinical actions are taken. It is assumed that faster clinical actions improve patient care and potentially improve the outcome for the patient but it has been difficult to get clinicians to record this information and to monitor and time the availability of images and subsequent action taken [Bryan et al 1998b, Watkins et al, forthcoming]. A more successful study has been undertaken by a group in Philadelphia [Arenson et al 1988, DeSimone et al 1988, Kundel et al, 1996]. This group had access to 24-hour CCTV monitoring of the viewing stations so that it could be seen exactly when images were viewed. In addition, several researchers were employed to follow up each image viewing and to elicit, by interview, the clinical action taken. They also had access to funding to reward the clinicians in monetary terms for each item of information which they provided (personal communication, Kundel). Their results showed that although images were available in the Unit faster, there was no significant change in the time of the image viewing by clinicians.

1.7.2 Benefits to patients associated with the availability of images

When film is used in radiography only one film image is produced, so if more than one person, in different locations, needs access to the same film at the same time, there are problems. The films can be copied but this process is both time-consuming and costly. Some clinicians 'solve' the problem for themselves and retain films which are interesting and could be used in a lecture or publication, thus making them unavailable to other clinicians. Sometimes when a clinician wishes to view a film it is in transit or in the radiology department for reporting. Lost and unavailable images cause a lot of frustration to clinicians who need to view them in order to make judgements about the progress of a patient's condition and to make decisions about the patient's management and treatment. The clinicians either make that judgement without using the images, or the images are repeated with an additional radiation dose to the patient. The use of PACS should ensure that images are always available, thus eliminating the frustrating and time-consuming task of trying to locate films, the necessity to repeat those which cannot be located, and patient treatment decisions being made in the absence of images.

1.7.3 Benefits to patients associated with reduced length of hospital stay

It has been suggested that the faster availability of radiographic images and the reduction in the number of images which are lost when PACS is used, contributes to the patients being discharged from hospital earlier than when film is used. There have been claims of a 3 day reduction in length of hospital stay (LOS) due to the use of PACS [Strickland, 1997]. There have been no rigorous studies which have shown that LOS reduction can be attributed to the use of PACS. Most studies have been naive comparisons of LOS in different hospitals [Mosser, 1994], or in the same hospital over different periods of time [Strickland,1997]. Kelley & Kolodner [1999] reported a 10% reduction in length of hospital stay but state that they have not been able to determine whether this is due to PACS or to the many other external changes which have occurred. The study by Watkins et al [Watkins et al, 1999] used regression analysis to determine whether PACS was a significant factor in changing LOS and found no convincing evidence of PACS-related reduction in LOS.

1.7.4 Benefits to patients in issues related to reporting times

An observational study was undertaken as part of the HERG evaluation of PACS [Bryan et al, 1998]. It was found that no difference in the time it took radiologists to make radiological reports could be detected. Thus in this aspect, PACS did not affect patient care. However, it was also shown that when PACS was used the radiologists viewed previous images more frequently than when film was used. The viewing of previous images is taken as an estimate of the quality of the report (Professor Peter Armstrong, personal communication) and thus from this viewpoint PACS reports may be of higher quality than film reports and may improve patient care.

1.7.5 Benefits to patients in issues related to clinician satisfaction with the technology

Studies in which the clinicians' views of, and satisfaction with, the radiology service and with the introduction of PACS were undertaken as part of the evaluations of the Hammersmith and Glan Clwyd PACS, and these papers have been published [Bryan et al 1999b, Watkins 1999]. These studies substantiate the claim that once they get used to using it, clinicians like using PACS. However, it was found that because they liked using the system, some clinicans overestimated its benefits. For example, at Glan Clwyd it was perceived that PACS images were available in ITU more quickly than film images but a timing study showed that there was actually no difference in the time of image availability on the Unit. It could be postulated that patients must benefit from anything which makes their doctors happier at work, but no studies have been found which have shown that patient care has improved when PACS is used.

1.7.6 Benefits to patients in issues related to rejected images

It has been suggested that when PACS is used the number of images which are rejected and which add no contribution to the final radiological report and thus the management of the patient is lower than when film is used. This is of direct benefit to the patients if the rejected images have to be repeated because each additional image requires an additional radiation dose to the patient. Fewer rejects are also

of benefit to the patient because each image of a very sick patient or a patient in pain may put the patient at risk or cause additional pain. Repeat images also extend the time of the examination and potentially the time of the diagnosis of the images which could be of detriment as well as inconvenience to the patient.

1.7.7 Benefits to patients in issues related to radiation doses

Dose studies which have been reported in the literature relate to the introduction of CR technology. It has been suggested that PACS has nothing to do with doses, which are determined solely by the CR technology. In PACS, image acquisition is predominantly by CR [Bick 1999], but viewing and reporting uses workstations with manipulation facilities with the potential for the provision of more information and allowing lower doses to be used for the production of each image. In addition the manipulation of the soft copy image may allow more images to be acceptable, thus reducing repeats and additional exposures. The digital storage and transmission of images should allow images to be always available when clinically required, eliminating this need for repeats. No studies are reported in the literature where the contribution of PACS to patient doses has been measured in respect to these three areas.

The dose issue is fundamental for all imaging equipment and needs to be determined for PACS. If the doses are increased, the increase must be justified on the basis of additional information being available which assists patient management. If doses are unchanged, since PACS have been shown to be associated with additional costs [Bryan et al 1999a, Bryan et al forthcoming], the additional cost can only be justified on the basis of improved patient care. If doses are reduced, then this might itself justify an increase in cost.

1.7.8 Benefits to patients in issues related to the cost of the equipment

If the use of PACS were related to cost savings it would be beneficial to the patients because it would release additional resources which could be used for other health based activities. However, the overall result of both the Hammersmith and Glan Clwyd PACS evaluations is that PACS is associated with higher costs than

conventional film based imaging systems. These additional costs might be justified if the use of PACS can be seen to be related to reduced population radiation doses. It has been suggested that because exposure to radiation may cause adverse effects including cancer, radiation doses can be given a monetary value which is based on the cost to the health service of treating the additional cancer [NRPB, 1990]. In this way, if radiation doses are reduced, it might be shown that PACS is cost saving.

1.8 THE AIM OF THIS THESIS

The aim of this thesis is to examine

- the implications on patient doses of the introduction of PACS into hospitals,
- and to determine whether any changes in dose can be justified by changes in patient management which could improve patient outcomes.

1.9 CONSTRAINTS ON METHODOLOGY

It was possible to collect data at two hospitals which were using PACS: the Hammersmith Hospital in West London, and Glan Clwyd Hospital in North Wales. The design of the evaluation of the Hammersmith PACS was very limited because there were no plans to operate both a conventional film system and a PACS simultaneously. Thus the only choice of methodology was a comparison of activities before PACS, while films were used, and the same activities after PACS became operational [Bryan et al, 1995]. At the same time, five 'comparator' hospitals which were not introducing PACS, were monitored, in order to determine what changes occurred which were unrelated to PACS. However, at Glan Clwyd Hospital both PACS and conventional film images were being used simultaneously, and so it was possible to conduct a randomised controlled trial.

The work which was undertaken at the Hammersmith Hospital consisted of a series of sub-studies which were independent of each other. Each sub-study was designed to identify changes which occurred when PACS replaced the use of a conventional film/screen system, but in addition where it was possible, to identify changes in patient management and outcome which could be attributed to the use of the new technology. Thus the aim was to undertake comparative studies of 'technical

output' which Fineberg et al classified as Level 1 in their hierarchy and 'therapeutic plan' which they defined as Level 3 in the same hierarchy [Fineberg et al, 1977] (Figure 1.1) and Level 4 in the hierarchy which was later suggested by Fryback and Thornbury [Fryback & Thornbury 1991, Thornbury 1994] (Figure 1.2).

1.10 THE STRUCTURE OF THE THESIS

There are nine further chapters in this thesis. Each chapter describes a self contained study which contributes to the overall aim of the thesis, and includes a discussion of the results and the issues relevant to the area of the study.

Chapter 2 reviews the published literature relating to the introduction of PACS utilising phosphor plate CR image acquisition and how it affects patient radiation doses and the associated quality of the images. It will examine the claims in the literature that the use of PACS reduces patient doses by three ways: a reduction in the radiation needed to produce each image [Sandmayr, 1997]; a reduction in the number of images which have to be repeated because the original is unsatisfactory [Siegel 1998, Pomerantz 1999]; and the elimination of repeat images which are necessary because the original images are 'lost' and unavailable when clinically required [Belloto, 1997].

The next five chapters of this thesis describe original studies undertaken to determine what changes in dose, if any, are required when a PACS utilising phosphor plate image acquisition, replaces a conventional film/screen system.

In chapter 3 three tests are described in which test objects are used in order to compare the response of the film, CR hard copy and PACS soft copy images in terms of high contrast resolution and to change in incident dose. The exposure latitude of the imaging systems are compared to examine the claims in the literature that the wide exposure latitude of phosphor plate imaging allows doses to be reduced.

The studies which are described in the following four chapters are pragmatic studies which consider the images of real patients and involve only images which were requested for clinical purposes. No additional images were undertaken for the studies. Since the images were those in normal use, the criteria for the quality of the images were that they were acceptable to the radiologists and clinicians in the hospitals.

Chapter 4 focuses on a comparative study of doses for the examination of the lateral lumbar spine. A before and after format was used for an observational study in which patient doses were monitored when firstly, conventional film images and secondly, PACS images were being used routinely. In order to control for the many confounding factors which had occurred between the two periods of dose measurement, regression models are used to identify the role of PACS in any changes in dose.

In 1994, 75% of hospitals in the UK used screen/film combinations with speeds equal to or greater than 400 [Hart, personal communication], and thus the Hammersmith Hospital which used a 300 speed film/screen system is atypical. A further dose study was therefore undertaken in a hospital which used a film/screen system with speed 400 and was thus typical of the majority of general hospitals. Chapter 5 describes this study which was part of a randomised controlled trial. All patients admitted to the Intensive Therapy Unit (ITU) were randomised to have all radiographic examinations undertaken using either conventional film or PACS images. The patient doses for all mobile chest examinations were measured and compared.

Chapter 6 considers the issue of additional radiation doses to patients due to unsatisfactory images being repeated, the change in the number of images which are rejected, and the reasons for image rejection. This chapter describes a comparative study which was undertaken at the Hammersmith Hospital of the number and type of rejected images during three periods when different types of images were in routine use: film, CR hard copy and PACS soft copy images.

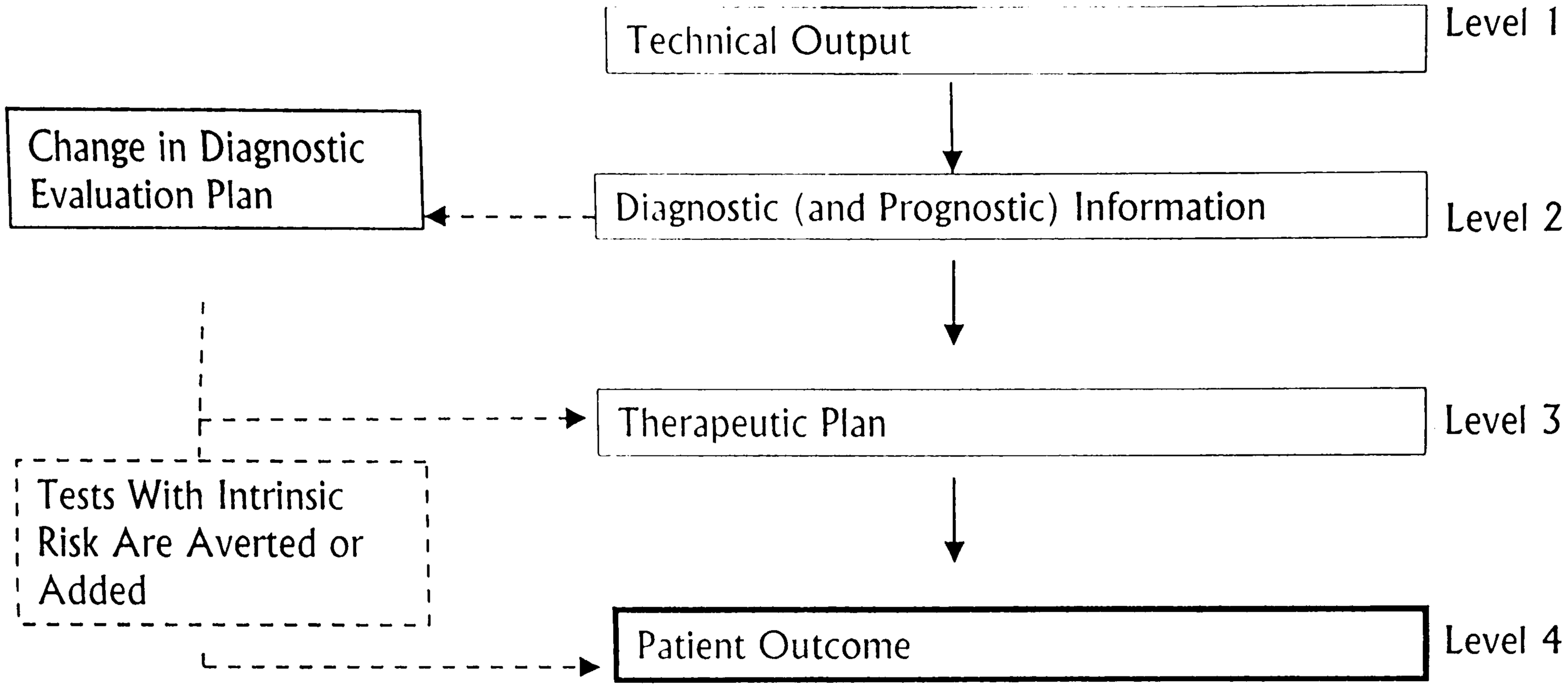
Chapter 7 addresses the issue of unavailable images. It describes a study which compared the images which were unavailable for outpatients clinics firstly when film was used, and secondly when PACS was used at the Hammersmith. In addition some of the results of a questionnaire survey of hospital clinicians are presented. The questionnaires which provided the subjective views of the clinicians on the lost image problem, were distributed annually to clinicians at the Hammersmith and five 'comparator' hospitals before and after PACS was used at the Hammersmith, and asked the clinicians whether they would request a repeat x-ray examination when images were unavailable, and if so, how frequently they made such requests. An estimation is made of the proportion of the hospitals' workload which is repeated due to lost images and thus the potential increase in patient doses due to lost images.

The following two chapters describe two studies which aim to determine whether the use of PACS changed the management of patients in the Accident and Emergency Department (A&E). Chapter 8 describes a study which was undertaken at the Hammersmith Hospital to determine whether the on screen manipulation facilities of PACS improved visualisation of the lateral cervical spine particularly in the region of the cervico-thoracic junction, and whether there was any difference in patient management following viewing of the images. A comparison is made of the CR hard copy and PACS soft copy images of a sample of 100 A&E patients who presented with trauma, and the proposed subsequent patient management.

Chapter 9 describes a second pragmatic study of normal working practices in A&E at the Hammersmith Hospital and considers the issue of whether the use of PACS resulted in fewer misdiagnoses of radiographic images by A&E staff to be made, and whether patients' management was changed. A comparison is made of false negative reports by A&E clinicians over a six month period when film was used and the same six month period when PACS was used.

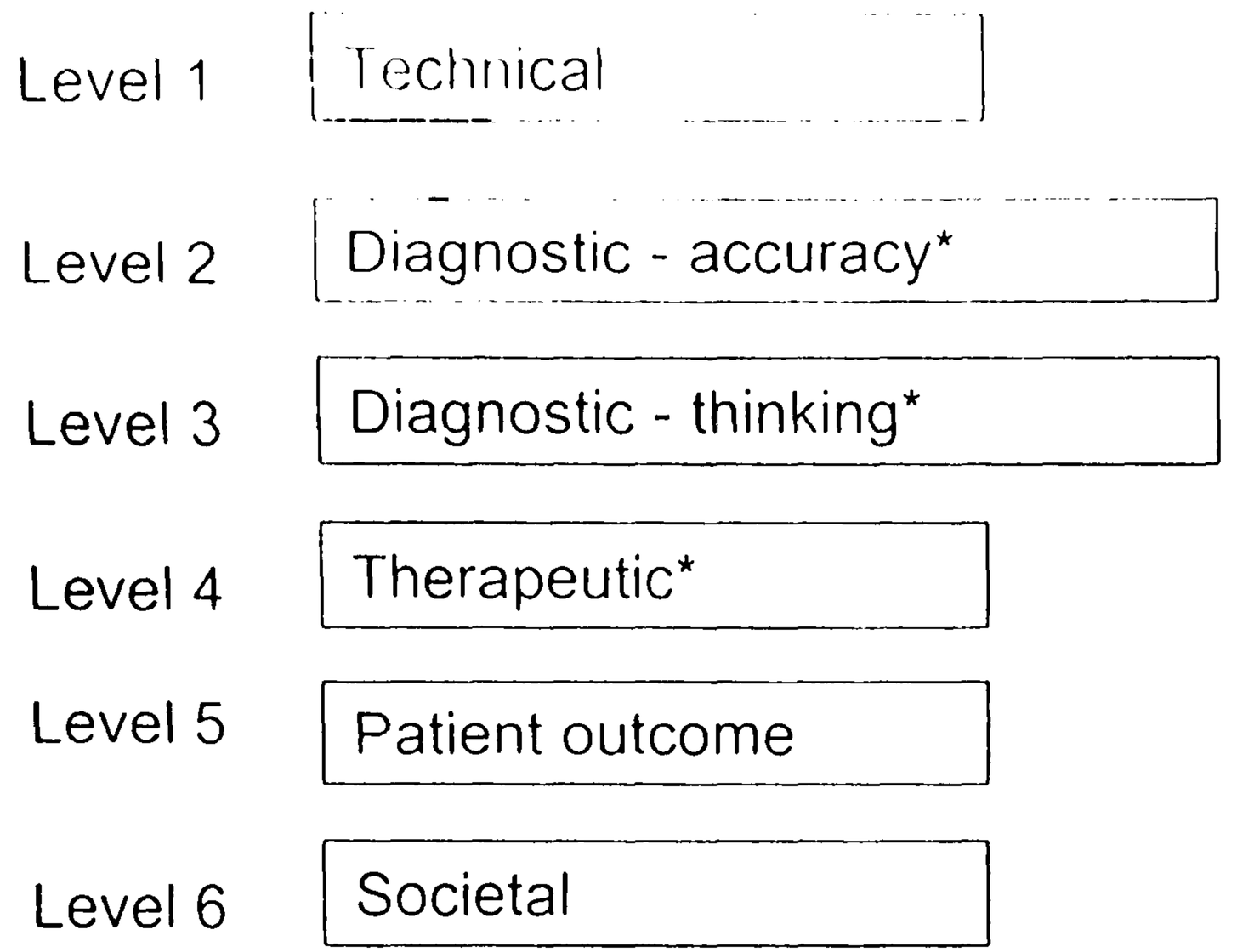
In chapter 10 the overall results of the thesis are discussed with reference to current legislation and recommendations concerning the introduction of new radiology equipment and radiation protection of the patient. In addition, suggestions are made about how the methodology could be improved and further research which might be undertaken.

Figure 1.1 Levels of clinical efficacy related to the use of a diagnostic test



Fineberg *et al* (1977) *JAMA*, vol 238 (3), 225-227

Figure 1.2 A hierarchical model of efficacy



* Level 2 + Level 3 + Level 4 = clinical efficacy

Thornbury JR (1994) Clinical efficacy of diagnostic imaging: love it or leave it. *AJR*, vol 162, 1-8

CHAPTER 2

A REVIEW OF THE LITERATURE

2.1 INTRODUCTION

In the previous chapter it was shown that for all radiographic imaging techniques a balance has to be drawn to provide images in which the information needed to allow patient treatment and management decisions to be made, can be seen and interpreted, and that these images are produced at the lowest possible doses. This thesis will consider these criteria applied to PACS technology and will endeavour to determine whether, for the production of images which are acceptable to radiologists, there is a change in radiation doses to patients and the magnitude and direction of any change when PACS is used compared with a conventional film/screen system. Currently PACS acquires images predominantly by computed radiography or phosphor plate technology (CR), and the doses required by these CR systems are a major contributory factor to the required doses. However, unlike stand alone CR systems, when PACS is used, the digital CR images are viewed on monitors as soft copy images and there are various tools available to manipulate the images. The soft copy images can be enlarged, the densities changed and the grey scale reversed, providing additional information which may aid diagnosis of the images. It is therefore important to consider both the effect of CR systems and the additional features of PACS and how these might affect patient doses.

In the previous chapter three aspects were identified where the use of PACS might contribute to dose reduction. Firstly, there might be a reduction in the dose required to produce each image, secondly, there might be fewer images which need repeating due to the use of incorrect exposure factors, and thirdly there might be fewer images which have to be repeated because the original is lost. A search of the literature was undertaken to determine what evidence was already available which was relevant to these three areas.

2.2 SEARCH STRATEGY AND RESULTS OF SEARCH

The search was conducted using the databases Medline, SIGLE, CINAHL, INSPEC and Embase, and using the words 'computed radiography', 'CR', 'Picture archiv* communication* system*', 'PACS', 'dose*', digital', 'image* and, 'diagnostic'. The papers obtained from the search were read and further papers identified from the references given in the papers. An initial search was undertaken at the start of each part of the research and then subsequent searches made at the beginning of 1999 and in January 2000.

There is no consensus of opinion about the magnitude and direction of change in doses when CR is used. Some authors suggest that dose changes are related to a difference in the sensitivity of the phosphor plates making a change in exposure factors mandatory in order to achieve acceptable image quality. There are suggestions that doses are increased [Galanski et al 1992, Artz 1997, Bragg et al 1997 and Tylen 1997], that doses are decreased [Pettersson et al 1988, Murphy 1992, Langen et al 1992, Wandtke 1994, Marshall et al 1994b, Seifert et al 1995, MacMahon & Giger 1996, Seifert 1996, Lindhart 1996, Jonsson et al 1996, van der Putten 1998 and Bowman 1998], and that there is no change in dose for comparable images [Langen et al 1993, MacMahon & Vyborg 1994, Krug 1994, Marshall et al 1994a, Busch 1997 and Huda et al 1997].

Some authors indicate that dose decreases are achieved by a reduction in the number of repeated images: the reduction being attributed to the wider exposure

latitude of the CR plates [Fraser et al 1989, Sagel et al 1990, Lee et al 1991, Salvini 1994 et al, Lindhardt 1996, Busch 1997, Artz 1997, Tylen 1997 Murphey 1997 and Bowman 1998] or to the use of CR plates within a PACS [Mosser et al 1994, Siegel 1995, MacMahon & Giger 1996, Sandmayr & Wallentin 1997, Esch et al 1998, Siegel 1998, and Pomerantz et al 1998].

Three authors [Mosser et al 1994, Belloto 1997 and Esch et al 1998] suggest that when PACS is used there is a dose decrease because there are fewer examinations which are lost or unavailable when clinically required, and which therefore have to be repeated necessitating an additional exposure and patient radiation dose.

Papers were identified which fulfilled the criteria shown in Box 2.1. If a paper fulfilled at least two of the criteria but information was missing in the paper so that it was unclear whether the other criteria were fulfilled, the author of the paper was contacted in order to elicit further details [Bragg at al 1997, Lindhardt 1996, Murphey 1997, Sandmayr & Wallentin 1997, Jonsson 1995, Jonsson 1996 and van der Putten 1998]. In addition, personal approaches for information were made at medical and scientific conferences (EuroPACS, CARS, BIR Congress, SPIE and Management in Radiology Congress of the European Association of Radiology) and meetings (organised by IPEM, BIR and Faxil).

Box 2.1 Criteria for assessment of publications

Publication should include details of:
A comparative study comparing CR and/or PACS with a film/screen system,
Measurements using adult patients or phantoms for general radiographic examinations,
How doses were measured or assessed,
Criteria for assessment of image quality.

The 27 papers which fulfilled at least two of the criteria given in Box 2.1 are summarised in Table 2.1. Of these publications, 6 described paediatric studies, one

dental images, one was not a comparison, one was a comparison of completely different methods and did not measure doses or record exposures used, and two described Direct radiography (DR) systems. These 11 papers were excluded from detailed study: those 16 papers which referred to studies which involved general examinations of adult patients or phantoms are summarised in more detail in Table 2.2. Only one paper other than those which were based on the material reported in Chapter 4 [Weatherburn et al 1998, Weatherburn & Bryan 1999a] referred to a comparison of PACS and film images [Sandmayr & Wallentin, 1997].

2.3 PUBLICATIONS RELATING TO COMPARATIVE STUDIES OF DOSES WHEN FILM AND CR WERE USED

An early comparison of film and CR images of the spine, large bones and joints indicated that doses could be reduced by 50% when CR was used [Pettersson et al, 1988]. The group undertook a study which compared images produced by a Philips CR system and a film/screen system with speed 140. The investigation was in two parts. Firstly images were taken of two phantoms, a hip and a shoulder and of two volunteers, knee and ankle. Each area was exposed so that a film image appeared to be correctly exposed and then, with constant kV, CR images produced at the same, and 50%, 20%, 10% and 5% mAs. The CR images were processed to produce an image similar to film and an edge enhanced image. Two of the authors independently compared the images using a 5 point scale for the visualisation of cortical bone, cancellous bone, joint space height, tendons and ligaments, joint capsule, subcutaneous fat and skin. They concluded that the features were identified at an acceptable level with reductions in dose of 50%, but not with higher reductions. The result of this first study was used in the second part of the study in which 85 patients (spine, shoulder and humerus, elbow, wrist, pelvis, hip and femur, knee, lower leg, ankle) who were suspected of having common musculo-skeletal lesions were imaged by film in the normal way, and then by CR using 50% exposure. Two viewers (authors) simultaneously viewed the images and produced a consensus opinion on the images. Conventional images were better for the demonstration of erosion and periarticular osteopenia. Soft tissue changes were seen better in the edge enhanced CR images, but this type of

image was worse for the demonstration of periosteal reaction in tumour and infection. The authors concluded that further work was needed in order to determine the role of CR imaging for musculo-skeletal work. This was a good comparative study which was undertaken when CR was first introduced. However, the sample sizes were small and no statistical tests were used to compare the results of the two types of images. In addition, the films and screens which were used would be used very rarely, if at all, today.

Further work was subsequently undertaken by two of the authors [Jonsson et al 1995, Jonsson et al 1996]. One of these studies considered the use of CR plates for scoliosis follow up examinations using lower doses than those used for the conventional film/screen system [Jonsson et al, 1995]. It was found that the anatomical landmarks which were required in such follow up images were seen when CR was used with lower doses than those used for the film system. With the available CR plates, separate images of the thoracic and lumbar spines had to be taken which had to overlap to ensure that all of the spine was seen. The authors suggested that if long cassettes were available to image the whole of the thoracic and lumbar spine together, doses could be further reduced. The small sample size contained both males and females and a wide age range and presumably a wide range of patient sizes. However, the speed of the film system with which the CR images were compared, was not given. The author was contacted but was unable to provide further details. In another study the anatomical landmarks and measurements required for lateral pelvimetry were demonstrated by CR images at lower exposures than those used for film [Kheddache et al, 1998]. Dose reductions of around 40% were achieved for lateral images of a pelvis phantom and around 80% for AP images and in this case the speed of the film/screen combination used was 200. In these two studies where the requirements of the images were very specific, the criteria for image acceptability was the visualisation of anatomical landmarks, not the detailed structure of tissues, and as such had lower thresholds for image acceptability than is normally required in radiographic images. Thus these results may not be applicable to other types of images of the spine and pelvis or to other body areas.

A subsequent study by Jonsson et al which used 11 cadavers, again investigated the effect on CR images of reducing doses below that used for normal film/screen images [Jonsson et al, 1996]. The speed of the film/screen system was not quoted but they were high detail films and screens which consequently have low speed. Personal communication with the author elicited the information that a 300 speed film/screen system was used, but this seems to be a high estimate for high detail films and screens. Film and CR images of the hand and the knee were produced at the same exposure, which was chosen to be optimum for the film images. Additional CR images were produced at 50%, 25%, 12.5%, 6.25% and 1.56% of the base line mAs with constant kV and focus to film distance. The CR hard copy images for each exposure were produced with two images on each film, one with default processing and one with edge enhancement. Four radiologists viewed the images and used a 5 point scale to rate the image quality for cortical bone, trabecular bone, joint space and soft tissue. It was found that for the hands, film was better than CR for the demonstration of cortical and trabecular bone but that soft tissue was demonstrated better on CR images produced with doses higher than 6.25% of the film exposure. For the examination of the hip the CR at 100% and 50% doses were at least as good as film for the demonstration of cortical and trabecular bone. Edge enhancement assisted in the demonstration of soft tissue structures. The study concluded that for the peripheral skeleton dose reduction may be achievable using CR and the default and edge enhanced CR images should be produced on one film, however, these conclusions had no statistical basis.

Prokop et al [1990] undertook an ROC study to determine whether the quality of CR images was suitable for the detection of cortical bone defects when different doses were used. They used pieces of human femoral shafts which had been split longitudinally and introduced cortical defects into half. They found that when doses were lower than for the film/screen combination (speed 250), the images were noisy, but they found no significant difference in the detection of the defects. When doses were increased to 8 times those for the film images, the quality of the CR images improved. This study had very sound methodology and analysis of results.

Langen et al [Langen et al, 1993a] used a macerated skull to compare images produced by a Siemens Digiscan CR system using standard and high resolution 18cm x 24cm plates, and a 200 speed film/screen system. The results were compared with t-tests. They found that it appeared that when using standard plates, doses could be reduced by approximately 35% without loss of image quality due to excessive noise in the image but high resolution plates needed higher doses. The authors did not investigate how high doses needed to be for satisfactory images from high resolution plates.

The same group of researchers conducted a subsequent study using the images of actual patients with skull fractures and undertook an ROC study using 100 images, 17 of which had no fracture [Langen et al, 1993b]. The same exposure factors were used for both systems and the film/screen speed was 200. Five experienced radiologists viewed the images (from different patients) in random order and were allowed to view each image for a maximum of 30 seconds after which the image was withdrawn. However, this is an artificial situation for radiologists and may have resulted in a bias in favour of the images with which they were more familiar. The radiologists made assessments on a 5-point scale about whether a fracture was present. In addition they assessed the quality of the images for trabecular structure, tabula interna and externa, petrous bones and nasal bones. Computed radiography was shown to be as good as conventional film/screen images for the demonstration of fractures of the skull when the same exposure factors were used. Thus the performance of this CR system equated to a 200 speed film/screen system.

A study which compared CR and 200 speed film/screen images of abdominal contrast examinations of the same patients concluded that a 50% reduction of radiation dose with CR is not possible for such examinations [Krug et al, 1995]. In the study four radiologists each viewed three images (one film and two CR images produced at 50% exposure, one processed to look like the film image and one with edge enhancement) of 326 adult patients in random order, and rated the quality of the images on a 3 point scale and indicated on a 5 point scale whether certain pathologies were present. The true diagnosis was determined from clinical

examination, ultrasound and CT examinations, endoscopy and surgical findings and patient follow up. The study did not compare the images when other exposure factors were used, and thus did not determine the relative speed of the CR system. This is a good prospective study which compares images of the same patients and with the patient follow up used to determine the true diagnosis. There were no time limits placed on viewing times and so the study was more similar to a real reporting session than that of Langen et al (1993b].

Huda et al [Huda et al, 1997] described a comparison of hard copy CR and film images of adult chests where the image criteria were the visibility of support lines and tubes. They found that, at the same radiation exposure, the film/screen images (speed 600) were superior to the CR images. However, after manipulation of the CR processing algorithm, they found that the CR images were superior for the detection of lines and tubes. It is possible that this study was flawed by the method by which the images were selected for the study. Twenty one CR images were selected from 137 studies. Images were excluded if the parameters were not ideal or if the positioning of the patient was poor for the demonstration of support lines and tubes in the chest. The criteria for the selection of film images were not given. In addition, all images included lines, so the viewers knew to look for them. It would have been better to have included some chests without lines.

An ROC study was conducted using portable chest images of patients in the ICU which found that doses had to be increased when CR was used [Galanski et al, 1992]. The CR images were compared with film/screen images of speed 300 and used the criteria of whether thin catheters could be seen. The detection of low contrast catheters, similar to central venous catheters, was significantly decreased in the CR images when exposures equivalent to the film/screen exposures were used. No further comparisons were made to determine the actual speed of the CR system. The author was contacted for more information but failed to respond to the request.

A comparison of portable chest images taken of the same patients in ICU over three

successive days using three image systems including film/screen and CR found that when CR images were produced at the same exposure as those for a 400 speed film/screen system, lines and structures in the mediastinum and lungs were better visualised [Niklason et al, 1993]. They found that the CR images were more noisy than the film images, but the radiologists preferred the CR images for the visualisation of lung structures, musculoskeletal details, tubes and lines. There was no clear preference for images of the mediastinum and upper abdomen. My criticism of this study which is otherwise good, is that if the radiographer thought the exposure was too light or too dark, the exposure factors were adapted for the next image. Since CR images would not show differences in density, CR images could be adapted after film images but not film after CR. The paper does not say how often this occurred and may have been a source of bias in the results.

A comparison of chest imaging systems [Marshall et al, 1994a] using phantoms of the adult chest showed that the same doses were required for the film/screen images and the CR images. However, the authors point out that the doses for the PA chests were between three and six times as great as would be expected from the evidence provided by the UK National Survey of patient doses [Shrimpton et al, 1986] and suggest that this could be due to differences in grid factors and the film/screen combinations used. In this study Agfa Curix film was used with Kodak Lanex Regular screens. The combined speed was not given in the paper but the authors imply that they are not rare earth screens since they suggest that lower film/screen doses have been achieved elsewhere by 'optimization techniques (which) include fast films, rare earth screens and high filtration'. For the same image quality, the CR system requires the same dose as the film/screen system used, but if lower quality images are adequate, considerable dose reduction can be achieved. The authors suggest that if patient doses are to be reduced using CR images, this would probably be achieved by a reduction in the number of images which need to be repeated.

A further study by the same authors [Marshall et al, 1994b] compared different systems used for imaging the abdomen. They found that compared with a 200

speed film/screen combination, the CR system produced satisfactory images at lower doses, but queried whether the images were acceptable due to the presence of noise. The criteria for assessing the images were not given in this paper and the authors did not determine what doses were required for CR images of the abdomen.

Seifert et al have reported a study which had very sound methodology based on an earlier study in which they compared images of the skull produced by a Digiscan CR system with those produced using a film screen system with speed 200 [Seifert et al, 1995 in German]. They used a head phantom and found that the CR system produced images with acceptable image quality when the exposure used for the film/screen system was reduced by 52%. In the subsequent study [Seifert et al, 1996] a female head from a cadaver was used in which a fracture had been made above the petrous bone. The surface entrance doses were measured by thermoluminescent dosimeters (TLD). The images were viewed by the same seven experienced radiologists who used a 5 point scale for assessing the images for optical density, contrast, and specified bone structure. It was found that the CR doses were 57% lower than the film/screen doses for acceptable image quality. No details of statistical analysis were presented to support the results.

Bragg et al [Bragg et al, 1997] stated that they have not found the claims in the advertising literature that dose reduction was a major attribute of CR to be true. Indeed they found that the relative speed of CR was nominally 200 which, with the lower kilovoltages required by CR, necessitated an average increase in dose of 50% compared with the 400 speed film/screen system. For all body areas there were increased doses: 80% for portable chests, 58% for the abdomen, 55% for the shoulder, 47% for the tibia and fibula, 40% for the knee, 37% for the lateral skull and 33% for the lateral groin. The paper does not provide details of how doses were measured or the criteria by which images were judged to be acceptable, and so the authors were contacted for further information. The doses were measured by one of the authors (DT) and were based on the average adult patient and newborn intensive care radiographic techniques used. Average techniques were obtained for CR and film/screen and then the doses were measured and compared using a

Keithley 35050A Dosimeter positioned at 100cm source to image distance (Tripp, personal communication, 1999). The methodology adopted in this study was very weak. It appears to have been a very rough exploratory study with more details unknown than were known. The comparison was with average doses previously used with film. The study barely fulfills the criteria for inclusion in this discussion, but information supplied by the author makes this possible.

A more recent study [van der Putten, 1998] which used a test object and thicknesses of perspex to simulate body areas, showed that CR doses were lower by a factor of 1.3 to 4, depending on the body area, compared with a 200 speed film system. Four physicists (personal communication, 2000) viewed the images and scored three different parts of the test object, from which results, an image quality factor was calculated

2.4 PUBLICATIONS RELATING TO STUDIES WHICH COMPARED DOSES WHEN FILM AND PACS WERE USED

Sandmayr & Wallentin [1997] described a pilot project of 90 chest examinations where diagnosis was made from both hard and soft copy images. No details of the methodology or patients were given in the paper. It was unclear whether the comparison undertaken was of film and CR hard copy or PACS soft copy images. In addition, Sandmayr suggested that doses had been reduced further by a decrease in the number of retakes which were required but no details were provided. Further details were requested from the author, but no reply has been received. This paper did not fulfill the criteria for inclusion in this discussion of the literature but is identified because it was the only paper which was found.

No other studies were found which related to comparisons of film and PACS doses apart from the publication which is based on the work reported in Chapter 4 of this thesis [Weatherburn & Bryan, 1999]

2.5 PUBLICATIONS RELATING TO REJECT ANALYSIS STUDIES WHEN CR AND PACS ARE USED

CR systems

Sagel et al [1990] described how the use of a Philips CR system in a hospital undertaking about 130 portable examinations a day, of which about 110 were chest examinations, had decreased the repeat rate from 4.5% (using Kodak Lanex medium speed intensifying screens and Ortho C film) to less than 1%. This reduction in repeats resulted in a reduction in patient doses and had been achieved by a reduction in the images which had to be repeated due to incorrect exposure factors and was due to the wide exposure latitude of the CR plates. The remaining repeats were mainly due to errors in positioning of the patients. However, no details of the methodology used were given.

A more recent study found that reject rates fell from 17% to 7% when hard copy CR images replaced conventional film images [van der Putten, 1998]. When film was used, 30% of all rejects were due to incorrect exposure factors and these were eliminated when CR was used due to its wider exposure latitude. The most common reason for the rejection of CR images was reprinting which did not involve irradiation of the patient. No further details of the study were provided.

PACS

Publications from the VA Hospital in Baltimore indicate that PACS reduced the number of reject images: '*the image retake rate has decreased from 5% to approximately 0.8%, an 84% reduction, due to the combination of the improved dynamic range associated with computed radiography and the ability to modify images using the PACS workstations*' [Siegel 1998, Pomerantz 1998]. However, no publications have been found which describe their methodology or provide details of the reasons for the repeated images.

A second publication was found during the search in early 2000 which described a comparison of reject rates when conventional film and PACS were used [Peer et al,1999]. They conducted a two month contemporaneous comparison of the reject

rates of film, used in the general department, and PACS, used in the trauma department. They found a reject rate of 15.6% in the department using film and 2.0% in the digital department. They did not provide any details about the body areas for which the examinations were undertaken and so it is not possible to know whether the case mix was comparable between the two departments. This was the only comparative study of film and PACS rejects which could be identified.

The only other publication found relating to reject rates was that based on the work reported in Chapter 6 of this thesis [Weatherburn et al, 1999] which was a three way comparison of the reject rates for film, CR hard copy and PACS soft copy images.

2.6 PUBLICATIONS RELATING TO LOST IMAGES

It has been claimed that *'with a secure and accessible archive of imaging studies (with PACS), the need for repeat exams is reduced, thereby decreasing the amount of unnecessary radiation to the public'* (Belloto, 1997). No publications were found which described a quantitative study to determine the change in the number of images which were available after a PACS was used.

2.7 CONCLUSIONS

At the start of the studies reported in this thesis there was no published evidence relating to comparative studies of doses when film and PACS are used.

Some studies related to comparisons of film and CR hard copy images with estimations of the associated doses but there were no studies in which patient doses were actually measured. There have been some comparative studies post dating the planning and commencement of this work but there have been very few studies where real patient doses have actually been measured, and none where doses have been measured within a Randomised Controlled Trial (RCT). There have been four comparative studies where doses for the same patients have been compared when imaged by film and CR but the sample sizes were relatively small [Pettersson et al 1988, Galanski et al 1992, Niklason et al 1993 and Krug et al

1995]. None of these studies have measured doses nor had both strong methodology and sound statistical analysis of the results. There was therefore a need for further work to be conducted.

Despite many claims that PACS reduced both rejects and lost images and thus reduced doses, no comparative analyses of rejected or lost images were found and therefore work was needed.

Table 2.1 Summary of publications about studies which measure doses/image quality when CR or PACS was used.
NB: The following pages of this table should be read in pairs: 20 features of each publication are presented on two consecutive pages

Study	Year/Journal	Patients	Age	Body Area	Phantom	Sample size	Comp	F/S Speed	CR	PACS
Petterson H et al 2 studies (study 1)	1988 Acta Radiologica	2 volunteers	?	Knee ankle hip shoulder	hip & shoulder	?	F/S v CR	Duport Quanta detail screens & CEA wicorex film 140ASA	FCR-90 Plate size 25cmx30cm	No
Petterson H etal 2 studies (study 2)	1988 Acta Radiologica	Yes	?	14 spine, 11 shoulder, 5 elbow, 4 wrist, 28pelvis, 13 knee, 4 l. leg, 6 ankle	No	85	F/S v CR &CR (EE)	Duport Quanta detail screens & CEA wicorex film 140ASA	FCR-90 Plate size 25cmx30cm	No
Kogutt MS et al	1989 Pediatric Radiology	Yes	4-18y	PA spine scoliosis	No	412	F/S v CR	Dupont Quanta fast detail screens, Cronex 10 film	FCR 101 (301), PCR/SP (111)	No
Prokop et al	1990 Radiology	No	n/a	femur	Yes femoral shaft	110	F/S v CR	250 Lanex medium screens, TMG film	Fuji FCR 901	No
Merlo L etal	1991 Pediatric Radiology	Yes	neonates	Chest/abdomen	No	200	F/S v CR	?	Philips CR	Yes
Cohen et al	Radiology 1991	Yes	neonates	chest	No	150	F/S v CR & CR at 50% mAs	200	Fuji	No

Table 2.1 (cont.) Summary of publications about studies which measure doses/image quality when CR or PACS was used

Study	Dose Measured	FFD cm	kVp	mAs	Grid	Method of Dose Measurement	Image Criteria	Dose Reduction?	Include
Petterson H etal 2 studies (study 1)	No	?	?	100% (Film) then 50% 20% 10% 5%	?	Reduced mAs	2 viewers, 7 structures, 5 point scale.	Yes 50%	Yes
Petterson H etal 2 studies (study 2)	No	?	?	100% & 50% film mAs	?	50% Film mAs	2 viewers simultaneously for consensus opinion	Yes BUT images unsatisfactory for periarticular osteopenia. Advise further work	Yes
Kogutt MS et al	Yes	182.9 (72in)	80	varied with weight	no	exp in air 10cm from cassette to evaluate entrance exposure	cortical outline, measurements possible	Yes 92% (40 lbs) - 95% (150 lbs)	No (paeds)
Prokop et al	Yes	125	60 and 90	various	Yes	ionisation chamber	detection of cortical defects	No	Yes
Merlo L etal	No	120	70	1mAs 2mAs if >73kg	?	Change in mAs	acceptability to radiologist	Yes 25%	No (paeds)
Cohen et al	No	35 ins	54	varied to body weight	?	reduced mAs	various given	No for same image quality	No (Paeds)

Table 2.1 (cont.) Summary of publications about studies which measure doses/image quality when CR or PACS was used

Study	Year/Journal	Patients	Age	Body Area	Phantom	Sample size	Comp	F/S Speed	CR	PACS
Arthur R & Pease J	1992 Pediatric Radiology	Yes	0-3 m	All exams Feb - Sept 1990 mostly chest and abdomen	No	386 CR, 355 Film	Film v CR	Quanta fast detail cassettes and Cronex 7 film	Siemens Digiscan CR	No
Galanski et al	1992 Fortschr Roentgenstr	Yes	?	portable chests in ICU	No	20	Film v CR	300	Fuji 901	No
Sanderink G	1993 Internat Dental Journal	No	N/A	Teeth	Yes	?	Film v 4 digital detectors	D speed dental films	4 types	Yes
Langen H et al	1993a Investig Radiology	No	N/A	Skull	Yes	20	Film v CR	200 Cronex4 &Hi plus screens	Siemens Digiscan	No
Langen H et al	1993b Investig Radiology	Yes	5m to 85 years	skull	No	50 film, 50 CR	Film v CR	200	Siemens Digiscan	No
Niklason et al	Radiology 1993	Yes	?	chest -portables in ICU	Yes	20	Film v CR	400	Fuji AC-1	No

Table 2.1 (cont.) Summary of publications about studies which measure doses/image quality when CR or PACS was used

Study	Dose Measured	FFD cm	kVp	mAs	Grid	Method of Dose Measurement	Image Criteria	Dose Reduction?	Include
Arthur R & PeaseJ	No	?	?	?	?		?	No Used same exposure factors	No (paeds)
Galanski et al	No	100	75	various	?	varied mAs	ROC for visualisation of catheters. 8 readers	No	Yes
Sanderink G	?	?	?	?	?	?	Caries detection	Yes - different % for each digital sensor	No- dental
Langen H et al (a)	No	110	70	Various	Yes	Change in mAs	detection of length of fracture by 5 radiologists	Yes 35%	Yes
Langen H et al (b)		90 -110	70	?	Yes	?	ROC for fracture 3 point scale for image quality	No	Yes
Niklason et al	No	168-183	100	varied	No	Same exposure, equip & patients on 3 consec days	Visibility of lines & structures in lungs and mediastinum	No, but CR images were better	Yes

Table 2.1 (cont.) Summary of publications about studies which measure doses/image quality when CR or PACS was used

Study	Year/Journal	Patients	Age	Body Area	Phantom	Sample size	Comp	F/S Speed	CR	PACS
Marshall et al	1994 British Journal of Radiology	No	N/A	Male chest	Yes	?	F/S v CR (and others)	Agfa Curix film with Kodak Lanex regular screens	Fuji AC-1 SP111 35cmx43cm plates	No
Marshall et al	1994 British Journal of Radiology	No	N/A	Abdomen	Yes	?	F/S v CR (and others)	Agfa ortho-medium screens with Curix film 35cm x 35cm speed 200	Fuji AC-1 ST111 35cmx35cm plates	No
Jonsson et al + *personal correspondence	1995 Acta Radiologica	Yes	7-25	thoracic & lumbar spine for scoliosis	no	9	F/S v CR	unknown by author*	Fuji ST 111 plates 35x43cm	No
Krug B et al	1995 Acta Radiologica	Yes	23-81	abdomen with contrast media	No	326	F/S v CR	200 Quanta fast detail + Cronex films	Philips CR	No
Van Heesewijk et al	1996 AJR	No	n/a	Chest	Yes	240	amorphous selenium v same at reduced dose	N/A	Thoravision Philips medical systems	No
Jonsson A et al + *personal correspondence	1996 Acta Radiologica	No	n/a	hand&hip	Yes	?	F/S v CR	Hip- CEA film + DuPont Cronex Quanta detail/fast detail Hand-Fuji film + MIN-R screens. * personal correspondence f/s speed = 300	Fuji CR Hip -plates Fuji ST 111 24x30cm Hand -plates HR 111 18x24 cm	No

Table 2.1 (cont.) Summary of publications about studies which measure doses/image quality when CR or PACS was used

Study	Dose Measured	FFD cm	kVp	mAs	Grid	Method of Dose Measurement	Image Criteria	Dose Reduction?	Include
Marshall et al (a)	Yes	?	117	?	Yes	9TLDS per view attached to surface of phantom and several exposures for each TLD per system	acceptable to radiologist	No	Yes
Marshall et al (b)	Yes	?	81	?	?	TLD and DAP Effective doses calculated	?	Yes 35 times reduction, but queried whether images acceptable due to mottle.	Yes
Jonsson et al 1995	Yes	345	90	5-10	23cm air gap	TLD	2 radiologists using a 3 point scale. Scoliosis landmarks seen in 16/18 images	Yes	Yes
Krug B et al	No	various	various	CR 50% Film	?	?	Four radiologists using 3 point scale for image quality, and 5 point scale for presence of pathology.	No	Yes
Van Heesewijk et al	?	200	125	2.0, 1.0, 0.5	No	solid state detector PMX111 ? where positioned	Detection of simulated diffuse interstitial pulmonary disease (DIPD) assessed by 6 radiologists	N/A	No-DR, also film not compared
Jonsson A et al	No	Hips 110 Hands 100	Hips 70 Hands 40	Hips 32 Hands 32	Hips yes hands No	None	Four radiologists using a 5 point scale for cortical & trabecular bone, joint space, soft tissue.	May be possible	Yes

Table 2.1 (cont.) Summary of publications about studies which measure doses/image quality when CR or PACS was used

Study	Year/Journal	Patients	Age	Body Area	Phantom	Sample size	Comp	F/S Speed	CR	PACS
Seifert H et al	1996 BJR	No	n/a	skull	Yes	?	F/S v CR	200 Agfa Curix MR200/Agfa Curix RP10000	Digiscan Fuji CR 24x30 cm plates	No
De silva	1997 Seminars in Roentgen.	No	n/a	n/a	Yes	?	CR under different conditions	?	Digiscan 2H, Siemens and Fuji plates	No
Bragg et al	1997 AJR	Yes	?	Portable chest, Abdomen, Lateral skull, Lateral hip, Knee, Shoulder, tibia & Fibula	No	?	F/S v CR	400 (except for extremities)	FCR 9000 FCR 9501 (200 speed system)	Limited network
Huda et al	1997 Journal of Digital Imaging	Yes	?	chest	no	21 CR v 7 film (diff. patients)	F/S v CR	600 Kodak Lanex Fast screens + Kodak T-Mat [TML] film	Fuji AC-1 ST 111N plates 35x43 cm	No

Table 2.1 (cont.) Summary of publications about studies which measure doses/image quality when CR or PACS was used

Study	Dose Measured	FFD cm	kVp	mAs	Grid	Method of Dose Measurement	Image Criteria	Dose Reduction?	Include
Seifert H et al	Yes	112	70	3.2-16	Yes	TLD-100.	7 radiologists Measured line pairs/mm, and used 5 point scale to assess optical density, contrast, bone structure,& whether further images required.	Yes 57% reduction	Yes
De silva	No	?	?	?	?	None	?	CR equates to 400 speed film/screen system for chicken phantom to simulate paediatrics	No (paeds)
Bragg et al	Yes	?	85-130	Higher mAs for CR	?	Entrance exposures in mR (mC/kg) for CR	?	No - dose increases due to use of lower kV & slower system. Reject rates increased with CR (4-5% - 12-15%) started to drop again after 18 months use.	Yes
Huda et al	?	100	75	1-2	No	?	5 radiologists used a 5 point scale for visibility of lines and tubes.	No	Yes

Table 2.1 (cont.) Summary of publications about studies which measure doses/image quality when CR or PACS was used

Study	Year/Journal	Patients	Age	Body Area	Phantom	Sample size	Comp	F/S Speed	CR	PACS
Strotzer M et al	1998 AJR	Yes	?	skeletal	No	120	F/S v DR	Kodak 400 Lanex regular/T-MAT plus DG film	DR ASD prototype. Speeds 400 and 800. 1600. Trixell	no
Hufton et al	1998 BJR	Yes	0-15yrs	abdo, chest, pelvis. skull	No	approx 900	F/S v CR	600	Fuji	No
Bury et al	1998 Clinical Radiology	No	n/a	n/a	Yes TO-20	?	CR v DR	n/a	Philips FDXD Philips AC-3 CR with ST VN plates.	No
Kheddache et al	1998 Radiation Protection Dosimetry	No	n/a	pelvis	Yes	?	F/S v CR	200	Philips PCR-Ace	No
van der Putten	1998 Radiation Protection Dosimetry	No	n/a	various	Yes. CDR + layers of perspex	?	F/S v CR	200	Agfa ADC	No
Manning et al	1999 Radiography	No	n/a	chest	Yes. Chest + coins	25 for each system	F/S v CR (and others)	Kodak T-mat G film + Lanex screens	Fuji AC-1	No

Table 2.1 (cont.) Summary of publications about studies which measure doses/image quality when CR or PACS was used

Study	Dose Measured	FFD cm	kVp	mAs	Grid	Method of Dose Measurement	Image Criteria	Dose Reduction?	Include
Strotzer M etal	yes	115	Various but same for each patient	Same for film & ASD plus ASD with 50%(all) 75% (some)	?	DAL ion. Chamber	5 point preference scale and 0-10 scale for image quality	Inconclusive - areas of beam not identical - but suggests lower doses might produce acceptable images	No Film v DR
Hufton et al	Yes	?	various	various	12:1 40l/cm	DAP. ESD calculated	CEC criteria for Paeds.	Yes 40% except for chests	No (Paeds)
Bury et al	?	?	75	?	?	?	DQE found from threshold contrast detail detectability measured by 3 viewers	It appears that CR doses can be reduced by two to three times for images of the same quality	No CR v DR
Kheddache et al	Yes	?	90, 125, 150	various- not given	?	Si detector (R100)	pelvimetry measurements	Yes approx 40% for lateral & 87% for AP	Yes
van der Putten	Yes	?	various, given	various, given for AP projection but not for lateral	?	change in mAs	image quality factor - product of scores for large & small targets & lp/mm counted	Yes by factor between 1.3 to 4	Yes
Manning et al	No	200	112 for film. 70 for CR	?	Yes for film, No for CR	Not measured	Location of coin lesions	Cannot be compared	No (at different hospitals)

Table 2.2 Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Pettersson et al (1988) Departments of Radiology, Lund and Malmo (2 studies described)	Study 1 Purpose To compare accuracy of Film (speed = 140)& CR H/C systems to image anatomic structures at different radiation doses Sample • two phantoms (hip, shoulder) • 2 human volunteers (knee, ankle) Images Film and CR with 100%, 50%, 20%, 10%, 5% film mAs and constant kV. Edge enhanced CRs also produced. Images assessed for: cortical bone, cancellous bone, joint space height, tendons and ligaments, joint capsule, subcutaneous fat and skin. Assessed on 5 point scale (5 = excellent, 1 = not evaluable). Viewers two of the authors viewed the images independently	Results Cortical & cancellous bone assessed equally by film and digital with 100% & 50% film exposure. Halo effect seen around cortical bone in CR images Joint space seen well with both systems and all dose reductions Soft tissue structures Modified CR better than film at 100% & 50% exposures. Film better than CR with standard processing Authors' Comments Further more detailed studies are required for musculo-skeletal studies.
My Comments	Good study especially since it was an early study. But small sample size and body areas limited to musculo-skeletal which are low risk areas. No statistical tests were used. Comparison was with an old 140 speed film/screen system.	

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Petterson et al	Study 2 Purpose To compare accuracy of film (speed = 140) & CR H/C systems to detect common musculoskeletal lesions Sample 85 patients thought to exhibit abnormality (degenerative disease and arthrosis, arthritis, trauma, tumour, infection, soft tissue disease, joint prosthesis) in various body areas: spine 14; shoulder and humerus 11; elbow 5; wrist 4; pelvis, hip and femur 28; knee 13; lower leg 4; ankle 6. All patients imaged twice - firstly with film at normal dose/exposure, secondly with CR and half dose and edge enhanced (CR (EE)) Viewers two of the authors viewed the images and produced a consensus opinion	Results Erosion - film better than CR in 3/15 cases Periarticular osteopenia - film better than CR in 4/15 cases Soft tissue swelling - CR (EE) better than film in 5/5 cases for arthritis and 7/30 for trauma, 3/3 for tumour, 5/5 for soft tissue lesion Soft tissue changes around elbow, wrist knee and ankle seen better with CR (EE) but not identified around shoulder and hip joints Periosteal reaction for tumour shown better in film 2/2 and CR 2/2 than CR (EE) Radiolucent zone around prosthesis seen better in film 10/10 and CR 10/10 than CR (EE) Authors' Comments • should use CR and edge enhanced (EE) CR • lower spatial resolution of CR limits visualisation of some structures • CR should not be used for periarticular osteopenia

My Comments This is another good study which is a comparison of the same patients imaged in the same session (I assume with the same radiographic equipment). But sample sizes, and different areas require different radiographic techniques. The comparison is with an old 140 speed film/screen system.

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Prokop et al (1990) Department of Diagnostic Radiology, Hannover	Purpose To compare the detectability of cortical bone defects in CR and film (speed = 250) images and to study the effect of variation in exposure on the CR images. Sample 55 segments of human femoral shaft with cortical defects introduced and 55 segments without defects. Segments placed in groups of 8 imaged together by both systems, the order of the segments rearranged for all positions on the image and images produced. All segments placed in 7.5 cm water bath. Images Images presented in random order in two sessions at least 9 weeks apart. First session compared film and CR processed to resemble film. Second session compared film and edge-enhanced CR images. A 5 point scale was used for the presence of cortical bone defect. ROC analysis undertaken Viewers 8 radiologists	Results At doses lower than those used for film images, the CR images had more noise but no significant difference in diagnostic performance was detected. When doses were higher than those for film, the CR images were better than the film images.
My Comments	This study has very sound methodology and is an ROC comparison of phantoms of the femur. The gold standard was the presence of induced cortical lesions. A water bath was used to simulate soft tissue but 7.5 cm is insufficient except at the thinnest part of the femur. The comparison was with a 250 speed system which is still slow for current practice.	

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Galanski et al (1992) Department of Radiology, Hannover	Purpose To compare the detection of catheters in the chest using film (speed = 300) and CR images Sample 20 patients in ICU, each had one film and three CR images. The CR images were taken with the same (2mAs), half (1mAs) and 2.5 times the mAs used for film (5mAs). Images In each image the mediastinum was divided into 18 fields and thin catheters were superimposed in half. A 5 point scale was used for an ROC study for the detection of the catheters Viewers 8 readers	Results At the same exposure, the detection of catheters was decreased in the CR images. The exposures had to be increased by 250% for the catheters to be seen in the CR images.
My Comments	This study compared the same patients with an ROC analysis. The authors did not investigate the use of higher exposures for CR in order to determine the dose required to produce images which were comparable with film images. The article was in German. I contacted the author for clarification of some details of the study, but the author did not respond to my request.	

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Langen et al (1993a) Departments of Diagnostic Radiology and Legal Medicine Aachen, Germany	Purpose To compare film (speed 200) and CR (standard (ST) and high resolution (HR)) for the detection of a small fracture (30mm length, 0.2mm wide) line in a skull phantom under varying imaging conditions Sample Macerated skull phantom with 14cm plexiglas to simulate the scattered radiation caused by soft tissue Images 5 images taken at different exposures with rotation of skull 0°, 10°, 20° and 30° (20 images) Exposure used for film/screen was 70 kV and 25 mAs, ffd 110cm focussed grid 12/40. Same conditions were used for CR images except mAs varied: 250, 50, 25 mAs (HR) and 16 mAs for ST. Images assessed for length of fracture line in mm expressed as % of actual length. Viewers 5 radiologists blinded to position of phantom and exposure conditions	Results Significance tested with student's t-test. The scores for film images were statistically better ($p<0.05$) than HR at same mAs. . HR better than film ($p<0.005$) when mAs doubled. No further significant difference at 10 x mAs. No significant difference was detected between film at 25 mAs and ST at 16 mAs Authors' Comments A dose reduction of 35% can be gained from the use of standard (ST) CR images. HR require higher doses than film with no additional diagnostic advantages and should be avoided

My Comments This was a fairly sound phantom study which investigated the effect on CR High Resolution plates of higher doses than those used for film, and one lower exposure for Standard CR plates. I think that it would have been better if the authors had used the same exposure as for film and both higher and lower exposures for Standard and High Resolution CR plates.

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Langen et al (1993a) Departments of Diagnostic Radiology and Legal Medicine Aachen, Germany	Purpose To compare film (speed 200) and CR (standard (ST) and high resolution (HR)) for the detection of a small fracture (30mm length, 0.2mm wide) line in a skull phantom under varying imaging conditions Sample Macerated skull phantom with 14cm plexiglas to simulate the scattered radiation caused by soft tissue Images 5 images taken at different exposures with rotation of skull 0°, 10°, 20° and 30° (20 images) Exposure used for film/screen was 70 kV and 25 mAs, ffd 110cm focussed grid 12/40. Same conditions were used for CR images except mAs varied: 250, 50, 25 mAs (HR) and 16 mAs for ST. Images assessed for length of fracture line in mm expressed as % of actual length. Viewers 5 radiologists blinded to position of phantom and exposure conditions	Results Significance tested with student's t-test. The scores for film images were statistically better ($p<0.05$) than HR at same mAs. . HR better than film ($p<0.005$) when mAs doubled. No further significant difference at 10 x mAs. No significant difference was detected between film at 25 mAs and ST at 16 mAs Authors' Comments A dose reduction of 35% can be gained from the use of standard (ST) CR images. HR require higher doses than film with no additional diagnostic advantages and should be avoided

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Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Langen et al 1993b Department of Radiology , Aachen, Germany	Purpose To compare CR and film images (speed =200) for the detection of skull fractures Sample • 50 CR and 50 film images (AP and lateral) of 85 patients (5 months to 84 years for CR and 3 months to 82 years for film). 66 had single fractures. Multiple fractures were excluded. Images Each image viewed for 30 seconds only. Bell sounded at 25 seconds and image removed at 30 seconds. Scored for fracture on a 5 point scale and ROC analysis. Image quality assessed on 3 point scale for trabecular structure of spongiosa, tabula interna, & externa, petrous bones and nasal bones. Diagnoses confirmed from other investigations and clinical follow up. Viewers 5 radiologists each viewed the CR and film images separately in 90 minute sessions	Results At the same exposure factors, the CR and film images were comparable for the detection of skull fractures in actual patients. CR was superior for the nasal bones. The petrous bones were underexposed with the CR system, but could be post processed.
My Comments	This study was a retrospective study of actual patients but using different patients for film and CR images. ROC analysis was undertaken. The radiologists had viewing time limited to 30 seconds which is an artificial situation for radiologists and may have favoured the system with which they were more familiar	

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Niklason et al (1993) Department of Radiology, Michigan	Purpose To compare three imaging systems including film (speed = 400) and CR for portable chest imaging. Sample • A chest phantom produced in-house which incorporated acrylic and teflon spheres and a resolution grid. • 20 patients in the surgical ICU imaged using the same exposure factors on 3 consecutive days with a different imaging system (in random order) but using the same exposure factors (60 images). Images Phantom images were assessed for limiting resolution, contrast using a densitometer, and noise in 10 small regions in the lungs Patient images were assessed for the presence of specified anatomical abnormalities and lines and catheters, using a 4 point scale. All images read in a single session, with each patient's three images side by side. A paired t-test was used to test for significant differences between viewers Viewers 3 radiologists	Results Phantom images The limiting resolution was 4.2 lp/mm for film and 2.0 lp/mm for CR. The CR images had approximately twice the noise of the film images. There was higher lung contrast and consistent density in the CR images. Patient images The radiologists preferred the CR images for the visualisation of lung structures, musculoskeletal details, tubes and lines. There was no clear preference for the mediastinum and upper abdomen.
My Comments	My criticism of this study which is otherwise good, is that if the radiographer thought the exposure was too light or too dark, the exposure factors were adapted for the next image. Since CR images would not show differences in density, CR images could be adapted after film images but not film after CR. The paper does not say how often this occurred and may have been a source of bias in the results.	

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Marshall N et al (1994a) Regional Medical Physics Departments Newcastle upon Tyne, UK.	Purpose • to measure entrance surface doses for film/screen, computed radiography (and other systems) using 2 chest phantoms one for PA and another for lateral chest. • to determine effective dose and effective dose equivalent • to compare effective dose equivalents of systems • to compare chest imaging techniques	Results Same exposure factors were used for both systems, so same doses measured and calculated Comments At the centre (Mannheim) they used the same exposure factors for CR nd F/S in order to get high quality images. If dose to patient is to be reduced using CR, it will be by a reduction in the number of repeated exposures
Research conducted at Mannheim	Images Field size of 32cm x 40cm used for both systems F/S exposure set to get acceptable image for radiologists. Then same exposure set for CR. Dose measurements By TLD on surface of chest phantom	

My Comments This study had very sound methodology but the film/screen system speed was not given.

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Marshall N et al (1994b) Department of Medical Physics Newcastle upon Tyne, UK	Purpose Comparison of entrance surface doses for several systems for abdomen images including F/S and CR using a phantom. Method - unclear Dose measurements Surface entry doses measured by TLD on surface of abdomen phantom	Results Dose reductions up to 35 times could be achieved using CR compared with the 200 speed F/S system. However a lot of mottle (along with a large reduction of image quality) was seen Comments Further work is required in optimizing image quality of CR images with respect to patient dose for a given imaging task

My Comments This was a theoretical rather than pragmatic study. The authors found that the CR images were unacceptable at much reduced doses but did not determine what dose was required for an acceptable CR image.

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Krug et al 1995 Departments of Radiology, Med Documentation & Stats, & Surgery. Cologne, Germany	Purpose A prospective study to compare film (speed = 200) and CR images of abdominal contrast studies. Sample 326 patients (168 female, 158 male, age range 23-81 years) for various contrast media examinations of the abdomen over a 9 month period. 153 images were normal. Diagnosis determined by results of other investigations and clinical follow up. Images Film and CR images were taken of each patient. The CR had 50% lower dose than the film image, edge enhanced CR produced. No clinical information provided and no time limit. Images assessed for image quality using a 3 point scale and the presence of pathology using a 5 point scale. Viewers 4 radiologists	Results Doses could not be reduced when CR was used for these examinations. Comment Edge enhanced CR images are of no value for the visualisation of abdominal contrast media examinations and should not be used for this purpose.

My Comments This is a good prospective study which compares images of the same patients and with the patient follow up used to determine the true diagnosis. There were no time limits placed on viewing times and so the study was more similar to a real reporting session than that of Langen et al (1993b).

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Jonsson et al 1995 Department of Radiology, Lund, Sweden	Purpose To determine whether CR images with low doses could be used for the imaging of follow-up scoliosis examinations. Sample • 9 (5 male, 4 female) scoliosis patients, ages 7-25 years, mean 14 years. Images Overlapping erect thoracic and lumbar spine images of each patient for the detection of the anatomical landmarks required for follow up of scoliosis. A 3 point scale was used. Dose measurement TLDs placed at the centre of the beam for the thoracic and lumbar spine images, and on the breasts. Viewers 2 skeletal radiologists	Results Doses could be reduced for scoliosis follow up examinations. Comment No details were given about the films and screens used with which the CR doses were compared. NB The author was contacted for further details but was unable to provide the speed of the film/screen system used. Because long cassettes for CR were not available, the 2 images per patient had to overlap. If a long plate were available, doses could be further reduced.

My Comments The sample size was small with a wide age range of children and young adults whose sizes would have varied greatly in the age range given (7-25 years). The sample also included male and female patients. No details of the film/screen system previously used were given in the paper. The author of the paper was contacted but was unable to provide the information. Thus the comparison was with an unknown system.

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Jonsson et al 1996 Department of Radiology, Reykjavik, Iceland	Purpose To evaluate the effect of dose reduction (compared with film) on the quality of images when CR was used. NB The speed of the system was not given but personal communication with the author provided the information that the film/screen speed was 300. Sample one hand and one hip of each of 11 cadavers Images Film exposure taken as the baseline, and CR exposed at 100, 50, 25, 12.5, 6.25 and 1.56% of the baseline mAs. Standard and edge enhanced CR images produced Images assessed for cortical bone, trabecular bone, joint space, and soft tissue. 5 point scale used. Viewers 4 radiologists	Results Hands: film better than CR except for soft tissue visualisation. CR images deteriorated at reduced exposures. Hips: CR images at 100% and 50% compared well with, and were slightly better than the film images. Comments Default and edge enhanced CR images should be printed on the same film. Edge enhanced images should not be used alone.

My Comments I question the accuracy of the retrospective estimation of the film/screens used as given by the author. He said that a 300 speed system had been used. However, 2 different combinations of films and screens were used for the 2 body areas and it is unlikely that they were the same speed or they would have just used the same combination. The imaging plates were not the same as those used in the studies reported in this thesis. The methodology used was sound except they did not determine the dose required to obtain hand images similar to those of film. No statistical methods given

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Seifert et al 1996 Departments of Physics and Radiology, University Hospital of Saarland, Germany	Purpose Comparison of film (speed =200) and CR images of the skull for the detection of fracture. Sample • Lateral images of the skull of a female cadaver with a skull fracture. • Grid to measure lp/mm Images Images were produced at 70 kV and with mAs varied between 16 and 3.2mAs for both film and CR, and 3.2-0.5mAs for CR only.. Lp/mm assessed A 5 point scale was used to assess anatomical structures, optical density and contrast and whether further images were required. Viewers 7 radiologists Dose measurement Doses were measured using TLD for entry dose, exit dose and eye dose and using 250 mAs. The doses for the lower mAs values used were calculated by extrapolation of the measured doses.	Results Acceptable images were produced by the CR system with a 57% reduction in dose compared with the film system. Comment The results were in good agreement with their previous study [Seifert et al, 1995, in German] using a head phantom which showed that doses could be reduced by 52%.
My Comments	This is a very sound comparative study of images of the skull of a female cadaver. Doses were measured using TLDs	

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Bragg et al (1997) Department of Radiology, University of Utah Health Sciences Center Plus personal communication	Purpose Comparison of film images (speed = 400) and CR images. Sample No details are given of sample sizes. Exposure factors used for CR imaging are compared with those used for the film/screen system previously used for average patients. Dose Measurement The method of dose measurement was not given in the paper. NB Personal correspondence with the author determined that doses had been measured by one of the authors using an ionisation chamber exposed at a 100cm FSD using the average exposure factors used for adults.	Results Doses were increased for all body areas: Portable chest 80%, abdomen 58%, lateral skull 37%, lateral hip 33%, knee 40%, shoulder 55% & tibia & fibula 47% Comments Dose increases were mainly due to the difference in the speeds of the two systems. The CR systems speed was 200 and that for the film/screen system was 400. In addition, lower kVs had to be used because the phosphor plates were very sensitive to scattered radiation, thus mAs values were increased with a subsequent increase in doses. Wide latitude - danger of overexposure of patients

My Comments This was really a descriptive account of issues which the authors raised having worked with CR. A lot of the details about the methodology used were not given in the paper eg sample size, and how doses were measured. The author was contacted for further details who indicated that doses were assessed only approximately.

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Huda et al (1997) Department of Radiology, University of Florida	Purpose To compare the visibility of tubes and support lines in the chest when film (speed = 600) and CR was used. Sample Chest images of patients in MICU. There were 9 two-thirds size CR and 12 half-size CR compared with 7 normal size film images. Images 5 point scale used to assess visibility of support lines and tubes. All images viewed randomly in a single session Viewers 5 radiologists	Results At the same exposure, the film images were superior for the detection of support lines and tubes in the standard CR images. Support line visibility improved with increasing radiation dose. Edge enhancement improved the visibility of support lines and tubes and should be used.

My Comments 21 CR images were selected from 137 studies. Images were excluded if the parameters were not ideal or if the positioning of the patient was poor for the demonstration of support lines and tubes in the chest. The criteria for the selection of film images were not given. All images included support lines, so the viewers knew to look for them. It would have been better to have included some chests without support lines.

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
Kheddache et al (1998) Department of Radiology Goteborg University	Purpose To determine the lowest doses for pelvimetry examinations of the pelvis when film (speed = 200) and CR were used (also image intensifiers) Sample AP and lateral projections of a pelvis phantom Images Lateral view for each type of image using 90kV, 125kV and 150kV with mAs values starting at the automatic value used and decreasing by a factor of 2 until no image was seen when film was judged as too low density, and CR was too noisy. AP views exposed using 70kV, 90kV, 109kV and 125kV with mAs reduced as for lateral. Images were assessed for the ability to undertake pelvimetry measurements using anatomical landmarks. Dose Measurement Skin and exit doses were measured and used to calculate the energy imparted from which the absorbed doses were calculated (Energy imparted = absorbed dose x volume irradiated) Viewers 10 radiologists	Results Lateral Projection: The comparative doses varied with the kV used. For film the lowest doses were obtained when 150kV was used. Lowest doses for CR were obtained using 90kV. When CR and film were exposed at 150kV, there was no difference in the doses but CR doses were 43% lower than film when CR was exposed at 90kV and film at 150kV. AP Projection: When film and CR were both exposed using 70kV, CR skin doses were lower by 62%. When the kV for CR was increased to 90kV, CR doses were 89% lower than film doses. Authors' Comments Low quality 'noisy' images are acceptable for the purpose of obtaining pelvimetry measurements, but more detail would be required for other examinations such as mammography. 'Noisy' images may be acceptable for fracture control.

My Comments This relatively recent comparative study of images of a pelvis phantom is interesting but some details were missing. The mAs values used were given for the AP projection only and no details were given about how scattered radiation was controlled. Scatter is an important factor in pelvimetry of the pregnant woman because the amniotic fluid produces a lot of scattered radiation. It has been documented that scatter is problematic for CR images [Tucker et al, 1993] and so for this examination the results of phantom studies may not be applicable to the clinical situation with actual patients.

Table 2.2 (cont.) Publications which describe studies where image quality and/ or dose changes are measured when CR or PACS is used

Study	Patients/Methods	Results/comments
van der Putten (1998) Dept Medical Physics, Galway, Ireland	Purpose To compare images of a test object using CR hard copy images produced at various mAs starting with the mAs used for film images (speed = 200) Sample Faxil test object CDR was used under (personal communication with the author) slabs of perspex to represent various body areas: abdomen, lumbar spine, thoracic spine, cervical spine, skull, colon, extremity, & chest. Images The kV & mAs normally used for clinical film/screen examinations for each body area was used and then images taken with reduced mAs. Images were scored for the visibility of the 11mm and 0.5mm diameter circles and the number of line pairs/mm. An image quality factor (IQF) was calculated from the product of these three results, at each mAs value. Dose calculations Entrance doses were calculated (personal communication), from which effective doses were calculated using the NRPB XDOSE software. Viewers 4 physicists (personal communication)	Results Doses could be reduced for all body areas: lateral lumbar spine, 25%; skull & cervical spine, 40%; AP lumbar spine, lateral thoracic spine & colon, 50%; abdomen, 60%; AP thoracic spine & chest, 75%. Comments The results were very similar to those which the radiographers had found for clinical examinations by trial & error.

My Comments I liked this paper. The author presented an experimental study incorporating standard methods for using phantoms and some novel ways of interpreting the results. The author was very helpful in providing further information. This paper presented many concepts very briefly

CHAPTER 3

THE USE OF TEST OBJECTS TO DEMONSTRATE THE EFFECT OF VARIATION OF DOSE ON THE IMAGE QUALITY OF FILM, CR HARD COPY AND PACS SOFT COPY IMAGES

3.1 GENERAL METHODOLOGY

3.1.1 Background and study design

The aim of this thesis is to determine whether the introduction of PACS affects patient radiation doses, and if dose changes are identified, whether these can be justified by improvement in the patients' management. Before patient dose measurement studies are discussed, a study is presented which compared the response of the three systems, film/screen, CR hard copy and PACS images of test objects, to variation in exposure factors. It was hypothesised that if a comparison of film, CR and PACS images of test objects demonstrated differences in image content, similar differences might occur in patient images. It might therefore be necessary to change patient doses in order to produce the quality of images which is required for the clinical diagnosis to be made.

The aim of the work in this chapter was to undertake tests to compare soft copy images produced by the PAC systems at Hammersmith Hospital and Glan Clwyd Hospital with CR hard copy images and conventional film images employing tests which

could be conducted by radiographers and physicists in the hospital situation and using equipment which could be readily available to the staff. It was not the intention to test the equipment under laboratory type conditions, since these tests would have already been carried out by the manufacturer. What was of interest was how the PACS equipment performed in the clinical situation and how, under these conditions, PACS images compared with images produced by the conventional film/screen and CR systems which it was replacing. Thus the aim was to test the operation of PACS by methods similar to those already widely used for quality assurance of conventional x-ray units.

At Glan Clwyd Hospital, where a Kodak mini PACS (Kodak Ektascan Storage Phosphor Reader [KESPR]) is used, the ITU clinicians viewed soft copy PACS images in order to make decisions about the management of the patients and were able to make use of all the facilities which were available on the workstation to manipulate the images and potentially provide additional information about the images. The radiologists in Radiology chose to use hard copy CR images when making reports on the examinations and thus did not have access to manipulation facilities. Throughout the rest of the hospital a conventional film/screen system was used which was also used in ITU if the PACS system was not working. Thus, since Film, CR and PACS images were used in this hospital for the imaging of ITU patients, it was of interest how these types of images compared with each other.

At the Hammersmith Hospital, hard copy Computed Radiography (CR) replaced the conventional film system in an intermediary step towards the use of a General Electric hospital wide PACS. The whole hospital is now virtually film less. Hard copy CR images are produced on film for patients who are subsequently seen at other hospitals and conventional film images continue to be used for dental examinations. The PACS includes CR acquisition units from two manufacturers, General Electric and Kodak. The Kodak unit was the same type of KESPR unit that is used at Glan Clwyd Hospital. The

testing of all radiographic equipment poses a dilemma where the aim is to undertake tests which are as close as possible to the clinical situation, but where it would be unethical to expose patients to ionising radiation for such purposes. Although anatomical body phantoms may be used, the images produced from these do not allow quantitative measurements to be made and thus test objects have to be used. There were no test objects designed specifically to test PACS systems and none was available from the manufacturers of the equipment, thus, after consultation with the Head of Imaging in Oxford (personal communication, Dixon-Brown) and the Head of FAXIL (personal communication, Cowan), a protocol using test objects designed for other purposes was devised. The imaging system was therefore tested with various existing Leeds Test Objects (produced by FAXIL) under specified conditions. This chapter describes three comparative tests using test objects.

3.1.2 General methodology

Comparative measurements have been made to compare the conventional film screen systems Film, (Kodak TMAT L film with Kodak Lanex Medium screens, speed class 300), used at the Hammersmith Hospital, and Film (Kodak TML RA film with Kodak Lanex Regular screens, speed class 400), used at Glan Clwyd Hospital with the CR hard copy images produced by the CR system and the soft copy images viewed with the use of all manipulation facilities on the PACS system. This comparison of 'technical output' is classified as a Level 1 study in Fineberg's hierarchy for the evaluation of imaging systems [Fineberg et al, 1977].

Images of test objects were produced at both hospitals for the purpose of this study. It was important that the images were produced under the correct conditions and that the equipment was operated correctly and therefore expert help was obtained at each hospital. At the Hammersmith, the assistance of the senior radiographer who was employed in the department as the trainer for PACS and one of the medical physicists for the hospital was enlisted. At Glan Clwyd, the senior radiographer in charge of, and

most knowledgable about, the PACS system assisted in the production of all images. As far as could be controlled, all images in a series were produced under the same conditions. Each test series of exposures was repeated three times in the same session to test for consistency of results; thus for each set of conditions, three images were obtained for each of Film, CR and PACS.

Processing of images

The processing conditions of the films and laser printed images employed were as used for clinical images and were checked for consistency at the start and end of each session, using sensitometry curves and Dmax readings. No changes were found. All CR plates were processed at a standard time interval after exposure since the time delay between exposure and processing is known to affect the resultant image (Langner et al, 1995). A pragmatic decision was taken to standardise the processing time at 5 minutes after exposure because this was the fastest reasonable time which allowed for the plates to be taken to the processor adjacent to ITU, processed and returned to the x-ray department ready for the next exposure. It was important to choose the shortest possible time because the room in which some of the tests were undertaken was required for a clinical examination later in the day, and for the sake of consistency of results, all exposures had to be undertaken on the same day. The 5 minute periods were timed with a stop watch.

Viewing and scoring of images

The CR and film images were mounted into individual numbered envelopes in which windows had been cut so that the images could be viewed, but all textual information on the images was hidden from the viewer. All film and CR hard copy images were viewed using a conventional x-ray illuminator under a protocol agreed by the viewers which reflected the advice given by FAXIL for a standard protocol [Launders et al, 1995]. All images were viewed and scored by four medical physicists who were experienced in undertaking such studies and who were familiar with the type of

information which was available from the test objects. Two medical physicists from Oxford scored the images at both hospitals and in addition two local physicists scored the images in each hospital. Tests were undertaken to determine whether there were differences between the viewers. In addition one image from each set of images in a test were re-scored by the local physicists at least one week after the first session in order to test for intra observer variation.

At Hammersmith Hospital the soft copy images were viewed in one of the soft copy reporting rooms using 2k monitors. At Glan Clwyd Hospital the soft copy images of the test objects could not be viewed in ITU, where they were viewed by the anaesthetists, because the workstation was situated in the middle of the clinical area. Instead they were viewed in the Radiology department on the same type of monitors (Kodak M24PMAX, 1660x1280) as in ITU and from which images would be reported if soft copy reporting were in operation. The viewing conditions in the room in which these monitors were located were better than in ITU: the room had no windows thus minimising aberrant light and the viewing conditions were chosen by each of the viewers to give them their own optimum viewing conditions. At both hospitals the viewers were allowed to use all the tools which were available for manipulation of the soft copy images, for example, windowing, magnification and image reversal to produce 'blackbone' images, in order to produce the images which they considered provided the most information. For the viewing of all images viewers were provided with card masks and they had the option of using a lens eyepiece if this was their normal practice. No limit was set on the viewing/scoring times or on the viewing distance. The conditions for viewing the images at each session were recorded on a proforma in case they varied between viewers.

Data analysis

The data were analysed using the SAS /STAT software (SAS Institute, 1994).

The above method was used for all tests: three tests were conducted and for clarity, the methods, results and discussion of results is given for each test separately. The tests were: Test 1 - high contrast resolution; Test 2 - threshold contrast detail detectability; and Test 3 - change in threshold contrast detail detectability with change in mAs.

3.2 TEST 1: COMPARISON OF HIGH CONTRAST RESOLUTION

3.2.1 Method

Test Object TOR (CDR) (Illustration 3.1) was used with no additional filtration in the beam at 50 kVp, 2.0 mAs and 180 cm FFD to give an optical film density of approximately 1.5 measured from an area outside the test object.

The test object was placed directly on the film/image receptor. Three exposures were made with the resolution grid parallel to the long axis of the imaging plate to test in the direction of the fast scan, and then three with the resolution grid perpendicular to the long axis of the plate to test in the direction of the slow scan (Siebert 1996). At Glan Clwyd Hospital the CR images were processed using the 'pattern' algorithm. At the Hammersmith there was no 'pattern' or 'test object' algorithm available on the GE unit and so the CR images were processed using the 'wrist' algorithm which the radiographer responsible for training considered was the most appropriate of those available.

The observers agreed at the outset of the study that if, when counting the line pairs (lp/mm) (adjacent bands of high and low density) on the image, they saw any sort of interference patterns between the resolution grid lines and lines in the system, they would stop counting and return to the part of the resolution grid where no interference

was detected.

At each hospital, mean scores for each type of image were calculated for each viewer and tested for the null hypothesis that for each viewer, there was no difference between the mean scores for each modality. Paired t- tests were used to test the pairwise null hypothesis that there was no difference between the means, and 95% confidence limits around the means were calculated. In addition, for each modality, and for images of the same test object taken under the same conditions, tests were conducted to establish whether differences between both viewers and images were statistically significant and to investigate if there were inter-viewer, intra-viewer or inter-image differences.

3.2.2 Results

Test object perpendicular to the long axis of the imaging plate (in the direction of the slow scan)

The results at Hammersmith showed significant differences between the types of images with more lp/mm being detected on Film (mean 5.91) than CR (mean 2.89), GE S/C (mean 2.60) and Kodak S/C (mean 3.05). No differences were found between the CR hard copy and PACS images (Table 3.1). There was a statistically significant difference between the scores for viewer number 1 and each of the other three viewers with Viewer 1 scores being larger. No statistically significant difference was found between the three images of each modality.

For the images from Glan Clwyd Hospital significant differences were seen between Film and both CR and S/C and also between CR and S/C (Table 3.2). No significant differences were found between viewers or between images of the same modality. A comparison between hospitals for Film and the Kodak S/C at each hospital showed no significant difference for Film, but for S/C there were more lp/mm seen at the Hammersmith than at Glan Clwyd (difference between the means = 1.04, 95% CI was

0.791 to 1.29)

Test object parallel to the long axis of the imaging plate (in the direction of the fast scan)

The results at Hammersmith showed significant differences between the types of images with more lp/mm being detected on Film (mean 6.11) than CR (mean 2.90), GE S/C (mean 2.48) and Kodak S/C (mean 2.40). No differences were found between the CR hard copy and soft copy images (Table 3.3). There was a statistically significant difference between the scores for viewers number 1 and 4 and each of the other three viewers with Viewer 1 scores being larger and Viewer 4 being smaller. No statistically significant difference was found between the three images of each modality.

For the images from Glan Clwyd Hospital significant differences were also seen between Film and both CR and S/C. (Table 3.4). No significant differences were found between viewers or between images of the same modality. A comparison between Film and the Kodak S/C at the two hospitals showed no significant difference for Film, but higher values at Hammersmith for S/C (difference between the means = 0.57, 95% CI was 0.339 to 0.801).

3.2.3 Discussion

Viewer 1 scored significantly higher than all other viewers for both positions of the resolution grid, which emphasises the need to have readings from several viewers if accurate results are required. Viewer 1 was the physicist with the most experience at viewing images of such test objects.

The images produced by the Kodak KESPR at the two hospitals were not of equal resolution. This may be accounted for because the x-ray equipment which was used to produce the images was not the same: the size of the focal spot of the x-ray tube was larger at Glan Clwyd (0.75mm) than at the Hammersmith (0.6mm). In addition the

viewing conditions and the viewers were not identical because the images were viewed at different hospitals and may have caused some bias in the results. This difference in results for the same type of equipment from the same manufacturer, emphasises the need to have constant conditions when comparisons between equipment are made.

3.2.4 Comparison with other studies

The results of the comparisons of the images of the resolution grid in the test object TOR (CDR) compare reasonably well with the results of another evaluation of the same equipment by FAXIL [Workman et al, 1995]. They measured 2.8 lp/mm with the test object parallel to the x-ray tube and 3.15 lp/mm in the direction perpendicular to the x-ray tube. There were three important differences in the method used to obtain the results which explain the differences found. Faxil conducted their tests in December 1994 while the old plates were in use. The study reported here was undertaken after the plates were replaced in March 1996 and which continued to be used throughout the RCT which is described further in chapter 5. Faxil's tests were undertaken in a fixed x-ray room and a 0.6 mm focal spot size was used. This study, which aimed to reproduce the clinical situation as far as possible, used the mobile x-ray machine which is normally used in ITU. This x-ray tube had a larger focal spot of 0.75 mm. In addition, Faxil restricted their tests to CR only and did not consider soft copy PACS images. Both studies compare well with the results of other authors (2.5 lp/mm for 25 cm x 43 cm plates [Seibert, 1996], 2.5 lp/mm for 35 cm x 35 cm plates [Cowan et al, 1993], 2.9 lp/mm for 35cm x 43 cm plates [Huda et al, 1995], 2.5 lp/mm for extremity cassette, Newton, 1995]) with the resolution of Film being better than CR hard copy and, where considered, PACS soft copy images. Thus the experimental method was considered appropriate for this type of comparison and was extended for further comparisons using another Faxil test object, the TO20.

3.3 TEST 2: BASELINE COMPARISON OF THRESHOLD CONTRAST DETAIL DETECTABILITY

3.3.1 Method

All images were undertaken at Glan Clwyd Hospital using the Kodak KESPR. Test Object TO20 (Illustration 3.2) was used with a 1 mm copper filter in the beam, at 81kVp, 1.0 mAs at 100 cm FFD and exposed using both film and KESPR cassettes. This test object assesses the minimum contrast required to visualise objects of different sizes above the noise threshold. Detail sizes range from 0.25 mm to 11 mm and contrast values range from 0.1% to 91.6%. The cones of the light beam diaphragm were opened to completely cover the KESPR plate because the system was not able to process the image coned to include the test object only.

It has been shown that the response of computed radiography plates to incident radiation is not independent of the kilovoltage used [Huda et al 1997]. Launders compared the threshold detail detectability of Film and CR hard copy and found the images comparable at 120kV [Launders and Cowan, 1995]. Oda et al [Oda et al, 1996] found that when phosphor plates are used, the optimum kilovoltage for chest images is 80kV. Since the examinations undertaken in ITU at Glan Clwyd Hospital are almost all of the chest, the kilovoltage selected for the comparison of contrast detail was that used in the hospital for mobile chest radiography ie around 80kV. The mAs was selected to produce a density reading on the film images of about 1.5, measured from an area outside the test object using a Melico/Photolag transmission densitometer (model TDX).

As far as could be controlled, all images were produced under the same conditions and repeated twice so that three images were obtained for each of film, CR and PACS in case there were fluctuations in tube output which could not be controlled. The

exposure indexes [Bogucki 1995] associated with the KESPR images and which give an approximate indication of the dose to the plate, were noted. These are similar to the exposure indexes produced by equipment from other manufacturers such as Fuji which uses a sensitivity number, S, for the same purpose [Seibert 1996, Cowan et al 1993].

The plates were all processed using the 'pattern' algorithm which is provided for the processing of non clinical examinations. The CR images were produced at default window settings (4095W, 2048L) and they were printed on transparency film by the laser printer (Kodak Ektascan LP2180 attached to a Kodak X-OMAT LP180 processor) currently used in Radiology to produce the CR hard copy images for reporting by the radiologists. The films were processed in a Kodak X-OMAT RA 480 daylight processor with 45 seconds processing using RA/30 developer and LO RP fixer.

Viewing and scoring of images was undertaken using the methods described earlier in this chapter (section 3.1.2).

For each image, the twelve sets of detail sizes were each scored by all four viewers. For the baseline test there were three images for each type of image, ie film, CR hard copy and CR soft copy (PACS). In addition, for one image of each type there were two scores which had been undertaken on each of two subsequent reading sessions by the local physicists. Thus for each type of image there were sixteen readings. The mean, maximum and minimum values of the scores for each set of sixteen readings were found and the results used to plot second order polynomial contrast detail curves using Fig P software [Fig P Software]. This software also produced statistics concerning the F- distribution [Studenmund, 1992] relating to the fit of the data on each curve.

The relative displacement of the curves from the bottom left hand corner gives an indication of the relative merits of the images of the test object. The curve with

greatest displacement from the bottom left hand corner towards the top right hand corner indicates the best image in terms of visualisation of the detail within the test object. The upper left of the curve represents the ability to detect large detail low contrast objects, whilst the bottom right represents fine detail, high contrast objects. The curves for the film, CR and PACS images which were produced when film and phosphor plates were exposed under the same conditions were plotted on the same axes to allow visual comparisons to be made.

3.3.2 Results

The mean exposure index for the CR images was 2033.

The results are presented graphically and are shown in Figure 3.1. This shows that the curves are almost identical for Film, CR and PACS soft copy images. The F-distributions showed that all curves had good fit for the data.

3.3.3 Discussion

The contrast detail curves for the three types of images compared were virtually identical when they were exposed at the kilovoltage normally used for mobile chest examinations (81kV) on ITU and with 1.0 mAs and 100 cm focus to film/plate distance. This is the result which was expected because all three types of image may be utilized in the Unit and the KESPR system was set up to produce images similar to film images. Thus the use of this test object to produce contrast detail curves appears to be a valid method for the comparison of the three types of images and to form a baseline for subsequent comparisons and could be incorporated in a routine QA programme.

3.4 TEST 3: THRESHOLD CONTRAST DETAIL DETECTABILITY: THE EFFECT OF VARIATION IN TUBE CURRENT (mAs)

3.4.1 Method

It has previously been demonstrated that the exposure latitude of hard copy CR images exceeds that of film [Broderick et al, 1993]. This test aimed to determine whether the

additional manipulation features of the PACS system increased, (or decreased), the latitude of CR hard copy images.

In order to obtain as wide a range of mAs values as possible without over exposing the film or plate, a higher output static x-ray unit was used (Phillips Medico 65CP generator and the broad, 1.3 mm focal spot of the Rotalix Super tube SRO 33 100) and the focus to film/plate distance was increased to 180 cm. The kilovoltage was reduced to 75kV and 1mm copper filtration was attached to the output of the x-ray tube. The mAs was then increased from the minimum value which could be obtained from the unit, 1 mAs, and doubled until 32mAs. Since the time allowed for the use of the clinical x-ray room was running out, the 64 mAs images were not produced but the 126 mAs and 250 mAs images were produced with all other exposure conditions and processing remaining constant. Since the digital images were still seen at 250mAs, and time allowed for only one further image to be taken, an exposure was made for CR using the maximum mAs (800mAs) which was possible from the unit. The associated exposure indexes were noted for all CR images and the density of the film and hard copy CR images was measured at a point outside the test object at a distance of 6cm below the beginning of the 'Faxil' sign in the image.

3.4.2 Results

The contrast detail curves which were produced with variation in mAs are shown in Figure 3.2. The densities of the film and hard copy CR images and the exposure indices associated with the KESPR images for each mAs are shown in Table 3.5 and presented in Figure 3.3.

For all three image types, the displacement of the curves from the large detail/high contrast part of the axes increased with increase in exposure from 1 mAs to 4 mAs. At 8 mAs the CR hard copy and PACS soft copy images improved compared with film which showed little change. Between 16 mAs and 250 mAs the CR hard copy and

PACS images improved very noticeably compared with film images which became too dense for any information to be identified. For film, the error bars on the curve obtained at 32 mAs extend down to the x-axis indicating that some readers could identify none of the details within the test object whereas for both CR hard copy and soft copy images more information was seen than in images produced at lower mAs values. In the curves for higher mAs values, both hard copy CR and PACS images improved as the mAs increased and were still found to be improving at 250 mAs. The contrast detail curves show the maximum exposure latitude for film to range from 1mAs to 32 mAs and that for CR hard copy and PACS to range from 1mAs to at least 250 mAs.

The response of the conventional film to increase in mAs was an increase in density from 0.37 at 1 mAs to 3.11 at 32 mAs. Further increase in mAs produced densities which were too high to be read, and too high for any of the image to be identified, even with a bright light. The density of the CR hard copy image remained almost constant when the mAs increased from 1 mAs to 250 mAs (mean 0.62, range 0.60 to 0.65), but was too high to be read by the densitometer for the 800 mAs image.

The value of the exposure index indicated on the hard copy CR films increased as the mAs increased to 250 mAs. However, at 800 mAs the exposure index had decreased below the value for 126 mAs. The CR images produced at both 1mAs and 2 mAs had a very mottled appearance due to underexposure of the plate and the associated exposure indices were 1470 and 1730.

3.4.3 Comparison with other studies

The results of the study of images with change in mAs were similar to those found by Broderick et al [Broderick et al 1993] who, using chest and pelvis images of anaesthetised rabbits, compared film/screen images with hard copy CR images. They found that the exposure latitude for film related to a range of 1.1 mAs and for CR

hard copy related to a range of 255.6 mAs. The results of the study described here confirmed the expected wider latitude of the CR hard copy images compared with film images, but, due to insufficient time, did not demonstrate the upper limit of mAs which could be used to produce a satisfactory image. In addition, this study showed that although soft copy manipulation facilities were available on the PACS workstations and were used by the viewers, little additional information was obtained compared with hard copy CR images. However, the increased latitude of the CR and PACS systems occurred at exposure values above the optimum film exposure value rather than below it, and additionally, that improved CR and PACS images were obtained with increased exposures. This is of concern because there is the danger that exposure factors which are higher than necessary will be used in order to improve images.

Some authors have suggested that the wide exposure latitude is one of the benefits of using CR technology. Bowman, who had seven years experience of using CR, wrote *'since the radiologic technologist will no longer need to be concerned with setting exposure factors, the need for repeats due to technical errors is virtually eliminated'* [Bowman, 1998]. However, other authors view the wide latitude as a danger [Parry et al, 1999].

3.4.4 Indication of image/patient dose

When film images are used the density of the image increases with mAs and when the film has received a dose of radiation which is too high, the corresponding film density can be seen to be too high. Conversely, underexposed films have densities which are too low. The radiographer is thus able to see over or under exposure of a film (and hence the patient), by visual inspection of the film image. Images produced by CR techniques do not have similar, observable indications of over or under exposure. It has been documented that the hard copy CR images provide an approximate indication of the plate/patient dose in the form of the exposure index, an increase in exposure index indicating an increase in dose [Workman and Cowan, 1992]. There was no such

indication of patient radiation dose on the soft copy image. Since the completion of this study and the circulation of a draft report, Kodak has adapted the system so that the exposure index can now be obtained for soft copy images. However, this information is not available on the *default* image. If any user wants to know the value of the exposure index associated with a soft copy image, it can be obtained by opening a window, clicking on a menu bar, and opening an information box, but it must be noted that this is *not part of the default information* on the soft copy image.

When a radiographer undertakes an examination of a patient who has already been examined using the KESPR system and whose image is stored locally on the hard disk of the work station, information about the first examination is available at the Quality Control Workstation (QCW) to assist the radiographer when undertaking subsequent examinations. Details of the exposure factors (kV and mAs), focus to film distance, patient position and processing algorithm used are immediately available but *the exposure index is not provided*. A paper has been published based on the work discussed in this chapter in which we suggested that the exposure index should be part of the information provided to assist the radiographer undertaking the next examination in order to allow the radiographic technique to be adapted if the exposure index indicates that the patient radiation dose is higher than expected [Weatherburn & Davies, 1999]. It is unlikely that, when images are satisfactory, users of the system will routinely search for information about the exposure index but likely that this information will only be sought when there is a problem with an image such as when the image has 'mottle' due to underexposure.

It should be noted that the optimum values of the exposure index depends on the set up and calibration of the unit, and may vary for the same unit after recalibration and is likely to vary between similar units. However, after calibration a baseline range of optimum exposure indexes is available and for the Kodak system, higher values suggest higher plate doses. For the PACS system discussed in this paper, during the period of

the study, the manufacturer recommended that exposure indexes in the range 1800 to 2000 should be obtained. It had previously been recommended that exposure indexes between 1600 and 1800 should be obtained [Price,1995]. The CR curves shown in Figure 3.1, which are almost identical to the film curve were produced with an exposure index of 2033, ie higher than the recommended value. Indeed it was found in clinical practice that it was necessary to obtain values around 2200, otherwise the radiologists commented that some images were unsatisfactory for diagnosis due to the presence of a mottled appearance and the examination had to be repeated. The information in Figure 3.1 suggests that if film were used and the same exposure factors selected, satisfactory images would be produced.

3.4.5 PACS equipment from other manufacturers

The CR system studied in this paper was manufactured by Kodak, but the lack of information relating to the patient dose on soft copy images is not unique to their equipment. The PACS systems produced by both General Electric and Agfa, which are installed and operating in the UK, also provide an indication of dose on hard copy images but do not provide this information on the soft copy images by default. In our publication which was based on part of the content of this chapter, we suggested that this information should be available *by default* on all soft copy images in order to prevent an increasing drift in exposures with a subsequent increase in population dose [Weatherburn & Davies, 1999]. One manufacturer has subsequently amended its equipment to conform with this recommendation.

3.4.6 Conclusions

The CR system tested had a much wider latitude than film with doses which were higher than those which produced acceptable film images. Since there is no indication of plate/patient dose by default on soft copy images there is the danger that, in order to improve the information in the images, patients will receive higher doses than are necessary for a diagnosis to be made. Users should be made aware that, whilst

increasing dose (by more than 250 times as demonstrated here) improves the image, this is not consistent with the ALARA (As Low As Reasonably Achievable) principle [ICRP (International Commission on Radiological Protection),1990]. Manufacturers of equipment should provide some information on the default soft copy images which gives some indication of the patient dose associated with the production of the image.

The experimental studies reported in this chapter have shown that film, CR hard copy and PACS soft copy images of test objects are comparable at certain conditions of exposure only. The response of film and the phosphor plate images (CR hard copy and PACS soft copy) varies at other exposures. The phosphor plates have a much wider latitude than film and the images improve with increase in exposure, and thus images of patients might also vary with change in exposure. The following two chapters describe two comparative studies of the patient radiation doses which were required to produce images which were acceptable to radiologists and clinicians for the diagnosis and clinical management of specific groups of hospital patients when conventional film and PACS were used.

Table 3.1 Hammersmith Hospital: Test Object Perpendicular to the long axis of the imaging plate (direction of slow scan)

MODALITY	mean score for all viewers (lp/mm)	SD (lp/mm)	Range (lp/mm)
FILM	5.91	1.11	4.5-8.45
CR*	2.89	0.34	2.24-3.55
GE PACS	2.60	0.38	1.8-3.35
Kodak S/C	3.05	0.34	2.5-3.35

Between modality comparison:

	Film & CR	Film & GE PACS	Film & Kodak s/c
Difference between means	3.01	3.3	2.86
95% CI for difference between means	2.65 to 3.38	2.91 to 3.71	2.21 to 3.51

No significant difference was found between GE PACS, Kodak S/C and CR images.

Between viewer comparison:

	viewers 1 & 2	viewers 1 & 3	viewers 1 & 4
Difference between means	1.14	1.29	1.74
95% CI for difference between means	0.11 to 2.17	0.26 to 2.32	0.84 to 2.63

Between image comparisons: there were no statistically significant differences at the 95% level between images within a modality.

Table 3.2 Glan Clwyd Hospital: Test Object Perpendicular to the long axis of the imaging plate (direction of slow scan)

MODALITY	mean score for all viewers (lp/mm)	SD (lp/mm)	Range (lp/mm)
FILM	5.38	0.72	4.75-6.7
CR	2.39	0.20	1.9-2.65
Kodak S/C	2.01	0.24	1.6-2.37

Between modality comparison

	Film & CR	Film & Kodak s/c	CR & Kodak s/c
Difference between means	2.99	3.37	0.38
95% CI for difference between means	2.61-3.36	2.99-3.74	0.005-0.75

Between viewer comparison: there were no statistically significant differences at the 95% level between viewers

Between image comparisons: there were no statistically significant differences at the 95% level between images within a modality.

Table 3.3 Hammersmith Hospital: Test Object Parallel to the long axis of the imaging plate (direction of fast scan):

MODALITY	mean score for all viewers (lp/mm)	SD (lp/mm)	Range (lp/mm)
FILM	6.11	0.97	5-8
CR	2.90	0.29	2.5-3.3
GE PACS	2.48	0.28	2-2.8
Kodak S/C	2.40	0.37	1.8-2.8

Between modality comparison

	Film & CR	Film & GE PACS	Film & Kodak s/c
Difference between means	3.21	3.63	3.71
95% CI for difference between means	2.81 to 3.61	3.18 to 4.08	3.23 to 4.19

No significant difference was found between GE PACS, Kodak S/C and CR images.

Between viewer comparison:

viewers	1 & 2	1 & 3	1 & 4	4 & 2	4 & 3
Difference between means	1.68	1.82	2.31	-0.63	-0.49
95% CI for difference between means	1.21 to 2.15	1.36 to 2.28	1.92 to 2.70	-1.04 to -0.22	-0.90 to -0.07

Between image comparisons: there were no statistically significant differences at the 95% level between images within a modality.

Table 3.4 Glan Clwyd Hospital: Test Object Parallel to the long axis of the imaging plate (direction of fast scan)

MODALITY	mean score for all viewers (lp/mm)	SD (lp/mm)	Range (lp/mm)
FILM	5.5	0.75	5.0-6.7
CR	2.15	0.21	1.9-2.5
Kodak S/C	1.83	0.11	1.6-2.0

Between modality comparison

	Film & CR	Film & Kodak s/c
Difference between means	3.35	3.67
95% CI for difference between means	2.98-3.73	3.29-4.04

No significant difference was found between Kodak S/C and CR images.
Between viewer comparison: there were no statistically significant differences at the 95% level between viewers
Between image comparisons: there were no statistically significant differences at the 95% level between images within a modality.

Table 3.5 The variation of the measured density of film and hard copy CR images and the exposure index of the KESPR images with change in mAs

EXPOSURE FACTOR (mAs)	Film Density	CR Density	CR exposure index
1	0.37	0.61	1470*
2	0.70	0.61	1730*
4	1.34	0.65	2000
8	2.13	0.60	2290
16	2.73	0.65	2610
32	3.11	0.64	2910
126	off scale	0.61	3510
250	off scale	0.62	3800
800	n/a	off scale	3490

* the image had a very 'mottled' appearance due to underexposure

Figure 3.1 Comparison of contrast detail curves for film, CR H/C and PACS S/C images exposed under the same conditions

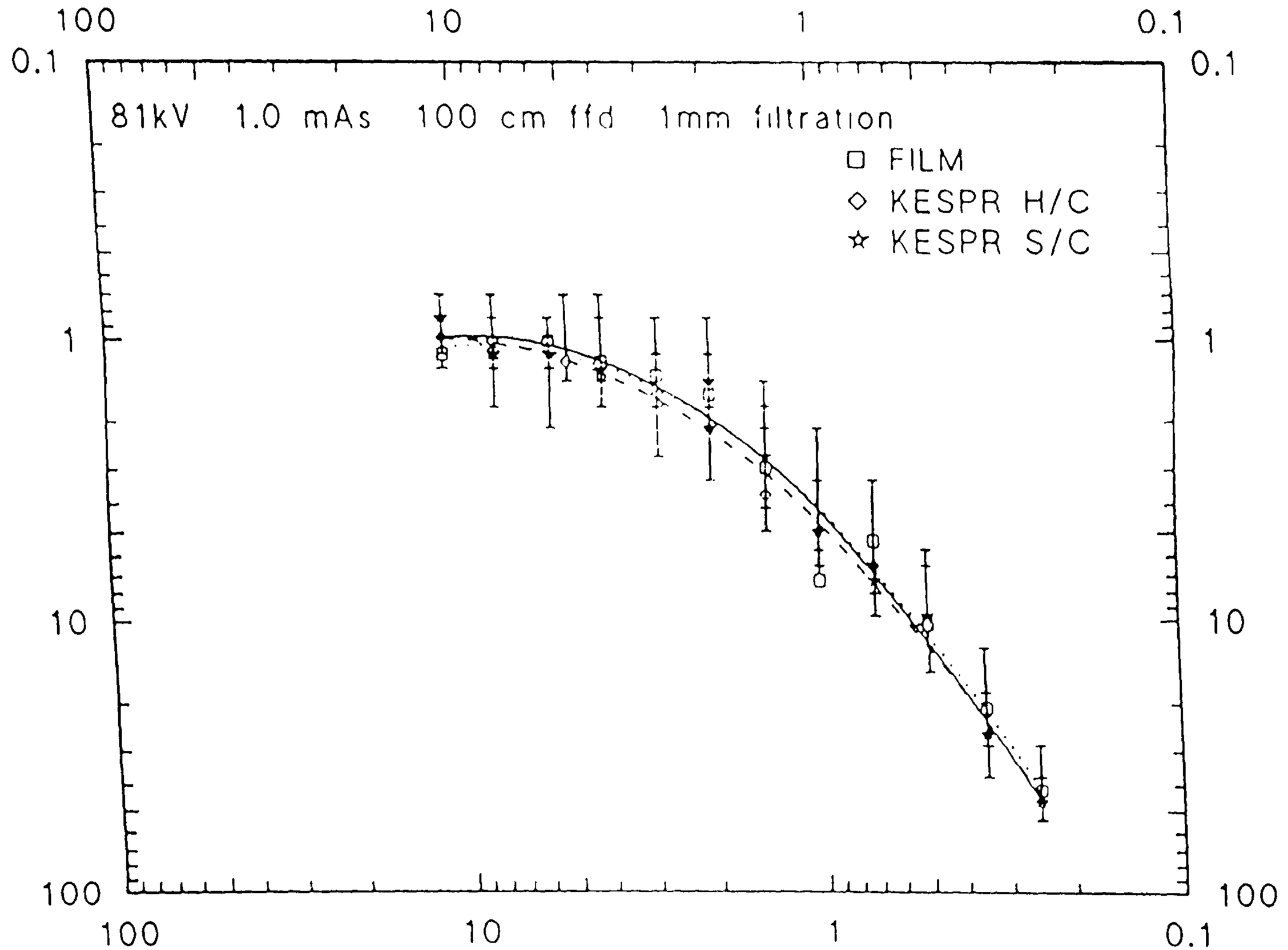
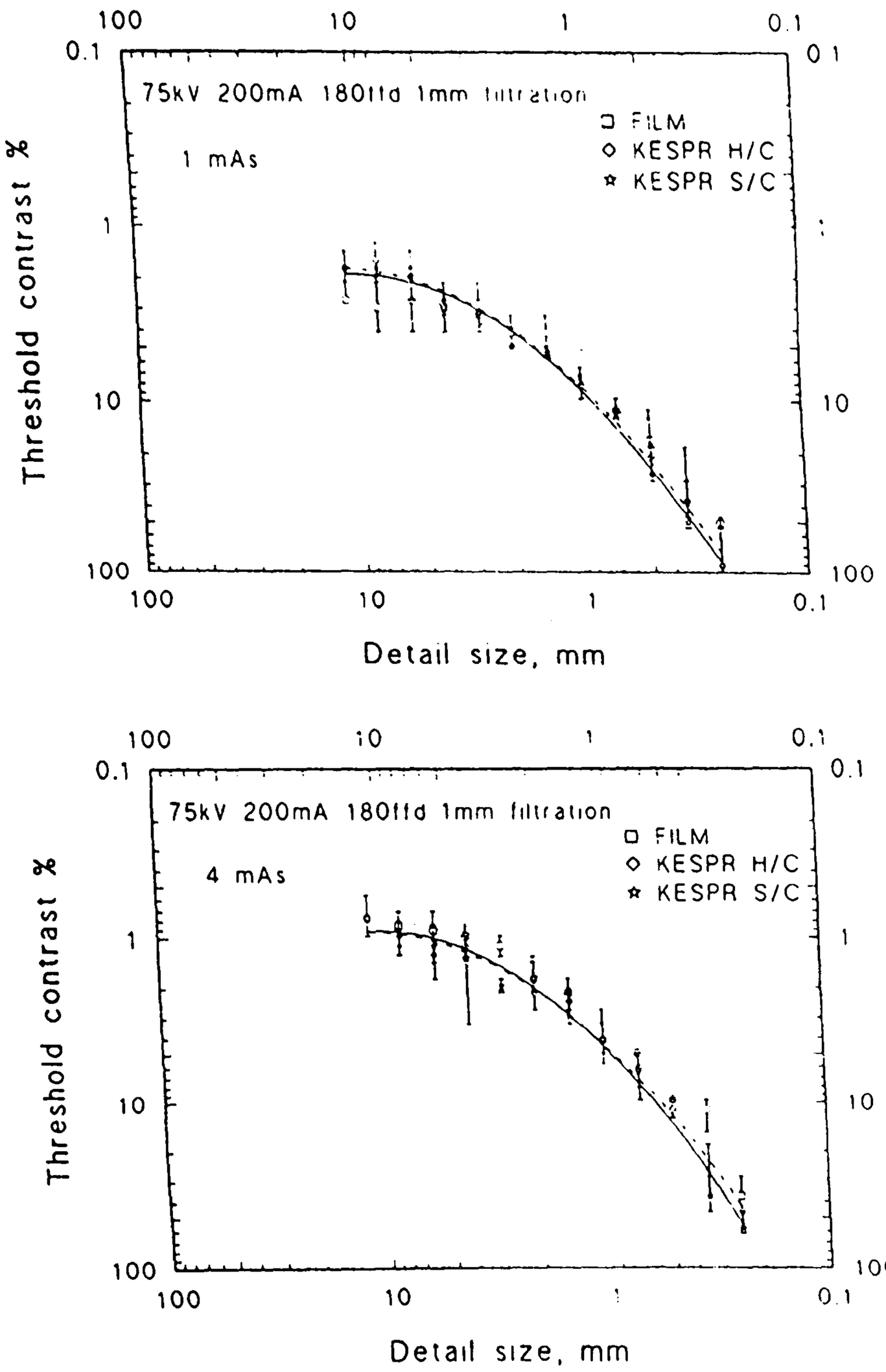


Figure 3.2 Comparison of contrast-detail curves for film, CR H/C and PACS S/C images exposed at varying values of mAs.



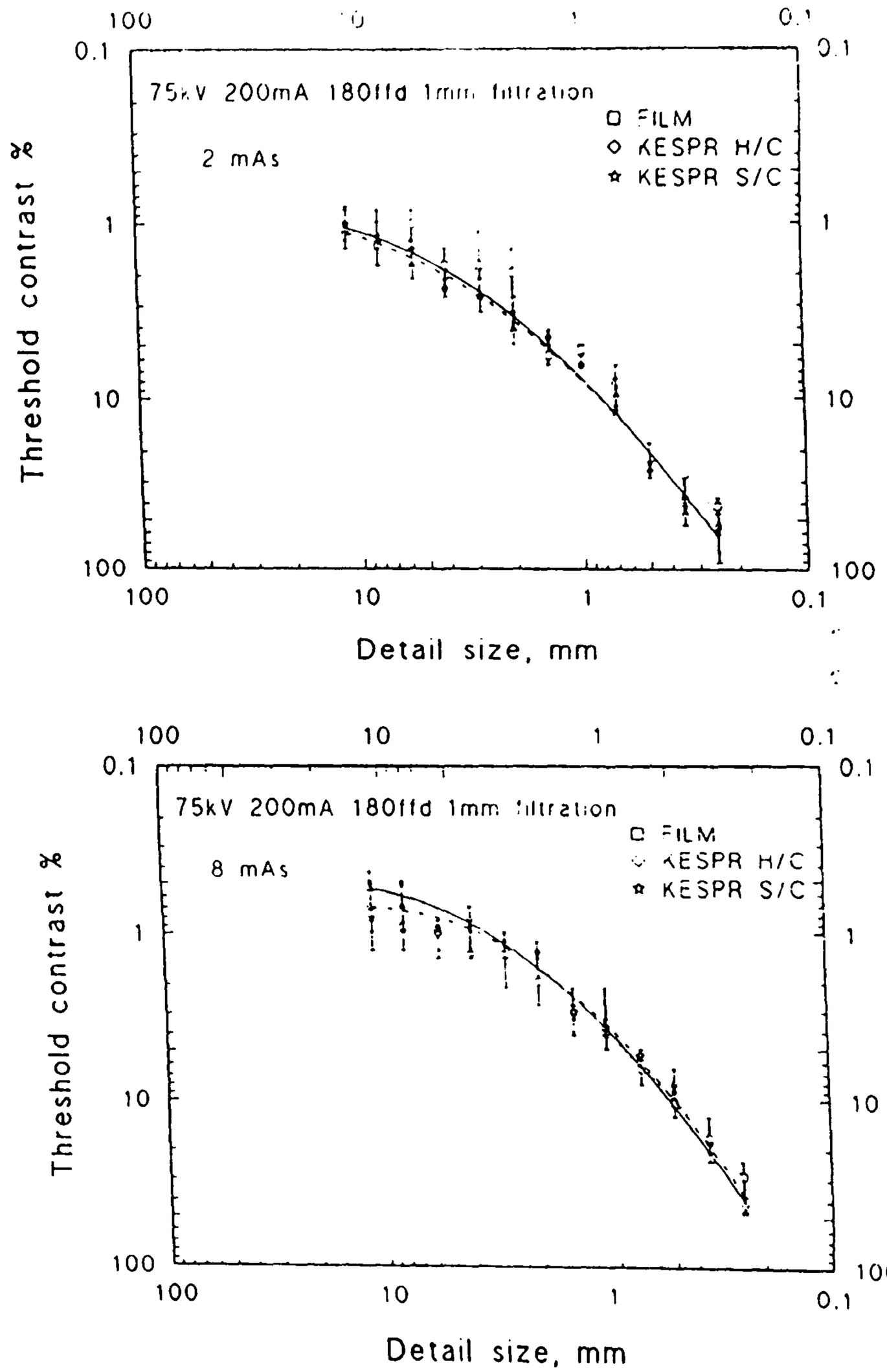
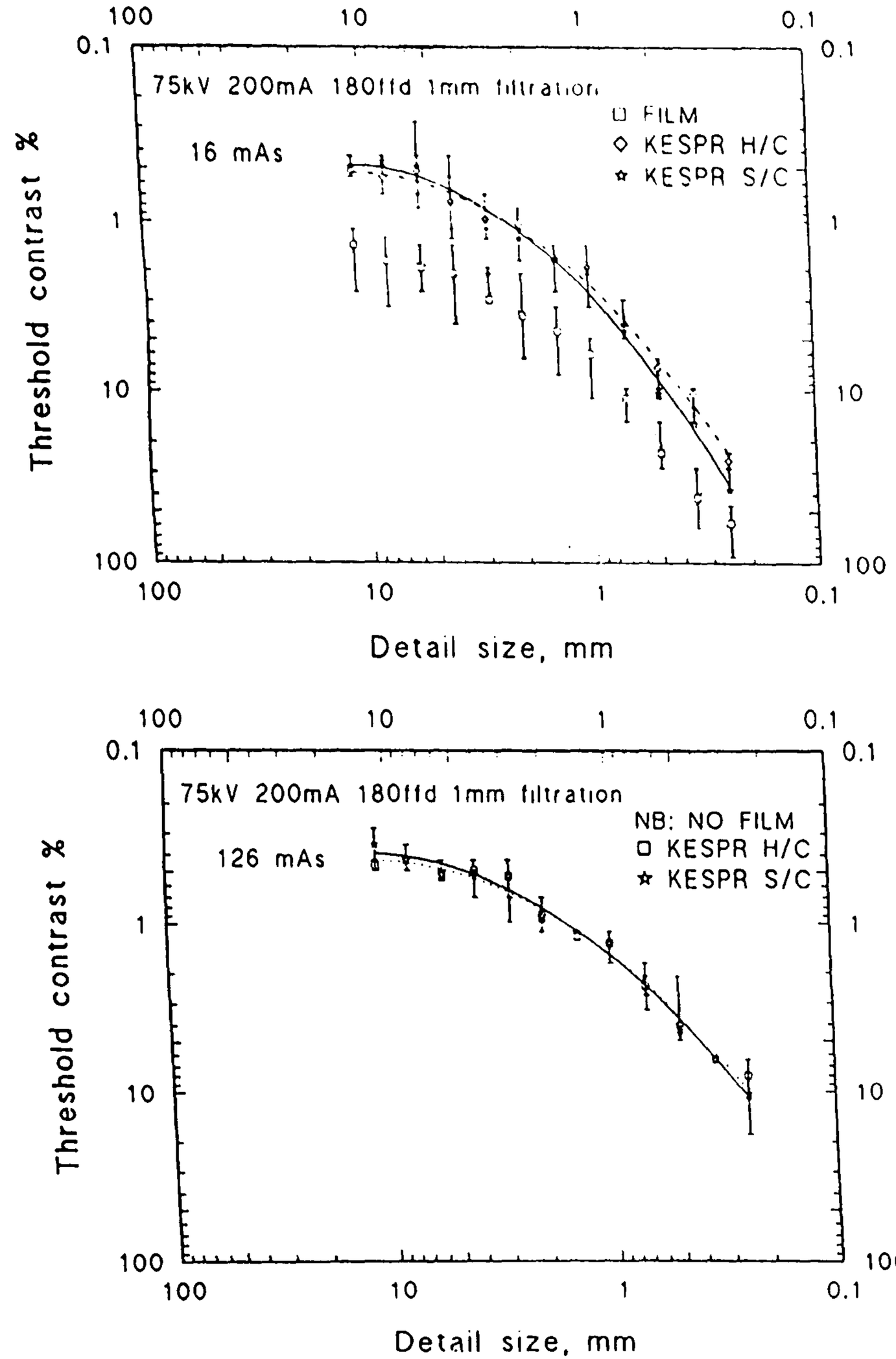


Figure 3.2 (contd) Comparison of contrast-detail curves for film, CR H/C and PACS S/C images exposed at varying values of mAs.



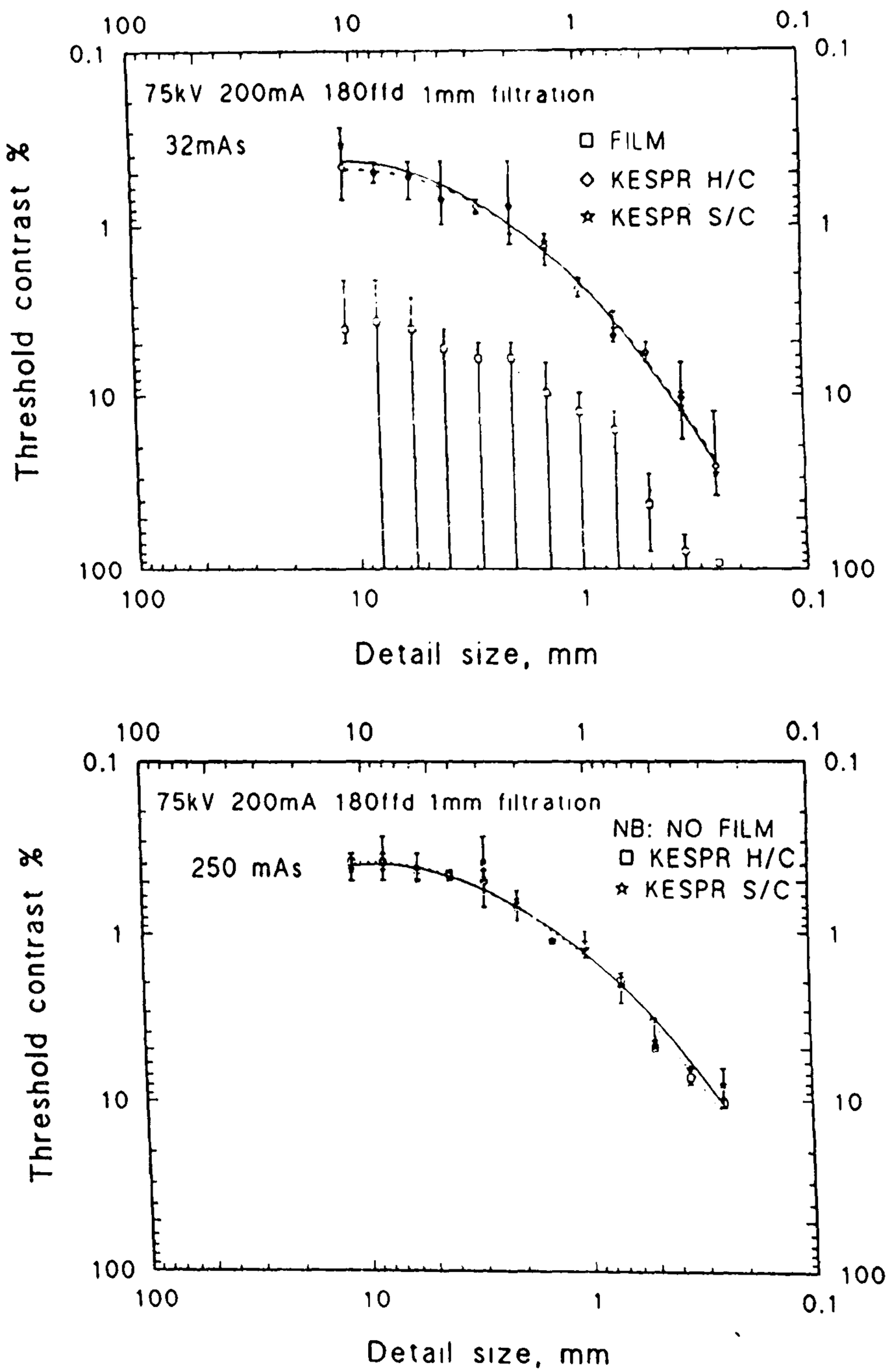


Figure 3.3 Comparison of the responses of film and CR hard copy images to variation in mAs

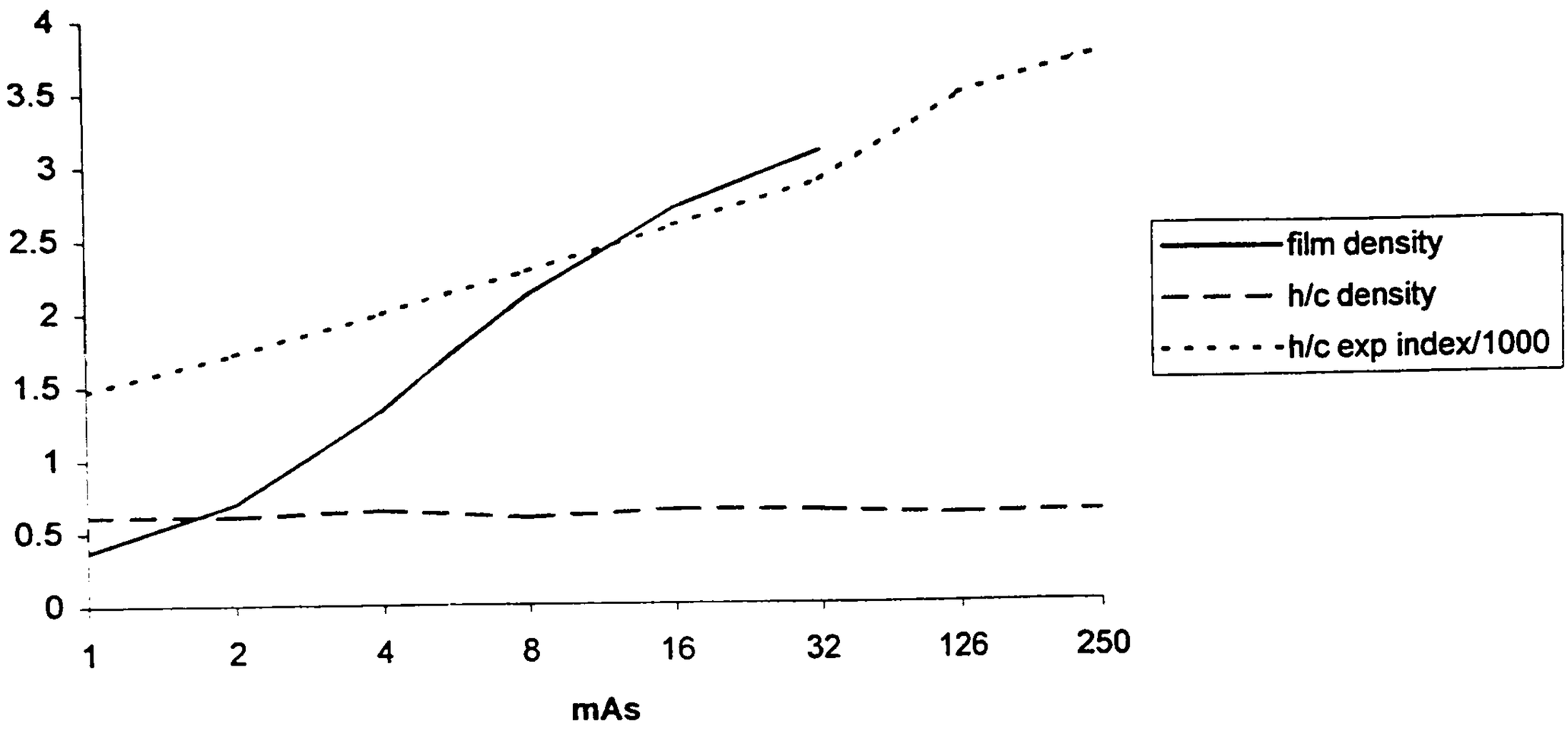


Illustration 3.1 The Leeds Test Object TOR (CDR)

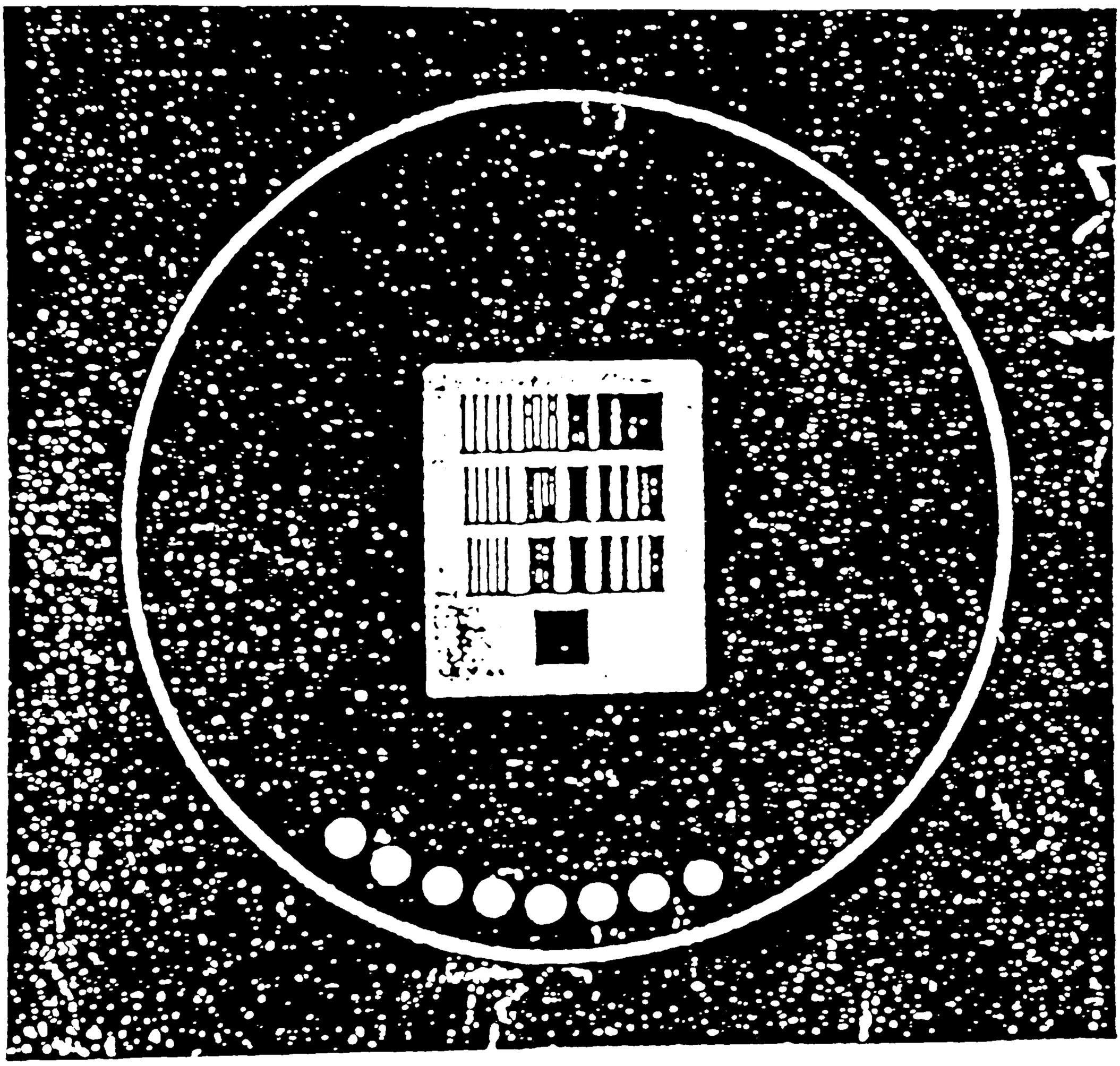
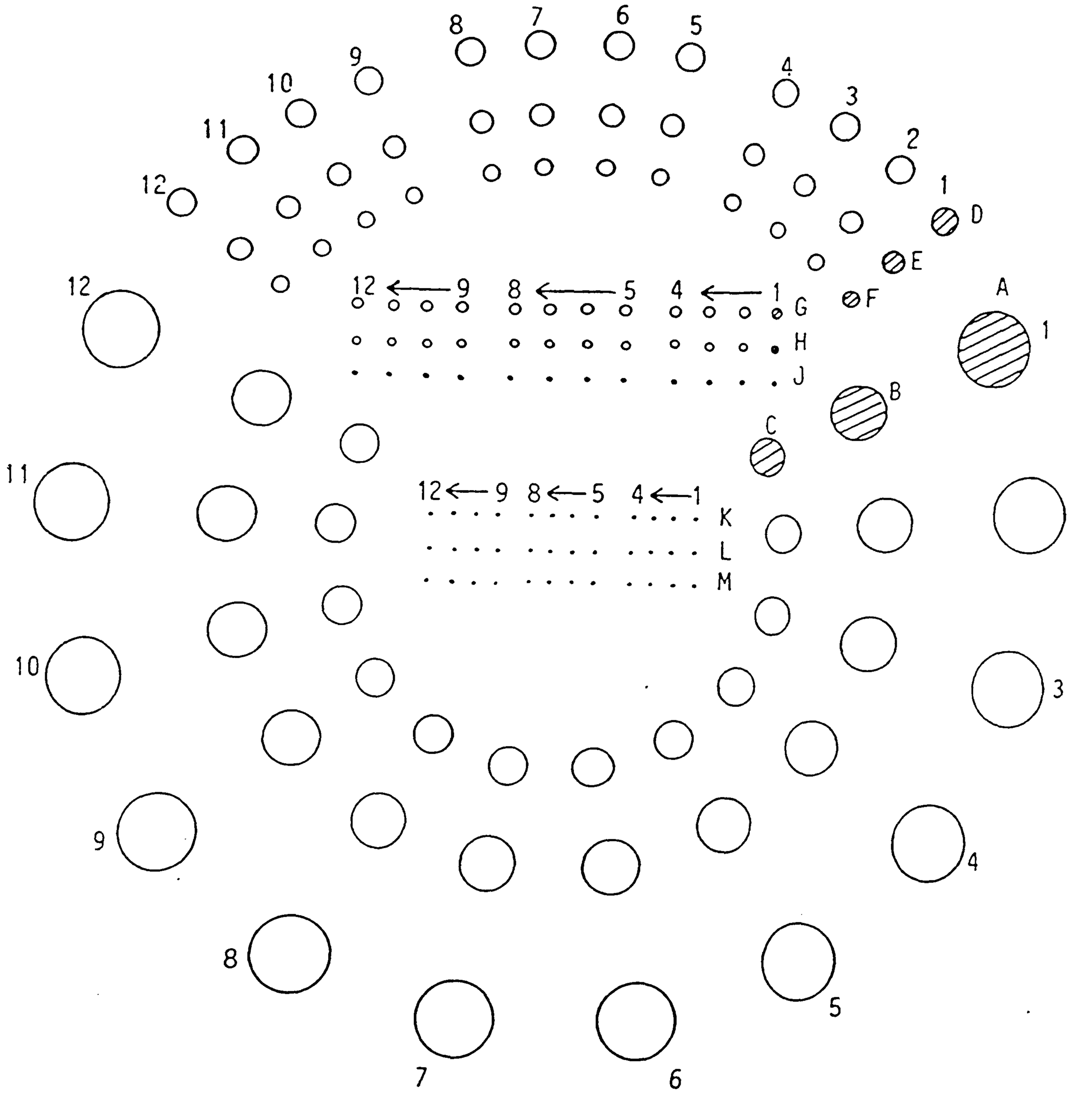


Illustration 3.2 The Leeds Test Object TO 20



Detail no.1 in each row (shown shaded) has the highest contrast, ie visibility decreases from 1 to 12

CHAPTER 4

THE EFFECT OF PACS ON PATIENT RADIATION DOSES: LATERAL LUMBAR SPINE

4.1 INTRODUCTION

In chapter 3 the response of film, CR hard copy and PACS soft copy images of test objects to change in exposure was compared. It was found that the exposure latitude of the CR and PACS images was much wider than that for film. In addition, it was found that the two digital types of images had better contrast detail responses with higher exposures, and that the images improved with increasing exposure, while the film images became too dark and were unacceptable. These results suggest that patient radiation doses might change if film is replaced by phosphor plate images within a PACS. In this chapter an observational study is reported which compared the doses used for the examination of real patients where the criteria for assessing the images was the acceptance by radiologists and orthopaedic surgeons for primary diagnosis.

4.2 METHODS

4.2.1 Background and Research Design

The hypothesis that was tested in this study is that the use of PACS reduces the total dose to the patient. It is anticipated that this will be achieved in three ways. Firstly, because the PACS imaging system utilizes computed radiography phosphor

plates, the dose for individual images is reduced. Secondly, because the system has a much wider latitude than film, the number of images required to image the body area is reduced. Thirdly, again due to its wider latitude, the number of repeat exposures due to unsatisfactory exposure factors is reduced.

The installation of the PACS at Hammersmith Hospital was accompanied by the move of the radiology department to a new location within the hospital and by the replacement of much of the department's equipment. Time constraints meant that examinations of only one body area could be monitored in this room when conventional film-based imaging was being used. Therefore, a decision was made to measure doses for examinations of the lateral lumbar spine. The lumbar spine is not only an area which is frequently examined (3.3% of all examinations nationally (Royal College of Radiologists and the National Radiological Protection Board, 1990) but also requires a higher dose than any other plain radiography examination. As a result lumbar spine examinations contribute 15% of the UK collective dose equivalent* for all medical and dental x-ray examinations (ICRP, 1990) and the lateral view routinely requires a higher dose than the antero-posterior and thus makes the major contribution to the overall dose for the examination.

Although the collection of baseline data was constrained by the closure of the old radiology department and the end of the use of conventional film image production, the equipment from one x-ray room was transferred in its entirety to the new department. Thus, a comparison of the patient doses received when this equipment was used before and after the switch to PACS-based operation could be made without the concern that differences reflected the introduction of new x-ray equipment. Details of the radiographic equipment used are shown in Table 4.1.

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* 'Collective dose equivalent' expresses a relationship between detriment and the distribution of dose equivalent in an exposed population and is expressed as the mean of the products of the individual dose equivalent in the whole body or individual organ of the members of each subgroup on the exposed population multiplied by the number of persons in that subgroup (ICRP 1990).

Baseline measurements of radiation doses received by patients who had an x-ray examination of the lateral lumbar spine were made prior to the start of PACS-based operation. These measurements were compared with similar measurements of radiation doses received by patients after a steady state of PACS-operation was achieved. Any differences observed between the pre and post-PACS measurements may result from the move to working with PACS. However, the weakness of a 'before and after' research design is that observed differences may be a product of changes in other factors such as the average patient size, the exposure factors used, the department's examination protocol or change in radiographic staff. Therefore, multiple regression techniques were applied in order to introduce statistical adjustment into the simple before and after comparison to allow for changes in other variables.

Doses were measured using two methods: thermoluminescent dosimeters (TLDs), to measure surface entry doses, and a diamentor to measure dose area product (DAP). Calibrated TLDs were obtained from the National Radiological Protection Board (NRPB) which quotes their accuracy for reading results as "for measurements of 0.5mGy and higher the overall uncertainty at the 95% confidence level will typically be about ± 12%, rising to ± 22% for measurements down to about 0.1mGy" (Shrimpton et al, 1994). Initially some tests were made on a test object (Leeds Test Object Type TOR[CDR]) to check the variability of NRPB's TLD readings and to determine how many TLD readings should be taken for each individual dose measurement**. On the basis of these initial tests it was decided that one TLD would be used to measure each entry dose for each study patient. The entry TLD was positioned in the centre of the beam and attached to the patient's skin with adhesive tape as recommended in the National Protocol for Patient Dose

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** Three TLDs were placed side by side and exposed simultaneously in a diagnostic x-ray beam. This was repeated for a further two groups of three TLDs. The TLDs were returned to NRPB for processing without any indication of the doses expected. The variability of the TLD readings was within the limits stated by the NRPB and it was, therefore, decided to use one TLD only for each does measurement. A further 76 TLDs were used in pairs to monitor entry doses to a phantom of tissue equivalent material exposed at 70kV and various values of mAs. The variation from the mean of all entry doses lay within 10%.

Measurements in Diagnostic Radiology (ICRP, 1990). An automatic exposure control was used throughout the data collection periods of the study but this was recalibrated by the hospital physicists when PACS was used in order to obtain sensitivity numbers (S)[xxxx] of around 200, as recommended by the manufacturer of the PACS equipment.

4.2.2 Patient Sample

The patients were almost all referred for radiographic examination of the lumbar spine by one orthopaedic surgeon from his routine orthopaedic clinic. A small number of study patients were ward or GP patients. The pre-PACS measurements were made on 18 working days between June 1993 and February 1994 and ended when the x-ray equipment was transferred to the new X-Ray department. Pre-PACS data were collected on 101 patients. The data concerning one patient was not used because the patient, at the request of the referring clinician, had a limited examination only. The PACS measurements were also made on 18 working days from May 1995 to November 1995 when the x-ray equipment was transferred to another hospital within the Trust, and data were collected on 97 patients. The data concerning one PACS patient was not used because part of the examination was undertaken in a different x-ray room. All measurements were undertaken by an independent research radiographer.

4.2.3 Data Collection

The full information collected on each exposure on each study patient is given in Table 4.2. Some study patients received only a single exposure of the lumbar spine (L1-5). Other patients received two or more exposures, either because the normal working practice of the radiographer was to take two views routinely to demonstrate the lumbar spine (both the L1-5 view plus the lumbo-sacral junction view, L5/S1), or because repeat exposures were undertaken for the same view when the first image was found to be unsatisfactory. If a patient underwent more than one exposure as part of the same examination, then details relating to all exposures were recorded.

The air ionisation chamber (diamentor) used to measure the dose area product (DAP) was fitted to the output of the x-ray tube and calibrated on installation in the room. It gave a digital display ($cGycm^2$) for each exposure and was reset for each exposure. The exposure factors, kV and mAs, were noted from the display on the control panel immediately after each exposure and the focus to film distance (FFD) noted from the tube column scale. The film size was taken from the standard manufacturer's cassette sizes used and the radiation field size on the processed film measured with a ruler. During the post PACS phase of the study, CR hard copy images were produced as well as soft copy images for all patients, except GP referrals. This allowed the size of the coned area on the hard copy images to be measured and the variable PATAREA to be calculated using the magnification/minification factor indicated on the image. In addition, the sensitivity number (S)[•••] which was indicated on all hard-copy images but not, by default, on soft-copy images, was noted for each PACS image.

Each patient's age and sex was noted, and height, weight and thickness were measured. Patient thickness at the centring point was measured with callipers while the patient was still in the examination position. More than one radiographer was responsible for the work in the chosen room on each day. In order to gain the cooperation of the radiographers, the identity of the radiographer undertaking the x-ray examination was not recorded. However, since the aim of the study was to monitor doses achieved by the imaging system in operation in the x-ray department, and not to monitor the performance of individual staff, it was felt that this was not detrimental to the study.

••• System sensitivity number (S) is approximately equal to 200/ exposure (mR). As the sensitivity number gets larger, a lower exposure is incident (and x-rays absorbed) on the imaging plate (Seibert, 1996)

The effective doses[****] were calculated using the NRPB software package SR262 (Hart et al, 1994) and XDOSE (Le Heron, 1994), using the data collected for tube kilovoltage and the surface entrance doses measured by TLD.

4.2.4 Analysis Methods

All data analysis was undertaken using the STAT module of the statistical analysis software package, SAS (SAS Institute, 1994). The comparability of the study patients in the 'before' and 'after' elements of this study was investigated by comparing the patient groups in terms of general characteristics: age, sex, weight, height and thickness at the centring point. These comparisons were made using Mann-Whitney, T-Test or Chi^2 tests depending on the nature of the data. The comparisons between film and PACS in terms of dose were made using the single data set but with the data grouped in five alternative ways.

Group 1 *Total dose received by the patient per examination*

Here each observation related to a study patient and the dose variable was the sum of all dose readings for all images that the patient had received for the examination of the lateral lumbar spine. For example, if the patient needed an additional image to demonstrate the lumbo-sacral junction (L5/S1) or was re-examined because the initial image was unsatisfactory and the image was rejected, then the total dose across all images was considered. This group reflects the total examination dose received by patients at this hospital for imaging of the lateral lumbar spine and is therefore the most important.

[****] ICRP now uses the term effective dose, *E*, to refer to the sum of the weighted equivalent doses. The units of effective dose are the joule per kilogram, which are given the name sievert (Sv). The effective dose, *E*, is given by

$$E = \sum_{T} w_T \sum_{R} w_R D_{T.R}$$

where $D_{T.R}$ is the mean absorbed dose in the tissue or organ T due to radiation R and w_T and w_R are the tissue weighting factors and radiation weighting factors, respectively (ICRP 1990).

Group 2 Dose per technically satisfactory examination

Here each observation related to the final examination of each study patient that was judged as technically satisfactory by the radiographer and submitted for reporting. This measure of examination dose excluded images that were rejected because they were technically unsatisfactory and thus were not submitted for reporting by the radiologist.

Group 3 Dose per single exposure of the whole lumbar spine (L1-5)

Here each observation related to a single exposure of the whole lumbar spine, of all patients in the study, where the exposure factors were judged by the radiographer to be satisfactory. If the image was repeated because it was unsatisfactory, the dose for the last image only was used so that there was one observation only for each patient.

Group 4 Dose per single exposure of the whole lumbar spine (L1-5) for patients between the weights of 65 and 75 kilogram

Here each observation related to a single exposure of the whole lumbar spine but the sample was restricted to include only those patients who were within the weight limit suggested in the 'National Protocol for patient dose measurement in diagnostic radiology' (IPSM, 1992), that is, patients whose weights were in the range 65kg to 75kg.

Group 5 Dose per single exposure of the lumbo-sacral junction (L5/S1)

Here each observation related to a single exposure of the lumbo-sacral junction of all patients in the study.

For each measure of dose accumulated during an examination (Groups 1 and 2), simple comparisons were made between the film and PACS observations in terms of the variables SUMEFF (examination value for effective dose, EFFECTIVE), SUMENTRY (examination value for entry dose, ENTRY) and SUMDAP (examination value for DAP readings, DAP).

For groups 3, 4 and 5, where each observation was a single exposure, comparisons were made in terms of ENTRY, DAP and EFFECTIVE, and the exposure factor variables: KV, MAS, FFD and FSD.

In order to control for the potential bias resulting from the before and after study design Ordinary Least Squares (OLS) regression analysis was used. Three regression models were built for each of Groups 1-4 to examine the effect of PACS on effective dose, entry dose and dose area product. The sample size in Group 5 was small because it was rare for patients to require this image and the sample was not distributed evenly between the two modalities (PACS N = 12 and FILM N = 29). It was therefore not possible to build valid models for this group.

In the first three models (Models 1-3), the hypothesis tested was that the use of PACS would reduce the total patient dose for the imaging of the lateral lumbar spine. The total examination dose would normally be expressed in terms of the sum of the DAP readings of all the exposures required to complete the examination (ICRP 1990). However, the diamentor used for this purpose was either not fitted or not working for several weeks during the PACS element of the study, so DAP readings were not available for twenty patients. Therefore, effective doses and entry doses were used as additional units for the calculation of total examination dose and three separate models were built to explore the effect of PACS on each measure of patient examination doses.

The dependent variables used in the three models for Group 1 were the total effective dose (SUMEFF), total entry dose (SUMENT), and total DAP readings (SUMDAP), received by the patient across all exposures for satisfactory visualisation of the lateral lumbar spine. The dependent variables were not normally distributed. In order to improve the specification of the models the natural log of SUMEFF, SUMENT and SUMDAP were used as the dependent variables. The variables included in the models are listed in Table 4.3. Variables which were associated with individual images but varied across images of the same patient, such as the exposure factors, thickness at the centring point and area of image irradiated could

not be included in the models since the dependent variables were measures of the total dose for the whole examination.

The second set of three models (Models 4-6), tested the hypothesis that when PACS was used the total patient dose for the technically satisfactory examination, that is, the images submitted for reporting, would be reduced compared with when the film system was used. The dependent and independent variables used were as above.

The third set of three models (Models 7-9), relate to data from Group 3 and examined the hypothesis that PACS would reduce the radiation dose to the patient for single views of the whole lumbar spine. The dependent variables were ENTRY, DAP and EFFECTIVE which were not normally distributed so these were transformed to create the variables LOGENT, LOGDAP and LOGEFF to improve the models. The independent variables included in this model are listed in Table 4. 3.

The fourth set of three models (Models 10-12) used data from Group 4 and examined the hypothesis that PACS would reduce the patient radiation dose for single images of the whole of the lumbar spine for those patients whose weight was within the range of 65 to 75 kilograms. The variables were as in the previous three models.

Ordinary least squares (OLS) regression analysis was used in the development of all models. Diagnostic tests were undertaken to investigate the following OLS assumptions: homoskedasticity of the error term (White's test) (White, 1980), no highly influential data points (Belsey et al, 1980)(using the DFFIT statistics), no serious multicollinearity (Studenmund, 1992) between the independent variables (using variance inflation factors) and normally distributed error term (Altman, 1991) (using the Shapiro-Wilk's test).

4.3 RESULTS

4.3.1 Initial Comparisons

Data were collected on 100 patients while conventional x-ray film imaging was being used and 96 patients when PACS images were being used. The results from the comparison of data collection periods in terms of patient characteristics are shown in Tables A1.1 to A1.4. The results indicate that the two patient groups were well matched in terms of sex ($p=0.79$), age ($p=0.99$), weight ($p=0.51$)and height ($p=0.96$).

Group 1 and Group 2

The comparisons of dose data between film and PACS data collection periods, for Groups 1 and 2, are reported in Tables 4.4 to 4.9. For these two Groups, statistically significant differences between PACS and film were found for variables SUMENTRY (Group 1 Mann-Whitney test, $p=0.02$; Group 2 Mann Whitney test, $p=0.01$), SUMDAP (Group 1 Mann-Whitney test, $p<0.001$; Group 2 Mann-Whitney test, $p<0.001$) and SUMEFF (Group 1 Mann-Whitney test, $p=0.05$; Group 2 Mann-Whitney test, $p=0.03$). For all three dose variables, the dose for PACS was lower.

No statistically significant difference was found in the number of images required (Chi square $p=0.08$, Table 4.10). There was no significant difference in the number of images repeated for specific reasons when PACS was used compared with when film was used (Chi square $p=0.18$) (Table 4.11).

Group 3

The comparison of patient and exposure characteristics, and dose data between film and PACS data collection periods, for Group 3 (single exposures of body area L1-5), are reported in Tables A1.1 to A1.5 and 4.12 to 4.19. There was no significant difference in the exposure factors used, kV, $p=0.19$, and mAs $p=0.73$ but the FFD and FSD were significantly higher when PACS was used ($p<0.001$). FILM patients in Group 3 were significantly thicker (t-test $p=0.03$) at the tube centring point. No statistically significant difference was found for either EFFECTIVE (Mann Whitney $p=0.16$) or ENTRY (Mann Whitney $p=0.12$). Statistically significant lower values

for DAP (Mann Whitney $p=0.004$) were found when PACS was used and PATAREA values were larger (T-test $p=0.006$).

Figures 4.1 and 4.2 show that the entry dose data collected at Hammersmith, for single exposures of the lateral lumbar spine of all patients using both conventional film (mean 15.81 mGy, median 11.8mGy) and PACS (mean 13.31 mGy, median 11.4mGy), are almost all lower than the National Reference value of 30 mGy recommended by the NRPB. For patients in the weight range 65-75 kg, when film was used only one patient had an entry dose higher than the National Reference value and all PACS entry doses were lower than this value.

When PACS was used the sensitivity number, S (Table 4.20), which did not exhibit normal distribution, had a mean value of 277, median value of 264 and range 52-711 for views of the whole of the lumbar spine L1-5 (Figure 4.3).

Group 4

Similar results were found using data from Group 4 (patients with weight between 65 and 75kg). These results are shown in Tables 4.21 to 4.28, A1.6 to A1.10 and Figures 4.4 and 4.5.

Group 5

Using data from Group 5 (single exposures of body area L5/S1), the film and PACS data were similar in all important aspects. The only variable found to be significantly different was FFD (T-test and Mann Whitney $p<0.001$) which were larger for the PACS group (Tables 4.29 to 4.36 and A1.11 to A1.15).

4.3.2 Regression Analysis

Group 1 Models

The results for model 1 are shown in Table A1.16. This model used data from Group

1. A model using SUMEFF as the dependent variable had residuals which were not normally distributed. The dependent variable was, thus, transformed by taking the natural log of SUMEFF to create the variable LOGSUMEFF which was approximately normally distributed. A regression model using the independent variables

PACSDUM, SEXDUM, JUNCTDUM, FREQ, BMI, and AGE was produced. The respecified model had a homoskedastic error term (White's test $p=0.62$). The residuals were normally distributed (Shapiro Wilk's test $p=0.97$) and there was no significant multicollinearity between the independent variables. The final model had an adjusted R^2 of 57%. The coefficients on the independent variables PACSDUM ($p=0.0047$), SEXDUM ($p<0.001$) and AGE ($p=0.001$) had a significant negative relationship with the dependent variable so that they contributed to a decrease in the total examination effective dose. The independent variables FREQ ($p<0.001$) and BMI ($p<0.001$) were also significant but were associated with an increase in the examination effective dose in this sample. The coefficient on the independent variable JUNCTDUM was not significantly different from zero and thus does not appear to explain differences in the examination effective doses in this sample.

The results for model 2 are shown in Table A1.17. This model also used data from Group 1 but used the total entry dose for each examination, SUMENTRY, as the dependent variable. This had residuals which were not normally distributed. The dependent variable was, thus, transformed by taking the natural log of SUMENTRY to create the variable LOGSUMENT which was approximately normally distributed. This respecified model ($p<0.001$) had a homoskedastic error term (White's test $p=0.38$). The residuals were normally distributed (Shapiro Wilk's test $p=0.97$) and there was no significant multicollinearity between the independent variables. The final model had an adjusted R^2 of 63% with the independent variables PACSDUM ($p=0.009$), SEXDUM ($p<0.001$) and AGE ($p=0.02$) being significant in reducing the examination entry dose. The independent variables BMI ($p<0.001$) and FREQ($p<0.001$) were significant in contributing to an increase in the total examination entry dose. The coefficient on the independent variable JUNCTDUM was not significantly different from zero and thus does not appear to explain differences in the examination entry doses in this sample.

The results for model 3 are shown in A 4.18. This model also used data from Group 1 but used the total dose area product for each examination, SUMDAP, as the dependent variable. This model had residuals which were not normally distributed.

The dependent variable was, thus, transformed by taking the natural log of SUMDAP to create the variable LOGSUMDAP which was normally distributed. This respecified model had a homoskedastic error term (White's test $p=0.31$), the residuals were normally distributed (Shapiro Wilk's test $p=0.25$), and there was no significant multicollinearity between the independent variables. The final model had an adjusted R^2 of 47% with the independent variables PACSDUM ($p<0.001$) and AGE ($p=0.02$) being significant in producing a decrease in the total DAP readings for the examination. The variables BMI and FREQ were both significant ($p<0.001$) in producing an increase in the total DAP readings for the examination. The coefficient on the independent variable JUNCTDUM was not significantly different from zero and thus does not appear to explain differences in the examination DAP readings in this sample.

Group 2 Models

The results for model 4 which uses data from Group 2 are shown in Table A1.19. A model using SUMEFF as the dependent variable had residuals which were not normally distributed. The dependent variable was, thus, transformed by taking the natural log of SUMEFF to create the variable LOGSUMEFF which was approximately normally distributed. This respecified model had a homoskedastic error term (White's test $p=0.41$). The residuals were normally distributed (Shapiro Wilk's test $p=0.20$) and there was no significant multicollinearity between the independent variables. The final model had an adjusted R^2 of 29% and the coefficient on the independent variables PACSDUM ($p=0.0003$), SEXDUM ($p=0.003$) and AGE ($p=0.04$) were shown to be significant in reducing the dependent variable. The coefficients on the independent variable BMI was shown to be significant ($p<0.001$) in producing an increase in LOGSUMEFF.

The results for model 5 are shown in Table A1.20. This model also used data from Group 2 but used the total entry dose for each examination, SUMENTRY, as the dependent variable. This had residuals which were not normally distributed and the dependent variable was, thus, transformed by taking the natural log of SUMENTRY to create the variable LOGSUMENT which was approximately normally distributed.

This respecified model had a homoskedastic error term (White's test p = 0.26). The residuals were normally distributed (Shapiro Wilk's test p = 0.05) and there was no significant multicollinearity between the independent variables. The final model had an adjusted R^2 of 20% with the independent variables PACSDUM (p = 0.0001), BMI (p = 0.0001)and SEXDUM (p = 0.04) being significant. The model indicates that the variables PACSDUM and SEXDUM had a negative relationship with LOGSUMENT, such that, when PACS was used and the patient was female, there was a decrease in LOGSUMENT and that an increase in BMI resulted in an increase in this dependent variable. The coefficients on the remaining independent variable AGE was not significantly different from zero and thus does not appear to explain variation in LOGSUMENT.

The results for model 6 are shown in Table A1.21. This model also used data from Group 2 but used the total dose area product for each examination, SUMDAP, as the dependent variable. This model had residuals which were not normally distributed and the dependent variable was, thus, transformed by taking the natural log of SUMDAP to create the variable LOGSUMDAP which was approximately normally distributed. This respecified model had a homoskedastic error term (White's test p = 0.48), the residuals were normally distributed (Shapiro Wilk's test p = 0.13), and there was no significant multicollinearity between the independent variables. The final model had an adjusted R^2 of 34% with the independent variables PACSDUM (p = 0.0001), BMI (p = 0.0001) and SEXDUM (p = 0.006) being significant. The model indicates that the variables PACSDUM and SEXDUM had a negative relationship with LOGSUMDAP, such that, when PACS was used and the patient was female there was a decrease in LOGSUMDAP and as BMI increased, there was an increase in LOGSUMDAP. The coefficients on the remaining independent variable AGE was not significantly different from zero and thus does not appear to explain variation in LOGSUMDAP.

Group 3 *Models*

The following models (7-12) are for single exposures of the lateral lumbar spine. If any image was repeated for any reason, the last image only was used so that there

was only one image for each patient in the study.

The results for model 7 are shown in Table A1.22. Effective dose (EFFECTIVE) was taken as the dependent variable but this model had residuals which were not normally distributed. The dependent variable was therefore transformed by taking the natural log to produce the variable LOGEFF. White's test on the error term from the model showed homoskedasticity ($p=0.16$). The residuals were normally distributed (Shapiro Wilk's test $p=0.54$). There was no significant multicollinearity between the independent variables. The model had an adjusted R^2 of 77% with the independent variables THICK, MAS and PATAREA having a positive relationship with LOGEFF. The coefficient on the variable PACSDUM was not significantly different from zero and, thus, does not appear to explain variation in LOGEFF for single images of the lateral lumbar spine.

For Model 8 (Table A1.23), surface entry dose (ENTRY) was taken as the dependent variable. The residuals were not normally distributed and so values of ENTRY were transformed to produce the natural log (LOGENT), and the residuals were approximately normally distributed (Shapiro Wilk's test $p=0.47$). White's test on the error term from the model showed homoskedasticity ($p=0.64$). There was no significant multicollinearity between the independent variables. The model had an adjusted R^2 of 83% with the independent variables THICK and MAS having a significant positive relationship with LOGENT and the variables FFD, AGE and KV having a negative relationship. The coefficient on the variables PACSDUM and PATAREA were not significantly different from zero and, thus, do not appear to explain variation in LOGENT for single images of the lateral lumbar spine.

In Model 9 (Table A 4.24), Dose Area Product (DAP) was taken as the dependent variable and since this was not normally distributed, it was transformed to produce the natural log LOGDAP. White's test on the error term from the model showed homoskedasticity ($p=0.59$). The residuals were normally distributed (Shapiro Wilk's test $p=0.58$). There was no significant multicollinearity between the independent variables. The model had an adjusted R^2 of 80% with the independent variables

THICK, MAS and PATAREA having a significant positive relationship with LOGDAP and the variable PACSDUM having a negative relationship. The coefficient on the variable KV was not significantly different from zero and, thus, does not appear to explain variation in LOGDAP for single images of the lateral lumbar spine.

Group 4 Models

The fourth set of three models (Models 10-12) relate to Group 4 which includes patients whose weight was in the range 65-75 kg as used in the National Protocol.

The results for model 10 are presented in Table A1.25. The dependent variable EFFECTIVE was not normally distributed so the variable was transformed to produce the natural log LOGEFF. White's test showed a homoskedastic error term ($p=0.34$). The residuals were normally distributed (Shapiro Wilk's test $p=0.26$). There was no significant multicollinearity between the independent variables. The model had an adjusted R^2 of 78% with the independent variables THICK, KV and MAS being significant and having a positive relationship with LOGEFF, and the variables AGE and FFD having a significant negative relationship. The coefficient on the variables PACSDUM, SEXDUM, BMI, and PATAREA were not shown to be different from zero and, thus, do not appear to explain variation in LOGEFF.

The results for model 11 are presented in Table A1.26. The dependent variable ENTRY was not normally distributed so the variable was transformed to produce the natural log LOGENT. White's test showed a homoskedastic error term ($p=0.37$). The residuals were normally distributed (Shapiro Wilk's test $p=0.25$). There was no significant multicollinearity between the independent variables. The model had an adjusted R^2 of 80% with the independent variables THICK, and MAS being significant and having a positive relationship with LOGEFF, and the variables AGE and FFD having a significant negative relationship. The coefficient on the variables PACSDUM, SEXDUM, KV, BMI, and PATAREA were not shown to be different from zero and, thus, do not appear to explain variation in LOGEFF.

The results for model 12 are presented in Table A1.27. The dependent variable

DAP was not normally distributed so the variable was transformed to produce the natural log LOGDAP. White's test showed a homoskedastic error term ($p=0.44$). The residuals were normally distributed (Shapiro Wilk's test $p=0.17$). There was no significant multicollinearity between the independent variables. The model had an adjusted R^2 of 63% with the variable MAS having a significant positive relationship with LOGDAP and the variable for PACS having a negative relationship with LOGDAP. The coefficients on the remaining variables were not shown to be significantly different from zero and do not appear to explain variation in LOGDAP.

4.4 DISCUSSION

The methods used to measure radiation doses are similar to those recommended in the National Protocol for Patient Dose Measurement in Diagnostic Radiology but with some additional features and measurements. Dose measurements were made using both TLDs and air ionisation chamber because there was uncertainty with respect to the changes that PACS might instigate. The aim was to measure individual doses for single images of the lateral lumbar spine and to combine the doses for single images to obtain the doses for the whole examination of the lateral lumbar spine. The method recommended in the National Protocol for the former is measurement by TLD, and for the latter, measurement by DAP. All TLDs were obtained from, calibrated by, and read by the NRPB, so a high degree of accuracy in the measurements can be expected. This argument is strengthened by the consistency of approach adopted in the study in that only one independent research radiographer undertook all measurements in both the film and the PACS periods of study.

While the National Protocol suggests data on ten patients whose weights lie in the range 65kg to 75 kg and with a mean of 70 kg, this study aimed at a much larger sample which would reflect the true range of sizes of patients with lumbar spine examinations being examined in the department. In this study the height and thickness of the patient at the centring point were measured in addition to weight to provide further information in the comparison of patient groups in the two parts of the study. A consideration of weight only could be misleading since there could

be a very large variation in the size of the patients at the area of interest even though they all had the same weight.

The effective doses were calculated using the entry doses rather than DAP because DAP readings were unavailable for 20 patients. The software package used to calculate effective doses, XDOSE, assumes that the area irradiated is constant for all exposures and thus that the organs and tissues irradiated are constant. For Group 3 a statistically significant increase in the area of the irradiated field was found ($p = 0.006$) when PACS was used, thus the calculated effective doses should be treated with caution.

PACS images are initially produced by a CR technique but have the additional advantages of soft copy manipulation. With both CR and PACS images there is a much wider exposure latitude than with conventional film and so the appearance of the image gives no indication to the radiographer if too high exposure factors have been used because the density of the image is almost always satisfactory. If the image has been underexposed, the image may have a mottled or a grainy appearance indicative of too little radiation reaching the plate. Thus, the radiographer is aware that the exposure factors selected were not optimum and can use this knowledge when selecting exposure factors for subsequent images. The sensitivity number or S number, which at the time of data collection, did not appear on each soft-copy image by default, is the only indication that the imaging plate, and hence, the patient, has received a dose which is higher than required. For the Fuji system an approximate optimum value for the S number is 200; a lower value indicates that the dose is higher than the optimum. In this study S numbers between 52 and 711 were obtained for PACS images of the whole of the lumbar spine (L1-5), with a median of 264 indicating that the doses for most patients were low as already shown by the TLD measurements of surface entry dose.

There was no significant difference in the number of images required, both including and excluding repeats, when film and PACS were used. This was not surprising since at the Hammersmith Hospital at the time of the film study, the radiographers

rarely routinely used two views to image the lateral lumbar spine although after viewing the L1-5 image it was sometimes seen that an additional view was required to demonstrate L5/S1. This was in line with the advice given in the publication Patient Dose Reduction in Radiology (1990). Between the two data collection periods of the study, the Royal College of Radiologists (Royal College of Radiologists and the National Radiological Protection Board, 1990) endorsed guidelines produced by a working party in Wales, which recommended that the number of projections for the examination of the lateral lumbar spine should routinely be one, and the Hammersmith radiographers continued using this practice during the PACS study.

The reduction in the values of SUMENTRY, SUMDAP and SUMEFF for both the total examination including repeats and the examination submitted for reporting during the PACS period of the study could be due to the demonstrated reduction in the size of the beam of radiation for single views of the lumbar spine (L1-5), and the increase in FFD for both L1-5 and L5/S1 when PACS was used. There were no other significant differences in the patients or exposure factors used during the two phases of the study which explain this finding.

Models 1 to 6 show that PACSDUM is significant in reducing LOGSUMEFF, LOGSUMENT and LOGSUMDAP for both the total examination and images submitted for reporting. These regression models could include only those variables which remained constant for each patient during an examination and could not include any exposure factors, thus the models, although significant, explain only about half of the factors which affect the dependent dose variables.

The result that there was no significant reduction in patient entry doses for L1-5 when PACS was used compared with when film was used, must be put in the context of other changes that took place between the end of the film data collection period (February 1994) and the start of the PACS data collection period (May 1995). In 1994 Wall (Matthews et al, 1994) reported that there has been a trend towards lower doses to patients for simple radiographic x-ray examinations, including lumbar spine examinations, since the 1986 National Survey of Patient Doses (Wall, 1994)

with mean reductions of about 30%. He reported that for patients with weights around 70 kilograms the mean surface entrance dose for the lateral lumbar spine had decreased from 23 mGy to 18 mGy, and the third quartile had decreased from 30mGy (the Reference Dose) to 21 mGy. It must be emphasized that at the Hammersmith Hospital when film was used, 94% of all measurements of surface entry dose for L1-5 were already less than 21 mGy, and when PACS was used 100% were less than 21 mGy. For the Hammersmith patients within the weight range 65kg-75kg all but two film patients' doses and all PACS patients' doses were below 21 mGy.

The effective doses should be regarded as the most important dose measurement because they reflect the detriment to the patient. Recently, in 1997, Wall (Wall & Hart, 1997) reported that typical (rounded values of the mean) effective doses for single views of the lateral lumbar spine and the lumbo-sacral joint were both 0.3mSv, (ranges 0.1-0.6, and 0.1-0.7mSv). The mean effective doses, calculated using surface entry dose, for single images of these areas at Hammersmith for both film and PACS have been shown to be below this typical value. As might be expected since the baseline film effective doses were low, no significant difference in effective doses has been demonstrated when PACS was used compared with when film was used.

It must be emphasised that while no reduction in doses for single exposures of the lateral lumber spine due to PACS has been found and that regression models have confirmed this, and that while doses with film were already low compared with the National Reference value, there has been *no increase* in patient radiation doses for the imaging of the lateral lumbar spine at the Hammersmith Hospital since the implementation of PACS. This is a very important finding of this study. Some very optimistic claims of large dose reductions with the use of PACS at other hospitals have been based upon little reported evidence (Hruby et al, 1994) and earlier comparisons were made with systems with sensitivities as low as 100 and 150 (Pettersson 1988). In this study of doses at the Hammersmith, doses with the PACS system have been compared with those found using a conventional

film/screen system with a sensitivity of 300.

When this study was designed a medical physicist indicated that she thought it would be important to demonstrate dose differences of 10% or more when PACS was used (Dixon-Brown, personal communication). There were no publications with which to refer from which an estimate of the size of the patient sample required to demonstrate such a difference could be made. A retrospective sample size calculation has been undertaken which indicates that for a sample of 200 patients, the study has an 80% power at 5% significance to detect a dose difference of 4.5mGy which is about 40% of the median dose [Altman, 1999]. In order to detect a 10% difference in surface entry dose a sample size of 1400 patients would be required. As indicated previously, it was not possible to extend the study to include a larger number of patients. If the study were reproduced with a much larger number of patients, it might be possible to demonstrate a statistically significant difference in patient doses.

4.5 CONCLUSION

The aim of this study was to test the hypothesis that the use of PACS, which utilizes CR phosphor plates and manipulation of the soft copy image, reduces the total dose to the patient. There were three subhypotheses. Firstly, that the dose for individual images of the lateral lumbar spine may be reduced. Secondly, because the PACS system has a much wider latitude than film, the number of images required to image the body area may be reduced, thus reducing the patient dose for the successful examination of the lateral lumbar spine. Thirdly, again due to the wider latitude of PACS, the number of repeat exposures due to unsatisfactory exposure factors would be reduced and thus the total dose for the examination including rejects may be reduced.

The results of this study of doses for the examination of the lateral lumbar spine have shown no significant PACS-induced reduction in patient surface entrance doses or effective doses calculated from the entry doses for *individual images*. However, there was a significant reduction in dose area product readings following

the use of PACS. Thus, the first subhypothesis was rejected for surface entry and effective doses but accepted for dose area product readings.

The second subhypothesis was accepted because significant reductions in total surface entry dose, dose area product readings and effective dose were found for the *examination submitted for reporting.*

The third subhypothesis was also partially accepted since there were significant reductions in the examination surface entry dose, dose area product readings, and effective dose for the *complete examination including rejected images* but not in the total number of images used.

The work discussed in this chapter found that for images of the lateral lumbar there was no PACS-induced change in patient surface entry doses when the hospital changed from using a conventional film/screen system with a 300 speed to a PACS which used phosphor plate image acquisition. The next chapter describes a comparative study of chest doses in which PACS doses were compared with a faster (400) speed film/screen system. Unlike the lateral lumbar spine, the chest is not a high dose examination, but it is the examination which is undertaken most frequently in all general hospitals.

Table 4.1 X-ray equipment used

X-RAY GENERATOR	Make: Siemens
	Type: 3 phase, 6 pulse equivalent
	Waveform: 6 pulse equivalent
X-RAY TUBE	Make: Siemens
	Type: Biangulex rotating anode
	Target Angles: 10° and 16°
	Focal Spot Sizes: 0.6mm, 1.2mm
	Total Filtration: 3mm AL
ANTISCATTER GRID	Grid Ratio: 12:1
	Strips/cm: 40/cm, fgd = 115cms
	Moving
	No carbon fibre cover
TABLE TOP	Material: Composite
TABLE TOP TO FILM	Distance: 8cm
FILM	Kodak : TMAT L
INTENSIFYING SCREENS	Kodak Lanex Med
FILM/SCREEN SPEED CLASS	300
CASSETTES	Non carbon fibre fronts

Table 4.2 Data collected for measurement of radiation doses

Variable	Description	Method
Patient characteristics		
SEX	male/female	observation
AGE	in years	from patient's notes
WEIGHT	in kilograms	measured on digital scales in the X-Ray room
HEIGHT	in centimetres	measured against a tape measure fixed next to the door frame in the X-Ray room
THICK	thickness of the patient at the centring point(in cms), from skin surface to table top.	measured with callipers while the patient was positioned for the examination.
Exposure characteristics		
KV	kilovoltage of x-ray tube	read from control panel
MAS	x-ray tube current	read from control panel
FFD	focus to film distance in cms	taken from tube column scale
FSD	focus to skin distance in cms	ffd minus table top to film distance
FILMSIZE	size of cassette/plate used	noted from manufacturers label on cassette/plate
PATAREA	area of image irradiated	size of area irradiated measured on processed film/hard copy image. If the PACS image indicated that magnification was present, the value was adjusted.
ENTRY	surface entry dose in mGy	measured by individual TLDs attached to the patient's skin at the centring point.
DAP	dose area product in $cGycm^2$	measured by air ionisation chamber fitted to the tube head.
EFFECTIVE	the sum of the weighted equivalent doses in mSv	calculated using NRPB software package SR262 and XDOSE, using entry dose and tube kV
BODYAREA	area of the patient for which the image was taken to demonstrate.	identified when the image was taken

Table 4.3 Variables used in OLS models
Independent variables

Variable	Description	Derivation
AGE	Patient's age on day of examination (years)	
PACSDUM	When PACSDUM = 1, PACS was being used. When PACSDUM = 0, film was being used.	
SEXDUM	When sexdum = 1, patient is female. When sexdum = 0, patient is male.	
JUNCTDUM	When junctdum = 1, L5/S1 image taken When junctdum = 0, L5/S1 image not taken	
BMI	Body Mass Index	BMI = Weight(kg)/Height^2 (m^2)
THICK	Thickness of the patient at the centring point	Measured by calipers in cm.
KV	Tube kilovoltage	
MAS	Tube milliamperage	
FFD	Focus to film distance	Measured in cm.
PATAREA	The area of the radiation beam on the image	The field size was measured in cm with a ruler directly from the processed film or hard copy CR image, and the area calculated (cm^2) adjusting for magnification factor of CR images.

Dependent variables

Variable	Description	Derivation	Models in which variable is used.
LOGSUMEFF	Natural log of the sum of the effective doses for each patient per examination	Sum of effective doses for individual images calculated using NRPB software SR262 and XDOSE.	1-6
LOGSUMENT	Natural log of the total entry doses for each patient per examination.	Sum of entry doses for individual images measured by TLD	1-6
LOGSUMREAD	Natural log of the total dose area product readings for each patient per examination.	Sum of DAP readings for individual images measured by air ionisation chamber.	1-6
LOGEFF	Natural log of the effective doses for the image.	Calculated using NRPB software SR262 and XDOSE	7-12
LOGENT	Natural log of the entry dose for each image	Measured by TLD	7-12
LOGDAP	Natural log of the dose area product reading for each image	Measured by air ionisation chamber	7-12

TOTAL DOSES RECEIVED BY GROUP 1 PATIENTS FOR ALL IMAGES TAKEN ie INCLUDES REJECTS.

Table 4.4 SUMENTRY (mGy)

	FILM (N = 100)	PACS (N = 96)
mean	26.45	17.99
SD	24.71	14.99
Median	17	12.25
Range	125.72 (0.78-126.5)	92.78 (2.52-95.3)
Q3-Q1	22.4	12.93

Mann-Whitney test $p = 0.02$

Table 4.5 SUMDAP ($cGycm^2$)

	FILM (N = 96*)	PACS (N = 76*)
mean	508.063	341.076
SD	349.582	243.086
Median	396	254.5
Range	1631 (94-1725)	1430.24 (23.76-1454)
Q3-Q1	459	227.5

Mann -Whitney test $p < 0.001$

* some data unavailable due to diamentor not installed/working

Table 4.6 SUMEFF (mSv)

	FILM (N = 100)	PACS (N = 96)
mean	0.433	0.341
SD	0.321	0.237
Median	0.306	0.264
Range	1.53 (0.019-1.55)	1.40 (0.0581.461)
Q3-Q1	0.337	0.247

Mann -Whitney test $p = 0.05$

Table 4.7 Number of images for the whole examination including repeats

	FILM (N = 100)	PACS (N = 96)
1	70	76
2 or 3*	30	20

* 4 patients had three images
Chi square p = 0.084

Table 4.8 Reasons for repeat images

Reason for repeat exposure	FILM	PACS
Patient position incorrect	6	3
Incorrect exposure	2	1
Pathology	0	2
Double exposure	0	1
Total repeat images	8	7

Chisq p = 0.178

TOTAL DOSES RECEIVED BY GROUP 2 PATIENTS FOR IMAGES SUBMITTED FOR REPORTING.

Table 4.9 SUMENTRY (mGy)

	FILM (N = 100))	PACS (N = 96)
mean	24.343	17.041
SD	21.698	14.712
Median	16.2	11.95
Range	125.72 (0.78-126.5)	92.78 (2.52-95.3)
Q3-Q1	22.03	10.625

Mann - Whitney test p = 0.01

Table 4.10 SUMDAP (cGycm^2)

	FILM (N = 96*)	PACS (N = 76*)
mean	475.969	319.628
SD	324.259	231.127
Median	385	252.5
Range	1631 (94-1725)	1430.24 (23.76-1454)
Q3-Q1	343.5	175

Mann - Whitney test p < 0.001
* some data unavailable due to diamentor not installed/working

Table 4.11 SUMEFF (mSv)

	FILM (N = 100)	PACS (N = 96)
mean	0.404	0.3212
SD	0.291	0.225
Median	0.3	0.259
Range	1.531 (0.019-1.55)	1.4031 (0.0579-1.461)
Q3-Q1	0.297	0.221

Mann - Whitney test p = 0.03

RESULTS FOR DATA RELATING TO GROUP 3 - SINGLE VIEWS OF THE WHOLE OF THE LUMBAR SPINE, L1-5.

Table 4.12 PATAREA (cm^2)

	FILM (N = 100)	PACS (N = 93*)
mean	746.96	799.46
SD	120.03	127.80
Median	774	796
Range	700 (400-1100)	742.5 (517-1260)
Q3-Q1	109.5	157.5

T-Test p = 0.006

*three patients were GP patients with no hard copy images for measurement of area

Table 4.13 KV

	FILM (N = 100)	PACS.(N = 96)
mean	92.38	94.18
SD	6.64	7.86
Median	96	96
Range	43 (66-109)	40 (77-117)
Q3-Q1	8.5	6

Mann - Whitney test p = 0.19

T-Test p = 0.098

Table 4.14 mAs

	FILM (N = 96*)	PACS(N = 96)
mean	68.75	65.47
SD	46.65	37.00
Median	50	57.9
Range	258 (8-266)	159.2 (18.8-178)
Q3-Q1	40.05	45.3

Mann - Whitney test p = 0.73

* The mAs meter did not retain its reading long enough to be read

Table 4.15 FFD (cms)

	FILM (N = 100)	PACS (N = 92*)
mean	105.42	116.86
SD	6.18	5.94
Median	105	115
Range	23 (92-115)	30 (102-132)
Q3-Q1	10	7.5

T-Test p = 0.0001

* for four patients the tube height was altered before the ffd could be noted

Table 4.16 EFFECTIVE (mSv)

	FILM (N = 100)	PACS (N = 96)
mean	0.322	0.28
SD	0.226	0.169
Median	0.251	0.244
Range	1.331 (0.019-1.35)	0.866 (0.028-0.894)
Q3-Q1	0.1935	0.157

Mann - Whitney test p = 0.16

Table 4.17 ENTRY (mGy)

	FILM (N = 100)	PACS (N = 96)
mean*	15.81	13.31
SD	11.20	7.67
median	11.8	11.4
range	67.02 (0.78-67.8)	36.5 (1.5-38)
Q3-Q1	9.88	8.92

Mann - Whitney test p = 0.122

*Reference Dose for lateral lumbar spine = 30mGy when weight is 65-75 kg.

Table 4.18 DAP ($cGycm^2$)

	FILM (N = 95*)	PACS (N = 76*)
mean	385.84	293.02
SD	271.15	180.06
Median	311	249
Range	1631 (94-1725)	877.24 (901-23.76)
Q3-Q1	244	171.5

Mann - Whitney test p = 0.004

* the diamentor was out of order for several weeks

Table 4.19 FSD (cms)

	FILM (N = 100)	PACS (N = 92*)
mean	69.405	81.61
SD	6.64	6.09
Median	69	80.25
Range	35 (52-87)	34 (66-100)
Q3-Q1	9.5	8

Mann - Whitney test p < 0.001

* the tube height was altered before ffd could be noted

Table 4.20 Sensitivity numbers for PACS images (S)

N	96
Mean	277.25
SD	102.80
Median	264
Range	659 (52-711)
Q3-Q1	98

RESULTS FOR DATA RELATING TO GROUP 4 FOR L1-5 EXAMINATIONS. (PATIENTS WITH WEIGHT 65-75 KILOGRAMS).

Table 4.21 Variable PATAREA - coned area on film (cm^2)

	FILM (N = 34)	PACS (N = 25*)
mean	771.42	750.80
SD	108.39	99.90
Median	774	756
Range	532.2 (567.8-1100)	427.5 (517-945)
Q3-Q1	152	94.5

T-Test p = 0.69

*1 patient's films were sent to clinic before measurements could be made.

Table 4.22 Variable kV - tube kilovoltage

	FILM (N = 34)	PACS (N = 26)
mean	94.03	93.77
SD	4.71	4.67
Median	96	96
Range	21 (81-102)	17 (85-102)
Q3-Q1	6	6

Mann - Whitney test p = 0.68

T-Test p = 0.6828

Table 4.23 Variable mAs

	FILM (N = 33*)	PACS (N = 26)
mean	52.55	55.43
SD	22.08	26.75
Median	44.7	51.55
Range	92.4 (26.6-119)	103 (16-119)
Q3-Q1	22	37.3

Mann-Whitney test p = 0.77

* The mAs meter did not retain its reading long enough to be read

Table 4.24 Variable FFD - focus to film distance (cms)

	FILM (N = 34)	PACS (N = 26)
mean	104.44	117.54
SD	5.96	6.38
Median	105	115
Range	23 (92-115)	30 (102-132)
Q3-Q1	10	7

Mann- Whitney test p < 0.001

T-Test p < 0.001

Table 4.25 Variable FSD - Focus to skin distance (cms)

	FILM (N = 34)	PACS (N = 26)
mean	68.63	82.98
SD	6.24	6.56
Median	69.25	81.5
Range	28 (52-80)	33 (67-100)
Q3-Q1	7.5	8

Mann-Whitney test p < 0.001

T-Test p < 0.001

Table 4.26 Variable EFFECTIVE dose (mSv)

	FILM (N = 34)	PACS (N = 26)
mean	0.27	0.24
SD	0.12	0.08
Median	0.24	0.22
Range	0.62 (0.116-0.732)	0.36 (0.06-0.42)
Q3-Q1	0.10	0.10

T-test p = 0.10

Table 4.27 Variable ENTRY- surface entry dose including scatter (mGy)

	FILM (N = 34)	PACS (N = 26)
mean*	13.13	11.39
SD	5.96	4.47
median	11.25	10.8
range	31.23 (5.37-36.6)	17.38 (3.12-20.5)
Q3-Q1	5.84	5.86

Mann - Whitney test p = 0.36

*NRPB Reference Dose for lateral lumbar spine L1-5 = 30mGy when weight is 65-75 kg.

Table 4.28 Variable DAP - Dose area product ($cGycm^2$)

	FILM (N = 33*)	PACS (N = 21*)
mean	325.76	248.67
SD	137.52	78.58
Median	290	253
Range	671 (130-801)	299 (103-402)
Q3-Q1	139	97

T-test p = 0.01

* the diamentor was out of order for several weeks

RESULTS FOR DATA RELATING TO GROUP 5 - SINGLE VIEWS OF THE LUMBO-SACRAL JOINT (L5/S1) N = 38

Table 4.29 Variable PATAREA - coned area on film (cm^2)

	FILM (N = 25*)	PACS (N = 12)
mean	384.6	388
SD	108.98	126.38
Median	378	369.5
Range	499 (221-720)	320 (240-560)
Q3-Q1	110.25	247.25

T-Test p = 0.52

*1 patient's films were sent to clinic before measurements could be made.

Table 4.30 Variable kV - tube kilovoltage

	FILM (N = 25*)	PACS.(N = 12)
mean	102.76	103.25
SD	7.96	8.87
Median	102	102
Range	29 (96-125)	27 (90-117)
Q3-Q1	6	13

Mann - Whitney test p = 0.90

Table 4.31 Variable mAs

	FILM (N = 24*)	PACS (N = 12)
mean	90.13	126.94
SD	52.66	48.52
Median	82.05	120.5
Range	220.2(16.8-237)	144.2 (66.8-211)
Q3-Q1	76.55	84.45

T-test p = 0.81
* The mAs meter did not retain its reading long enough to be read

Table 4.32 Variable FFD - focus to film distance (cms)

	FILM (N = 25*)	PACS (N = 11*)
mean	104.32	116.36
SD	6.85	3.35
Median	100	115
Range	25 (90-115)	10 (112-122)
Q3-Q1	10	5

Mann- Whitney test p < 0.001
T-Test p < 0.001

Table 4.33 Variable FSD - Focus to skin distance (cms)

	FILM (N = 23*)	PACS (N = 11*)
mean	64.43	76.04
SD	6.87	3.81
Median	61.5	75.5
Range	27 (50-77)	11 (71-82)
Q3-Q1	9	7

T-test p = 0.06
* the tube height was altered before ffd could be noted

Table 4.34 Variable EFFECTIVE dose (mSv)

	FILM (N = 22*)	PACS (N = 12)
mean	0.37	0.33
SD	0.20	0.16
Median	0.32	0.32
Range	0.88 (0.117-1.0)	0.63 (0.08-0.71)
Q3-Q1	0.32	0.19

Mann - Whitney test p = 0.46
*there was one missing value for each of ENTRY and KV and two values of KV > 125 which could not be used to calculate EFFECTIVE dose.

Table 4.35 Variable ENTRY- surface entry dose including scatter (mGy)

	FILM (N = 25*)	PACS (N = 12)
mean**	33.93	29.75
SD	21.43	15.33
median	27.6	28.6
range	92 (7-99)	58.37 (6.43-64.8)
Q3-Q1	30.1	16.35

Mann - Whitney test p = 0.28

* one film was taken before a TLD could be positioned

**Reference Dose for lateral lumbo-sacral junction = 40mGy when weight is 65-75 kg.

Table 4.36 Variable DAP - Dose area product ($cGycm^2$)

	FILM (N = 24*)	PACS (N = 6*)
mean	351.83	367.33
SD	185.82	182.75
Median	294.5	347.5
Range	629 (87-716)	486 (113-599)
Q3-Q1	298.5	299

T-test p = 1.00

* the diamentor was out of order for several weeks

GROUP 3 DOSE PER TECHNICALLY SATISFACTORY IMAGE

Figure 4.1: Film entry doses (mGy) for L1-5 (all patients)

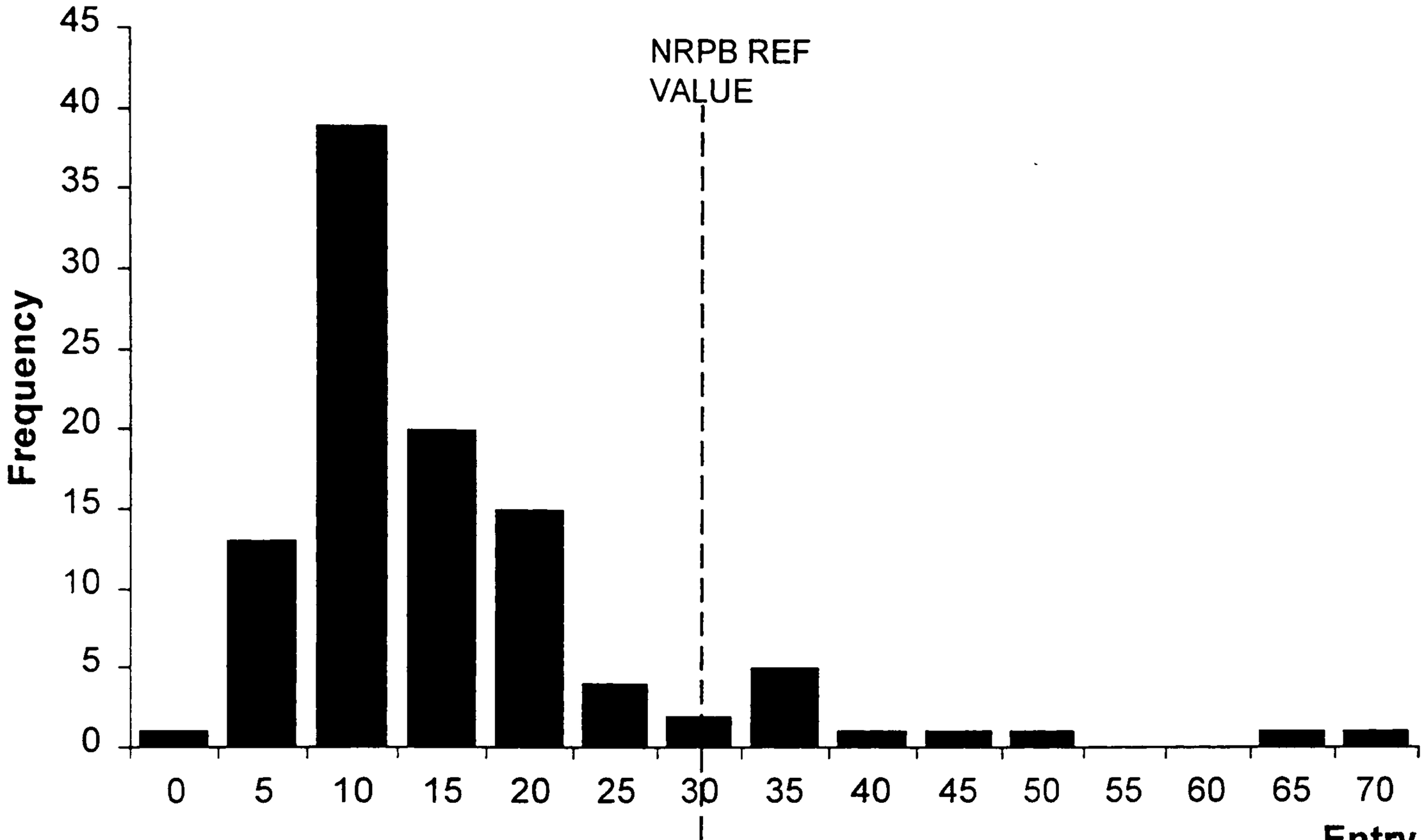
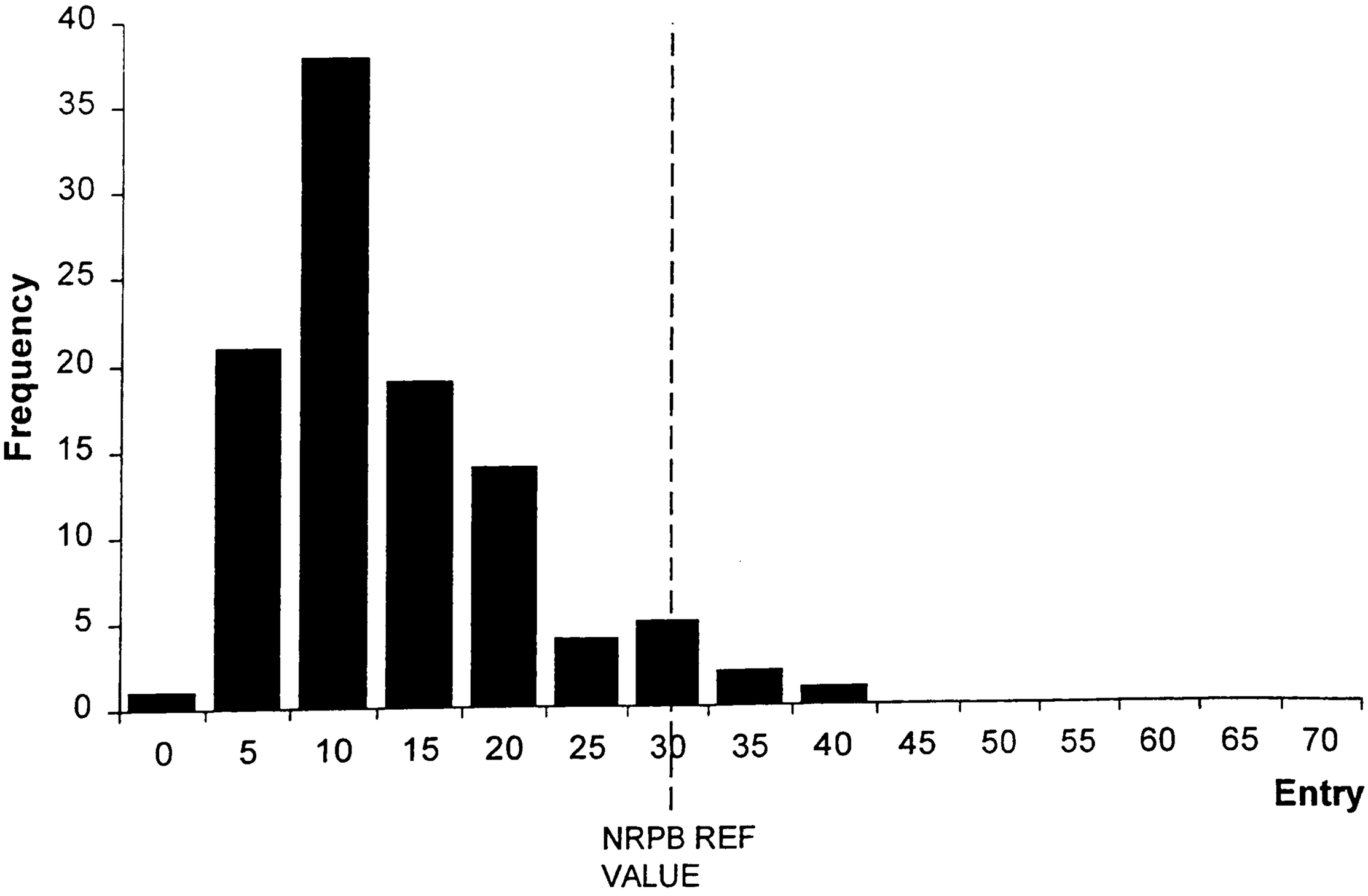


Figure 4.2: PACS entry doses (mGy) for L1-5 (all patients)



GROUP 4 **DOSE PER SINGLE EXPOSURE OF THE WHOLE LUMBAR SPINE (L1-5) FOR PATIENTS BETWEEN THE WEIGHTS OF 65 AND 75 KILOGRAMS**

Figure 4.3: Film entry doses (mGy) for L1-5
(patients within 65-75 kg weight range)

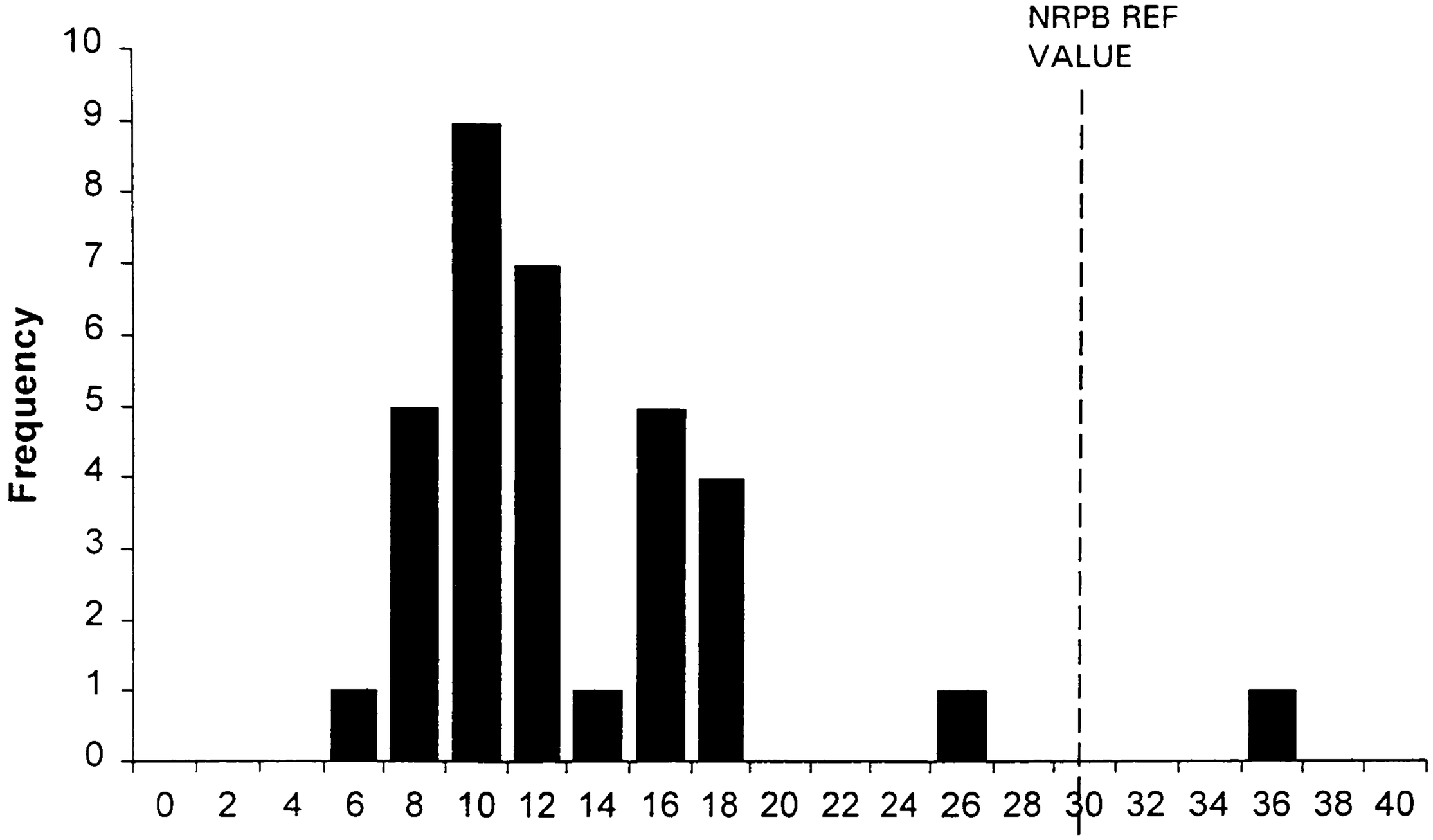


Figure 4.4: PACS entry doses (mGy) for L1-5
(patients within 65-75 kg weight range)

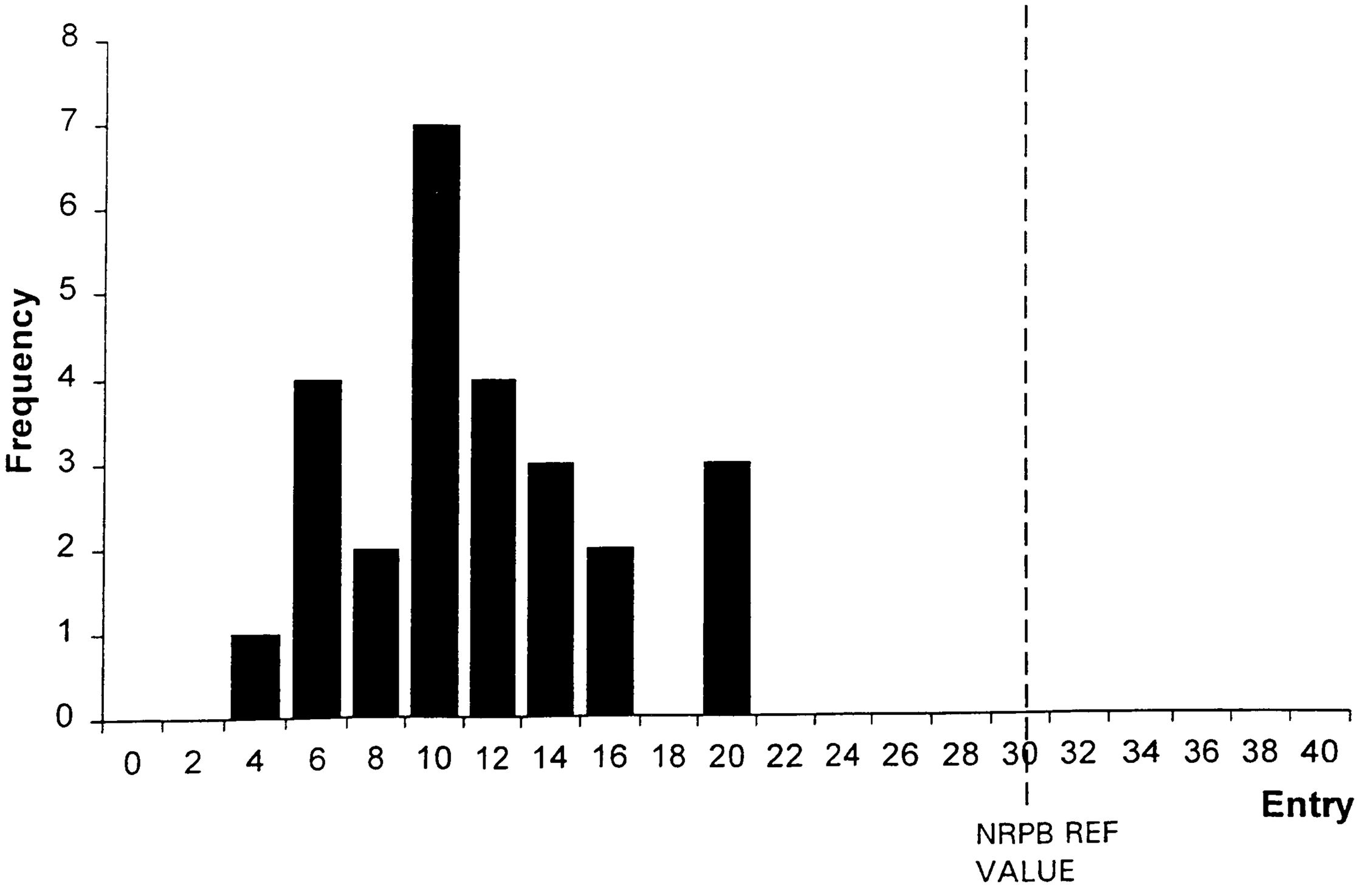
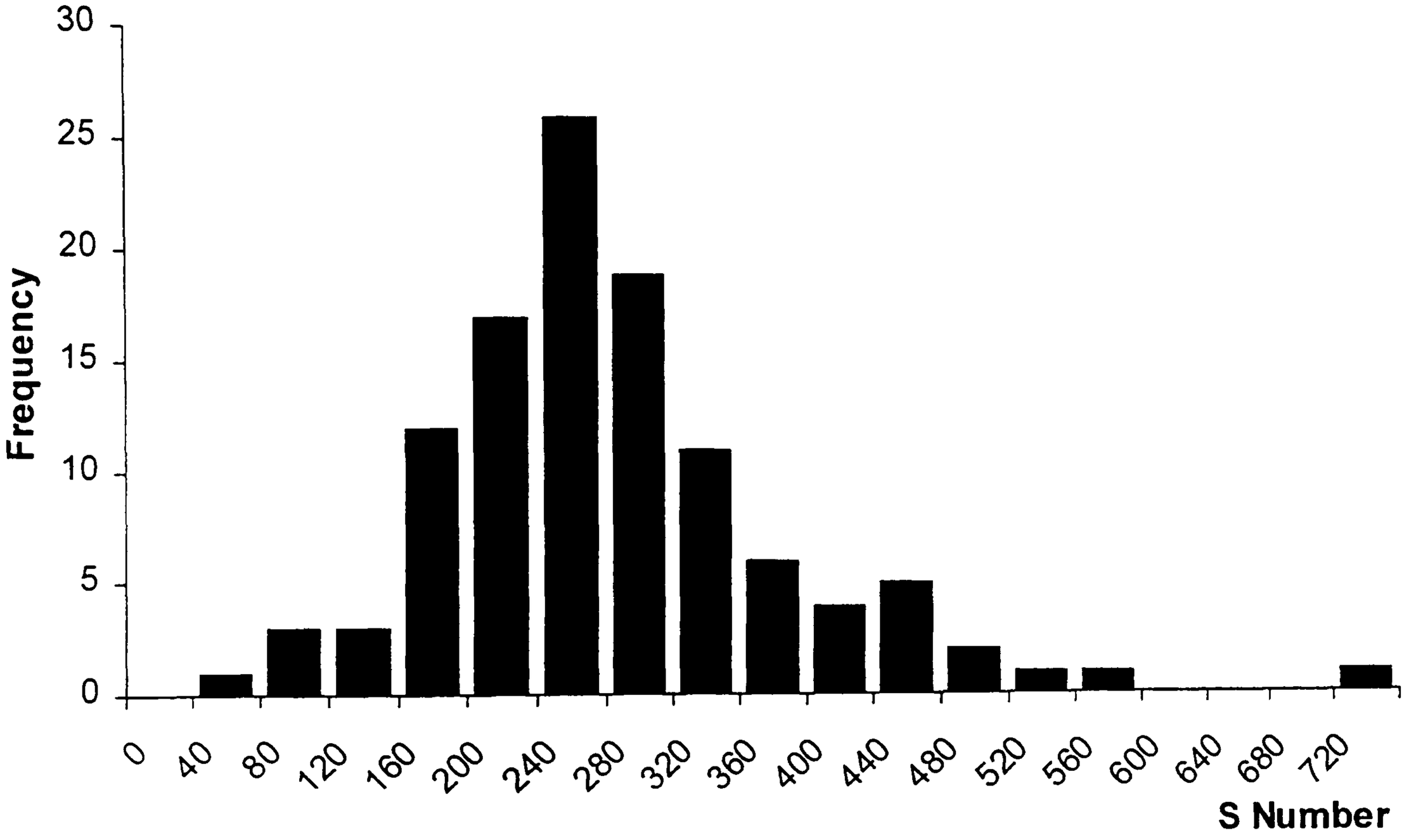


Figure 4.5: Sensitivity number (S) for lateral lumbar spine (L1-5)



CHAPTER 5

THE EFFECT OF PACS ON PATIENT RADIATION DOSES: MOBILE CHEST EXAMINATIONS

5.1 INTRODUCTION

In chapter 4 it was found that for each image, the radiation doses to patients being examined to demonstrate the lateral lumbar spine did not change when the hospital moved from using a 300 speed film/screen system to a hospital-wide PACS. The 1995 survey of patient doses in the UK showed that more than 75% of hospitals use film/screen combinations which have speeds higher than 300 [Hart et al, 1996]. The study reported in this chapter was undertaken at a different hospital (Glan Clwyd Hospital) and compared patient doses when a 400 speed film/screen system were compared with PACS doses. The body area under investigation was the chest which is the single area most frequently examined in all general hospitals and accounts for 24% of all plain images [IPSM, 1992]. All the chest images were taken as portable examinations, the use for which phosphor plate imaging is most frequently advocated [Busch et al 1992, MacMahon and Giger, 1996]. The criteria which were used for the quality of the images were that the images were acceptable to the radiologists and clinicians who were using the images for the care of the patients.

5.2 Method

The research design chosen was a randomised controlled trial (RCT) which included all patients (almost all adults) who were admitted to the Intensive Therapy Unit (ITU), at Glan Clwyd Hospital. An RCT was possible because the PACS was solely used for mobile examinations in ITU. Mobile examinations on all other wards were made using a conventional film/screen system (Kodak TMat LRA films with Lanex Regular screens with speed class 400). If the KESPR unit was out of service, the convention system was routinely used. Thus both imaging methods were currently in routine operation in the hospital and it was possible to undertake a contemporaneous comparison of doses of patients. The approval of the Ethics Committee was obtained for the trial. Informed consent was not required because the patients were having only radiological examinations which had been requested on clinical grounds, and no additional exposures for the study. In addition, the two radiographic systems were already being used for examination of patients in the ITU. When each patient was admitted to the Unit, the patient was randomly allocated to have all x-ray images taken using either the KESPR system or the conventional film/screen system being used in the Hospital[1]. If the patient was readmitted to the

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[1]The order of the randomisation was determined by tossing a coin 600 times. Repeated strings of randomised numbers were not used so that it was not possible to predict the arm of the trial for any patient. The randomisation process was carried out by an ITU nurse who opened a numbered sealed opaque envelope. The envelope had a tamper proof seal and was taken from the top of a numbered stack in a box kept at the reception desk in ITU. It contained two coloured adhesive labels indicating the arm of the trial to which the patient was allocated, a white adhesive label and instructions on how to use all labels. The coloured labels were either orange and labelled 'CR' for KESPR imaging or blue and labelled 'FILM' for film imaging. One coloured label was attached to a sheet of paper on the wall in the reception area next to the white label on which the nurses wrote the patient's name and hospital number. By this method the nurses, radiographers and clinical staff could obtain information about the arm of the trial to which each patient was allocated. The list was continually updated during the trial by the research radiographer on site so that it included only the patients on ITU. The second coloured sticker was attached to the patient's 'nursing process' record which was always kept at the foot of the patient's bed. By these methods, when a member of the ITU staff made a telephone request for an x-ray examination, the staff in Radiology were told to which arm of the trial the patient belonged, and the radiographers were able to go to ITU with the correct type of imaging device, that is either a conventional film/screen cassette or a KESPR phosphor plate. It was not possible to place any indication on or near the patients' beds about which arm of the trial the patients were in, because the ITU staff felt that any such indication might be misinterpreted by patients' visitors and cause distress. Thus the radiographers had to check on the list in the reception area for the trial arm before x-raying each patient to ensure that the correct modality was used.

Unit during the trial, the patient remained in the same arm of the trial as allocated on the first admission.

During the period February 1995 to February 1996 for *each* examination of *each* patient data were collected about the exposure conditions used and all data were recorded by the radiographers on a separate green data form for each examination. If it was necessary to repeat an examination because the image was unsatisfactory, data were also collected for the repeat exposure. Details of the data collected are given in Table 5.1.

Each radiographer was allocated a personal identifying number and the radiographers were asked to enter this number on each form recording details of each examination carried out. The number identifying each radiographer was not known to any member of the research team so that the anonymity of all radiographers was maintained.

The aim of this study was that on each occasion when a radiographer went to ITU to undertake chest x-ray examinations, the radiation dose to the patient should be measured. In order to do this a thermoluminescent dosimeter (TLD) was attached to the front of the patient's chest at the centring point. A separate, numbered TLD was used for each exposure. The TLDs were obtained from, calibrated by and read by the NRPB in the same way as those for measurement of lateral lumbar spine doses in the previous chapter. [Shrimpton et al, 1994]. The TLDs were obtained in batches of 70 or 100 and stored away from sources of radiation in a labelled box in the room in which the KESPR processor and Quality Control Workstation were housed. Used (exposed) TLDs were placed in a separate labelled box in the same room. This box also contained the transit control TLDs

Details of the exposure factors used and the conditions under which each examination was conducted were recorded. Routinely the radiographers used the mobile x-ray unit, a Picker Explorer PX301V, 3 phase 12 pulse generator battery unit with a single focus focal spot size 0.75mm, which was parked in ITU but if this

was out of operation, another mobile (VMX) was brought to the Unit.

The position of the patient was determined by the patient's condition. All patients in ITU are very sick and are invariably examined in bed in the anterior-posterior position. Where possible the patients are examined erect but if the patient is too unwell to adopt this position, the semi-erect or supine position is used. When the patient is supine, the distances between the x-ray tube head and both the patient and the imaging plate are restricted by the maximum height to which the tube head can be moved vertically. When the patient is erect or semi-erect, longer distances can be achieved. Ideally, long distances are used in order to produce less magnification of the image and give an accurate heart size [Bryan G, 1995].

The effective doses were calculated using the NRPB software package SR262 [Hart et al, 1994, Le Heron, 1994]. The calculations required the use of surface entry doses as measured by TLD and the tube kilovoltage used for each exposure.

5.3 Data analysis

The data were analysed using the STAT module of the statistical analysis software package, SAS [SAS Institute, 1994]. The analysis was undertaken firstly by actual modality which was used for each examination. The analysis by 'intention to treat' [Schwartz and Lellouch, 1967] was also of interest because, if the patient was imaged by the incorrect modality, the radiographer may have used experience gained from a previous examination with the other modality and this may have influenced practice. The analysis by 'intention to randomise' was not considered relevant in this context because it was unlikely that an incorrectly allocated envelope would be known to the radiographer at the time of the examination and the radiographers were not involved in the randomisation process.

The comparability of the study patients in the two arms of the trial was investigated by comparing the patient groups in terms of the general characteristics: age, adult or child, sex, patient size and thickness of the chest (ffd-fsd).

Comparisons of the radiographic techniques used were made by comparing the exposure factors (kV, mAs, ffd), mobile unit used, patient position and radiographer undertaking the examination.

Comparisons of patient doses were made in terms of surface entry dose for each examination as measured by TLD. Since the patient was the unit of randomisation, it would have been inappropriate to analyse the dose data with the examination as the unit because some patients had more than one examination. Thus, the examination dose data are repeated measures and as such do not represent independent observations. Two separate analyses were undertaken, firstly using the first examination of the patient and secondly using the last examination of the patient. This was done because if the patient had more than one examination, it was likely that the technique used by the radiographer in subsequent examinations might be adapted after the first image was viewed in order to improve the image and that doses might change after the first examination and that the final image in a series would be the best. Some patients had many x-ray examinations during their stay on the Unit while others had only one. Some patients had no x-ray examinations at all. Where the patient had more than two examinations, the doses for examinations other than the first and last were not used in these analyses because they would cause bias. In addition a comparison of doses for the *successful* imaging of the chest was made which included any *repeat* examinations which were required because the first examination was unsatisfactory.

These comparisons of the exposure of patients in the two arms of the trial were made using Mann-Whitney and Chi-square or Fischer's Exact tests depending upon the nature of the data.

5.4 RESULTS

During the period of this study 269 (65%) ITU patients were x-rayed during their stay on the Unit with the number of examinations ranging between 1 and 81 (Figure 5.1).

The analyses were conducted on those observations for which there were data on the single entry dose and the total examination dose, which included repeat images. Dose data might have been missing for one of three reasons: there were no TLDs available in ITU for the radiographer to use, it was not possible to match the TLD reading provided from NRPB with other data on the exposure, and the radiographer did not comply with the data collection process and failed to use a TLD. Radiographer non compliance was very rare.

5.4.1 Patient characteristics

An analysis of all data showed that all the data were not normally distributed and therefore non parametric analyses were performed.

The patients in the two arms of the trial were well matched for sex (Chi square test $p=0.95$), mix of adults and children (Chi square test $p=0.49$), age (Wilcoxon test $p=0.99$) and thickness of the chest (T-Test $p=0.44$) which showed that the randomisation process had been successful.

There was a statistically significant difference in the size of the patients as estimated by the radiographers when film and PACS (Chi square test $p=0.01$) with more medium sized patients being in the Film group (Table 5.2).

5.4.2 Exposure conditions

Statistically significant increases in both kilovoltage (kV) (Wilcoxon test $p<0.001$) and milliampere seconds (mAs) used (Wilcoxon test $p=0.002$) were found when PACS was used. There were no statistically significant differences in focus to skin distance (Wilcoxon test $p=0.16$), focus to film distance (Wilcoxon test $p=0.22$), patient position during the examination (Chi-square $p=0.97$) or mobile used (Chi-square $p=0.30$) (Tables 5.3 - 5.8).

5.4.3 Patient doses

There was a statistically significant increase in the entry dose (Wilcoxon test $p=0.003$), examination dose (Wilcoxon test $p<0.001$) and effective dose (Wilcoxon

test p=0.002) when PACS was used (Tables 5.9 - 5.11).

There was a significant difference between groups (p=0.016) in the number of repeat exposures (Table 5.12). The vast majority (over 90%) of examinations for both groups did not require a repeat image but there were fewer repeats in the PACS group. Neither the focus to film distance (FFD) nor the focus to skin distance (FSD) differed significantly between the two groups (Tables 5.11 and 5.12). This implies that there is unlikely to have been a difference between the two groups in the use of non-routine ITU beds, for example a Clinitron bed (Hill-Rom, Charleston) which might have resulted in larger patient to film/plate distances being used. The tube kV and the mAs were significantly higher ($p<0.001$) when PACS was used (Tables 5.3 and 5.4)

5.4.4 Comparison of doses for *first* and *last* examinations

For the first exposure, both radiation entry dose per image (ENTRY) and radiation entry dose per examination (EXAMDOSE) were found to be significantly higher for PACS than for film ($p<0.01$). The median values for ENTRY were 0.21 mGy for PACS, and 0.16 mGy for film; an increase of 31% in moving from film to PACS (Table 5.9). The median values for EXAMDOSE were also 0.21 mGy for PACS, and 0.16 mGy for film (Table 5.10). Similarly, the median effective dose was significantly higher, by 36%, for PACS ($p<0.05$), with the median PACS effective dose being 0.036 mSv and the FILM effective dose being 0.027 mSv (Table 5.11).

When the last rather than the first examination was used for the analysis, very similar results were found. Again there was an increase in the median entry and examination doses when PACS was used compared with film. However, the increase was lower than when the entry doses for the first images were compared and was 20% (Table 5.9). This lower percentage increase was achieved mainly by PACS doses for the last examination being lower than PACS doses for the first examination, rather than by changes in film doses. There was a significant increase ($p<0.05$) in the effective doses, by 17.6%, when PACS was used, with the median for PACS being 0.031 mSv and the median for film being 0.026 mSv (Table 5.11).

A paired t-test showed that there was a significant ($p=0.03$) decrease in surface entry doses and effective doses between the first and last examinations when PACS was used, but not when film was used ($p=0.90$). Thus, there is an indication that for PACS the radiographers tended to over estimate the dose required to produce the first image but on subsequent examinations they were able to reduce the dose and still produce a satisfactory image. Paired t-tests applied to the exposure factors, the mobile machine used and patient position revealed that, for film only, significantly more patients were examined in the erect or semi-erect position for the last examination, compared to the first. The only other differences for the last examinations related to the focus to skin distances and the focus to film distances used, which were significantly larger for film for the last examination (Tables 5.5 and 5.6). There was no significant difference in the number of repeats for the last image taken, whereas for the first image taken where there were significantly more repeats for film (Table 5.12). This implies that, as would be expected, radiographers used experience gained from the first examination to be more accurate in the last film examination and that the wider exposure latitude of PACS does reduce the number of repeats required for first images.

A significant ($p=0.01$) difference between groups for patient body size was found for first images but not for last images (Table 5.2). However, assessments of patient size were based upon the subjective opinion of the radiographer and there are concerns about the quality of the data. Of the 126 patients in this sample who had more than one x-ray exposure, 66 (52%) had assessments of body size which differed from one observation to the next. Seven patients were assessed as being 'small', 'medium' and 'large' on different occasions. Therefore, these data must be viewed as unreliable. No statistically significant difference was found in the measured thickness of the chest of the patients for the first and last examinations ($p=0.44$ and $p=0.06$).

5.4.5 Missing data

Dose data were missing for 72 patients in the sub-sample (26%). In order to assess the importance of this problem, comparison was made of the observations where

dose data were missing with the observations where the data were available. The only significant difference between groups was found in the x-ray machines used. The machine normally used in ITU was the Explorer and it was only when this was unavailable that the VMX was used as an alternative. Using data relating to the first examination for each patient, the Explorer was used in 92% of examinations where data were provided and in 60% where data were unavailable. In contrast, the VMX was used in 8% of examinations where data were provided and in 40% where data were unavailable (Table 5.13). This is to be expected since the use of the VMX is not routine and implies that the radiographer was working under difficulties and would, understandably, have less time and inclination to collect the data. Similar results were found for the last examination for each patient.

The dose data were re-analysed using an 'intention to randomise' analysis. There was no difference in the nature of the results obtained.

5.5 DISCUSSION

An important negative aspect of the PACS installation at Glan Clwyd is the finding that patient radiation entry dose per exposure was higher for PACS by between 20% (for the last examination of each ITU patient) and 31% (for the first examination of each ITU patient). This is of concern, particularly since some patients had several examinations. For example, one patient underwent more than 80 x-ray examinations while in ITU.

Sample size

A sample size calculation could not be undertaken at the start of this study because no similar studies had been reported previously. A retrospective calculation based on the results of this study for the sample size of 200 patients, where a 30% difference in dose was detected, shows that the study had a 94% power at 5% significance level for detecting this difference in dose [Altman, 1999]. Thus the sample size used in this study was sufficient.

Comparison with other studies

The findings of this trial are neither entirely unexpected nor in contradiction with other studies. The increase in dose must be seen in the context of a comparison with a 400 speed film/screen system. Studies of the effect of PACS on patient radiation doses at other sites have reported reductions in dose of 60% (Pettersson 1988) and 50% (Hruby et al 1994), but Pettersson compared CR with a 100-150 speed film system and Hruby produced no data to support his claim. In the study reported in chapter 3, no change in surface entry and effective doses for lateral lumbar spine were found when the Hammersmith Hospital replaced their 300 speed film/screen system with a hospital-wide PACS.

A study which was reported at a meeting of the Queensland Physical Sciences and Engineering in Medicine Group (Smith et al, 1998) estimated skin doses for three types of chest examinations: adults using a dedicated chest unit, adults on wards and paediatrics in order to compare film and CR techniques. They found that the CR system (which was a KESPR and used the same type of plates as those used in the trial) had a speed which was equivalent to a 200 speed film/ screen system and that the CR patient doses were 1.1 to 4.2 times higher than for the film system used. For mobile adult CR examinations, doses were increased by 81% compared with the film images (Fuji HR film with HR medium screens, speed 300-400). These doses are higher than those found in the study reported in this chapter but the technique used was different. The Australian study used a grid and 120kV. This study used no grid and approximately 80kV. Thus the numerical value of the doses varied but the direction of the dose change was the same in both studies.

The increase in patient doses found in this study must be put into context. The difference in the effective dose per examination between film and PACS was approximately 0.01mSv. The mean number of examinations per x-rayed patient was 3.3 examinations and so the additional effective dose per x-rayed patient with PACS was 0.033 mSv. The effective doses for chest examinations is very low compared

with other body areas such as an anterior-posterior view of the abdomen or pelvis each of which have a typical effective dose of 0.7mSv (Wall & Hart, 1997). Indeed, for the group of 269 x-rayed patients in the dose sub-study, the increase in collective effective dose was approximately 10 mManSv (ICRP 60, 1990). In *this population* where the mean age was approximately 58 years, the use of the PACS imaging system represents an increased risk[2] of 0.0003 of developing a fatal cancer, other cancer or other serious defect including hereditary effects, over the course of their life. This means that approaching one million similar patients would each have to receive 3.3 chest examinations using this system in order to produce one additional health defect in this population. An alternative way of looking at this issue is in terms of the expected loss of life years associated with the dose increase. The total loss in life years to this population of 269 patients if they had all received PACS examinations of the chest during the study period is approximately 2.7 days (Robb & Webb, 1993). The risk associated with exposure to radiation is related to the age of the patient; older patients have a lower risk. The majority of study patients were over 65 years of age on admission to the ITU, and the above calculation has taken this into account. Therefore, although an increase in patient doses was found in this study, the increased risk to the population is very small. However, if this system were used more widely for the examination of other body areas which require the use of higher exposure factors, or with a younger population, and a similar increase in effective dose was seen, there would be an increased risk to the population which might be of greater importance.

The small but significant reduction in the number of images requiring a repeat image is important. The reject rate of all images at Glan Clwyd Hospital was small so no difference between the dose per image and the dose per examination was found. However, the reduction in repeats might be more important for other examinations or in other hospitals with higher repeat rates. A comparative study of reject rates

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[2]The additional effective dose for 269 patients each having 3.3 PACS images is 0.033mSv x 269 = 9 mMan Sv.
The mean age of this population is 58 years and the risk factor of developing a serious health defect (fatal or non fatal cancer or hereditary detect) can be taken to be 3.5% per Sievert.
The additional risk to this population is therefore 9mManSv x 3.5/100 =0.0003

when film, CR and PACS images were used is therefore the subject of the next chapter.

Table 5.1 Data collected for measurement of radiation doses*

Variable	Description	Method
Radiographer ID	Numerical value preceded by 'CR' for qualified radiographers and 'S' for student radiographers	Numbers were in sealed opaque envelopes & a sealed envelope was chosen by each radiographer.
Trial Arm	'CR' or 'FILM'	From list in ITU
Patient details		
Size	small/medium/large	Subjective assessment made by radiographer doing the examination
Sex	male or female	
Adult	Adult or child	Adult > 16 years Child < 16 years
Age		
Exposure conditions		
Patient position	supine/semi-erect/erect	Position of patient during the exposure
Mobile unit		Each mobile was labelled for identification
kVp	kilovoltage across x-ray tube	Noted from control panel
mAs	tube milliamperage	Noted from control panel
FSD	focus to skin distance in cm.	Measured by radiographer
FFD	focus to film distance in cm.	Measured by radiographer
TLD number	number attached to TLD	
Entry dose	Surface entry dose in mGy.	Measured by individual TLDs attached to patient's skin at the centring point.
Effective dose	in mSv	Calculated using NRPB software SR262
Repeat image required	Yes/No	
Reason for repeat		

* Some data are missing in subsequent tables of results for one of three reasons: it was unavailable, the radiographer forgot to record it, or the data could not be matched with the patient.

ANALYSIS BY MODALITY USED FOR EXAMINATION

PATIENT CHARACTERISTICS

Table 5.2 Size of patient

	FIRST EXAMINATION		LAST EXAMINATION	
	PACS	FILM	PACS	FILM
Small	34	27	9	15
Medium	58	79	35	41
Large	38	21	14	12
Chi-square test	p=0.012		p=0.511	

EXAMINATION CONDITIONS

Table 5.3 Kilovoltage across the tube

	FIRST EXAMINATION		LAST EXAMINATION	
	PACS	FILM	PACS	FILM
N	138	122	68	70
Mean	78.02	75.89	78.03	76.33
SD	3.84	4.48	3.40	5.24
Median	78.5	76	80	77
Range	27 (63-90)	24 (60-84)	19 (66-85)	33 (50-83)
Q3-Q1	4	6	4	5
Wilcoxon test	p=0.0001		p=0.0155	

Table 5.4 Tube current time product (mAs)

	FIRST EXAMINATION		LAST EXAMINATION	
	PACS	FILM	PACS	FILM
N	137	129	68	70
Mean	2.00	1.79	1.98	1.69
SD	0.85	1.20	0.812	0.68
Median	1.8	1.6	1.6	1.6
Range	4.2 (0.8-5)	11.7 (0.8-12.5)	3.2 (0.8-4)	4.2 (0.8-5)
Q3-Q1	0.4	0.7	0.4	0.4
Wilcoxon test	p=0.0023		p=0.0063	

Table 5.5 Focus to skin distance (cm)

	FIRST EXAMINATION		LAST EXAMINATION	
	PACS	FILM	PACS	FILM
N	128	122	64	65
Mean	95.01	100.14	95.58	106.59
SD	14.83	18.49	19.10	23.49
Median	96	97	95.5	98
	107 (50-157)	104 (60-164)	105 (60-165)	93 (70-163)
	13.35	15	15	22
Wilcoxon test	p=0.1596		p=0.0181	

Table 5.6 Focus to film distance (cm)

	FIRST EXAMINATION		LAST EXAMINATION	
	PACS	FILM	PACS	FILM
N	119	110	59	63
Mean	117.0	121.23	119.03	127.38
SD	15.53	19.24	19.14	21.77
Median	116.0	117	116	120
Range	102 (80-182)	96 (90-186)	105 (85-190)	87 (98-185)
Q3-Q1	12	12	17	22
Wilcoxon test	p=0.2206		p=0.0259	

Table 5.7 Patient position for examination

	FIRST EXAMINATION		LAST EXAMINATION	
	PACS	FILM	PACS	FILM
Supine	104	107	43	36
Semi erect	17	16	13	20
Erect	4	4	6	10
Chi-square test	p=0.972		p=0.225	

Table 5.8 Mobile used for examination

	FIRST EXAMINATION		LAST EXAMINATION	
	PACS	FILM	PACS	FILM
Explorer	100	105	50	57
VMX	22	16	11	6
Chi-square test	p=0.302		p=0.168	

PATIENT DOSES

Table 5.9 Surface entry dose (mGy)

	FIRST EXAMINATION		LAST EXAMINATION	
	PACS	FILM	PACS	FILM
N	103	95	56	57
Mean	0.22	0.18	0.193	0.156
SD	0.107	0.09	0.09	0.077
Median	0.21	0.16	0.18	0.15
Range	0.62 (0.02-0.64)	0.68 (0.04-0.72)	0.55 (0.02-0.57)	0.39 (0.02-0.41)
Q3-Q1	0.13	0.09	0.08	0.08
Wilcoxon test p = 0.0028			p = 0.0175	

Table 5.10 Examination dose (mGy) - dose for examination including any repeats

	FIRST EXAMINATION		LAST EXAMINATION	
	PACS	FILM	CR	FILM
N	106	95	56	57
Mean	0.22	0.18	0.19	0.17
SD	0.11	0.11	0.10	0.12
Median	0.21	0.16	0.18	0.15
Range	0.62 (0.02-0.64)	0.68 (0.04-0.72)	0.55 (0.02-0.57)	0.72 (0.02-0.74)
Q3-Q1	0.12	0.09	0.08	0.08
Wilcoxon test p = 0.0008			p = 0.0404	

Table 5.11 Effective doses (mSv)

	FIRST EXAMINATION		LAST EXAMINATION	
	PACS	FILM	CR	FILM
N	103	95	56	57
Mean	0.038	0.030	0.034	0.027
SD	0.020	0.015	0.017	0.014
Median	0.036	0.027	0.031	0.026
Range	0.12 (0.004-0.122)	0.085 (0.007-0.092)	0.097 (0.004-0.1)	0.070 (0.0022-0.072)
Q3-Q1	0.022	0.016	0.016	0.014
Wilcoxon p = 0.0016			p = 0.0109	

Table 5.12 Repeat examination required

	FIRST EXAMINATION		LAST EXAMINATION	
	PACS	FILM	PACS	FILM
No repeat	116	96	56	48
Repeat	3	11	1	3
Chi-square test	p = 0.016		p = 0.257	

Table 5.13 Comparison of observations for the FIRST examination of each patient where dose data (ENTRY) is available with those where ENTRY is missing, in terms of the mobile machine used

Mobile machine used in examination	Observations where ENTRY available (column percentage)	Observations where ENTRY missing (column percentage)	Total
Explorer	158 (92%)	35 (60%)	193
VMX	14 (8%)	23 (40%)	37
Total	172 (100%)	59 (100%)	231

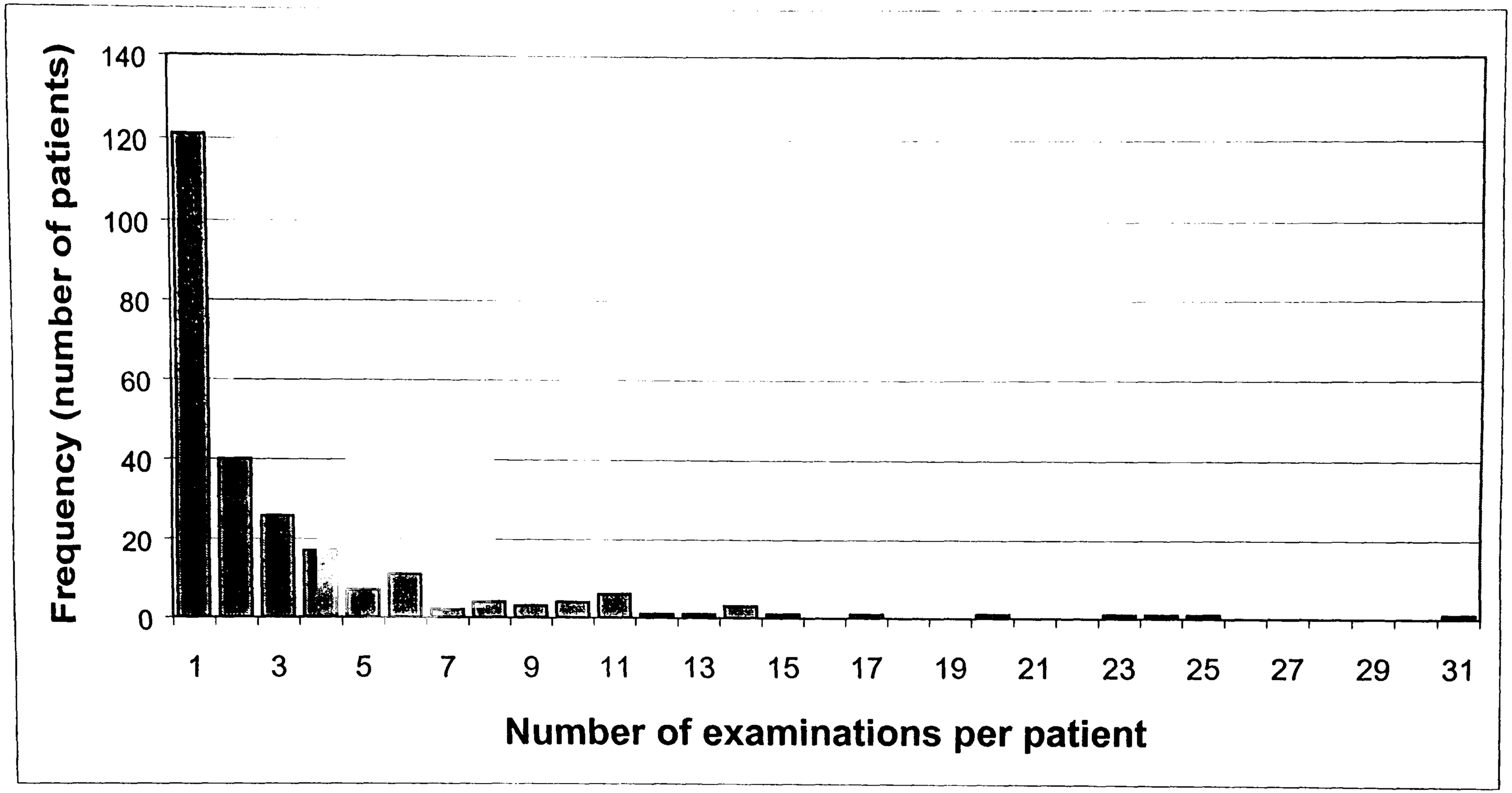

Figure 5.1 Number of chest examinations per patient: 61% of patients radiographed had a single chest image while in ITU, the mean number of images was 3.3.

CHAPTER 6

THE EFFECT OF PACS ON IMAGE REJECT RATES

6.1 INTRODUCTION

In the preceding two chapters the effect of PACS on the doses required for images of the lateral lumbar spine and the chest was determined. In this chapter a study is reported which considered whether the number of images which were rejected, and thus potentially necessitated repeat examinations and additional patient radiation doses, changed when PACS was used.

The British Institute of Radiology describes "reject analysis" as "the critical evaluation of radiographs which are used as part of the imaging service but do not play a useful part in the diagnostic process" (British Institute of Radiology, 1988). Analysis of rejected films gives an indication of the sources of radiographic errors and can highlight areas in which improvement can be made. Various studies have found reject rates to vary between 2% and 13% (Mazzafero *et al*, 1974; McKinlay & McCanley, 1977; Bowne, 1969; Mustafa *et al*, 1987; Arvantis *et al*, 1991; Gadeholt *et al*, 1989; Nixon *et al*, 1995; Lewentat & Bohndorf, 1997). In July 1990 the North East Thames Region quoted the average reject rate in the UK to be 10% (North East Thames Regional Health Authority, 1990): this implies that if rejected images are discarded and the exposure is repeated, nationally, rejected images are

responsible for an unnecessary increase in the radiation dose to the patient population (Berry & Oliver, 1976) and to the costs of film and associated processing. The introduction of a Picture Archiving and Communications System (PACS) into a hospital is expected to reduce the reject rate for two reasons. Firstly, the phosphor plate computed radiography system for acquiring images has a wider latitude than conventional film so that repeats due to incorrect exposure factors should be eliminated. Secondly, in images of body areas where there are large differences in density and thickness within the patient, or there is unexpected pathology, the facilities to manipulate soft copy images should allow most areas of the images to be visualised. So the hypotheses being tested in this study were that compared to when conventional film is used,

- the reject rate of images would be reduced after the introduction of phosphor plate technology,
- the reject rate would be reduced further after the introduction of PACS and soft copy images with manipulation facilities.

6.2 METHODS

6.2.1 Reject analysis of films

Annual reject analyses were performed at the Hammersmith Hospital by the medical physicists and radiographers and data are available from studies in 1990 and 1991. On each occasion data were collected over the month of July. The reject rates for the four weeks of data collection ranged from 7% to 12% in 1990 and from 10% to 13% in 1991.

Three detailed reject analyses were undertaken: in 1992 when conventional film was still being used, in 1994 after radiology started using computed radiology (CR) hard copy images, and 1995 after PACS was in use throughout the hospital. The main focus of the study was on images which involved irradiation of the patient, and thus ultrasound and MRI images were excluded. This was because radiation dose reduction was of particular interest. However, because the study required the input of the radiographers there were also pragmatic reasons for excluding the non ionising modalities. MRI examinations of clinical patients which were undertaken

by radiographer staff was very limited since most of the time was allocated to research projects, and only a minority of ultrasound examinations were undertaken by radiographers, thus it would not be possible to obtain large enough samples of images in these modalities.

The reject analysis of film was undertaken during August 1992. All examinations of all patients being x-rayed were included in the study. Each film was viewed and a decision was made as to whether it was acceptable for diagnosis or should be rejected. There was no formal policy in the department for defining films as rejects. If the radiographer was responsible for producing the film, the initial decision was made by that radiographer, based on professional judgement. In instances where the radiographer was uncertain, the decision was made by the radiologist who would subsequently produce the report. When the radiologist conducting the examination was responsible for film production, that radiologist made the decision whether to accept or reject the film; a trainee radiologist would consult a senior radiologist for guidance. Thus, all decisions were to some degree subjective judgements following professional guidelines.

The reasons for rejection of films are as follows (the codes indicated are used in Table 6.3-6.6).

A- These are rejects where the patient has not been positioned correctly to show the whole of the body area or the position which adequately demonstrates pathology. This is less subjective than some other aspects since there are set protocols which should be followed. However, some variations in these protocols are present dependent upon where the radiographer trained and has had previous experience.

B- Unsharpness or blurring of the image resulting from movement of the patient or equipment can also lead to the film being rejected. The patient movement may be voluntary, such as breathing, or involuntary such as heart beat. This category of rejects is less subjective than some others but there will be

differing degrees of movement and a decision has to be made on whether the diagnosis can be made from the film and whether the movement can be eliminated with a repeat exposure.

C- These are rejects where the incorrect exposure has been used and the film density (blackening) is too high or too low to demonstrate the body area of interest. This over and under exposure may be due to incorrect selection of exposure factors for the size and density of the patient or to the presence of unexpected pathology, such as emphysema, resulting in overexposed lung fields, and fluid, resulting in underexposed films. There is no absolute value defining 'correct density'. Decisions about rejections are very subjective with quite considerable variations between films of the same body area.

D- Rejects can also result from the equipment operating in a faulty manner, such as time, including automatic exposure device, errors or a fall in output due to rectification fault. These rejects are made on a less subjective basis than some other categories.

E- Rejects can result from faulty processing equipment. In a department using conventional film there are wet processing errors such as static build up, and physical damage during transport which results in the removal of the film emulsion bearing the image. Again this category of rejection is less subjective than some.

A film will be rejected if light fogging occurs. This is caused by light entering the cassette and producing an area of high density on the film. There is some degree of subjectivity in this category: some staff will reject all films with any areas of fogging, whereas others only reject the film if the fogging obscures part of the area of interest.

F- Films will also be rejected when they are considered to be of no value in aiding diagnosis. This decision is normally made by the radiologist and

includes films from automatic sequence radiography. It also includes laser images which have been printed following CT (Computed Tomography), and DSA (Digital Subtraction Angiography) but which are not in the correct sequence required for reporting and are, therefore, rejected. It should be emphasised that these rejected laser films do not reflect additional exposure to the patient and have a cost implication only. There is an element of subjectivity in this category.

G- The miscellaneous category includes double exposure of the film resulting in two superimposed images and the presence of opacities such as jewellery (these could be included in the incorrect technique category). Most of these decisions are not subjective.

When a decision was made to classify a film as a 'reject' the radiographer involved in the examination attached to the film a label which indicated the following details:

- exposure factors;
- patient size (small, medium, large);
- x-ray room number;
- reason for rejection.

The rejected films with labels attached were then placed in a box in the film viewing area. At the end of the study all rejected films were viewed in order to identify the body areas examined. If any labels were missing, the physicist, in consultation with a radiographer coded the film for the reason for rejection.

In addition the radiographers were asked to record on the x-ray request form the numbers and sizes of all films used and the x-ray room in which the films were taken. All request forms were then collected by the x-ray secretaries when the films were reported. From the information on the request form, details of film usage and body areas examined in each room were obtained. In addition details of the numbers of each body area examined were obtained from the radiology information system (CRIS).

6.2.2 Hard copy CR images

This part of the study was undertaken in September 1994 at a time when Radiology staff were happy with the use of the CR system. The method used was essentially the same as for film but the reject images were sorted and coded when necessary by the research radiographer from HERG (GW) because the radiographer allocated to take charge of the study internally did not have time to proceed with it and subsequently moved to another job.

There were some new additional codes for rejects relating to the CR system. These were:

H- CR technique/scatter/position of image on cassette/are too small

A PRIEF is an algorithm that is used to detect areas in the irradiated field. Each PRIEF has specific exposure precautions relating to irradiated field positioning, size and shape. There are five PRIEFs that are preselected for each individual examination. Data obtained outside the irradiated field eg scattered radiation can adversely affect the histogram analysis and the resultant image. Therefore, the positioning of the irradiated field within the imaging plate area and the limitation of scatter is very important.

J- Incorrect organ code

The radiographer has to select an organ code for each plate before it is processed. The plate reader uses the organ code to identify the image processing parameters for the plate. Thus if the incorrect organ code is selected, the plate may not be processed under optimum conditions for the body area under examination.

K- Digiscan fault

The Digiscan refers to the plate reader in which the phosphor plate is scanned by a laser beam to convert the latent image into a digital image which, if required, will be transferred to a film for hard copy CR production.

Faults in the Digiscan include artefacts on plates, plates jammed and plates not read properly etc.

L- ACI fault ie fault in the processor of the CR film

When a hard copy CR image is required, the film has to be transported via a roller system in order to be processed by chemicals. Faults in this system are similar to processing faults of film eg when the chemicals need replacing, and roller marks etc.

6.2.3 Soft copy PACS images

This study took place over November and December 1995 after the staff in radiology felt that there had been sufficient time to adapt to the use of PACS. The method used here was of necessity different from the previous two rounds because of changes which had occurred with the use of PACS relating to the rejected images and the examination request forms. After PACS was fully operational, there were no hard copy images produced routinely. When an image was identified on the work station as unsatisfactory, it was not possible to delete the image from the system but it was transferred to the reject file by the radiographer. The reject file work list retains details of all patients and their examinations from which images have been rejected. It did not provide details of how many images or which view/s were rejected or the reason for their rejection. In the reject file there was a compulsory field which had to be completed giving the reason for rejecting the image. The images were annotated with the reason for rejection so that they could be seen when the image was viewed. Standard codes for reasons for rejection were agreed for this study. (The coding system was found to be useful and has been retained for routine use in the department.) Images could only be viewed in the reject file for 8 days after which time they could no longer be viewed. If they were not viewed within 8 days the reason for their rejection was unknown. For the purposes of this study, an academic file was set up where the images could be viewed after any length of time so that a permanent record was available which could be viewed and rechecked. The HERG researcher (GW) copied most images from the routine reject file to the academic file. In 36 (7%) cases this did not

happen because the 8 day limit was exceeded. The reasons for this were that the images could not be fetched from the long term archive into the WSU or the examination was not verified by the radiographer. In these 36 cases the body area examined was known, but not the reason for rejecting the image. The order in which images were fetched from archive was not always the same order in which they appeared on the folder work list so that there was the possibility that an image could be transferred to the academic folder more than once and thus, counted twice. In order to ensure that there was not duplication of images transferred to the academic file, the images transferred were annotated with a letter 'Z' in the patient's folder. However this caused a problem with overloading the disc with the academic folder so that the folder could not be accessed, and additional academic folders had to be generated and the 'Z' was not retained on the original image. To ensure that no duplication had occurred, at the end of the study two HERG researchers (GW & SB) checked the images in the academic folder with the list for the reject analysis folder while each list was on screen on adjacent work stations.

The other major change in routine involved the use of the x-ray examination request form. After the implementation of PACS the radiographers entered the patient's clinical details and the details of the examination request onto PACS where it was available to the radiologists when reporting the examination. After the radiographers had used the forms for this purpose, the forms were destroyed. The department did not want to change the new system so the method employed in the previous two rounds to record the number of images taken for each examination on the request form had to be changed. The same information could only be obtained from PACS by counting the number of images produced for each patient for each type of examination during the period of the study from the work list on the work station which was a potentially inaccurate procedure. Unfortunately, this process could not be performed by PACS and PACS could not produce a paper print out which could have been counted more accurately. Thus it was decided to use the reject rate over all examinations as the basis of the whole study ie for Film, CR and PACS images, and not reject rate over all images taken which is the usual method.

An additional change in the system of working, which only became apparent some months after the study, was that the radiologists undertaking fluoroscopy did not pass rejects to the reject analysis folder but deleted these from the local hard disk. Thus, because rejects in this group of examinations which were controlled by the radiologists were unknown for the PACS study, they had to be excluded from the Film and CR studies. The comparison is, therefore, of rejects of plain radiography images only during the periods when Film, CR and PACS was used.

6.3 RESULTS

During the study of the reject rate for Film there were 3904 plain radiography examinations and 385 rejected films. This represents a 9.9% reject rate per examination[1]. During the study of the reject rate for CR there were 4502 plain radiography examinations and 365 reject films. This represents a 8.1% reject rate per examination. During the study of the reject rate for PACS there were 6617 plain radiography examinations and 483 rejected images which involved irradiation of the patient. This represents a 7.3% reject rate per examination. There were an additional 43 PACS images rejected which did not involve irradiation of the patient but were sent to the wrong folder, sent twice or were blank. A comparison of the reject rates show statistically significant reductions in the reject rates per examination of both CR ($p<0.01$) and PACS ($p<0.01$) compared to Film but no statistically significant reduction when comparing PACS with CR (Table 6.1).

The reject rates per examination for body areas are shown in Table 6.2. When Film was used, the body area with the highest reject rate per examination was the

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[1] Reject rates are normally expressed as a percentage of the total number of images taken. In this study, it was not possible to obtain the total number of images taken for all three periods of the study, thus the total number of examinations is used throughout. Since an examination may include more than one image, the rejects rates quoted in this chapter will be higher than if the standard method is used. However, the comparison of the reject rates for the three periods when Film, CR and PACS was used, is made using the same method of calculation of reject rate. Since these rates are inflated when compared with reject rates expressed as a percentage of all images taken, and after the completion of this study, it became possible to obtain further information from PACS concerning the total number of images produced, the number of rejects for each body area and the reasons for the rejection of images, calculations of reject rates expressed as a percentage of all images taken have been made for both the Film and PACS periods. The results are shown in Table 6.7. Similar data are not available for the CR period.

thoracic spine (50.8%) followed by the skull (25.8%) and cervical spine (23.8%). When CR was used the body area with the highest reject rate per examination was the hip (37.2%), followed by the skull (36.3%) and the cervical spine (23.9%). When PACS was used skulls became the area with the highest reject rate per examination (23.2%), followed by the hip (21.2%) and the cervical spine (19.6%).

The reasons for rejection of images are shown in Table 6.3. During the Film study incorrect patient positioning and other errors in radiographic technique accounted for 44.7% of all rejects and incorrect exposure factors, for 32.5%. The rejects which were expected to be completely eliminated when film was no longer used were rejects caused by film processing and fogging of films which were 3.4% of the total rejects. When CR was used, 83.3% of all rejects were caused by incorrect patient position and technique and only 1.6% by incorrect exposure. The CR specific reasons for rejecting images (CR technique, incorrect organ code, Digiscan and ACT faults) were together responsible for 6.3% of all rejects. When PACS was in use, the main reason for rejecting an image was again, incorrect patient position and technique (78.5%) and the CR specific reasons for rejection accounted for 7.4% of all rejects.

Tables 6.4 to 6.6 show the reasons given for rejecting each image for each body area. A comparison of the reasons for rejecting thoracic spine images which was the area with the highest reject rate per examination for Film, shows that positioning and exposure errors were each responsible for 44.8% of rejects. In the CR and PACS studies, the number of rejects was much less but the main reasons for rejection had not changed. For all other body areas the rejects due to incorrect exposure factors dropped dramatically when CR was used compared to when Film was used. When PACS was used, there were increases in the rejects due to exposure errors for the hip and upper limbs. For the skull, in all three studies, the major reason for image rejection was incorrect patient position and radiographic technique.

6.4 DISCUSSION

The nature of the activity of the department is broadly as expected in a department undertaking general and specialised work. The overall reject rates per examinations undertaken for Film (9.9%), CR (8.1%0 and PACS (7.3%) cannot be directly compared with rates reported at other sites, which vary between 2% and 13% (Mazzafero *et al*, 1974; McKinlay & McCanley, 1977; Bowne, 1969; Mustafa *et al*, 1987; Arvantis *et al*, 1991; Gadeholt *et al*, 1989) since these use the reject rate per image and not the reject rate per examination. However, a 1994 study at Nottingham City Hospital which included rejects of the chest, abdomen, pelvis, cervical, thoracic and lumbar spines, did use reject rates per examination as the basis of its results and found a reject rate of film examinations undertaken to be 7.4% [Rogers, personal communication]. For the same body areas, the reject rates at the Hammersmith were 9.9% per examination for Film, 6.4% per examination for CR and 7.8% per examination for PACS.

The aim of this project was to be able to identify changes in reject rates which were due to the implementation of PACS. However caution must be used in interpreting all results as the process of rejection is a subjective exercise and it could be that the changes following the introduction of CR and PACS is a result of changes in the threshold of acceptance of images by the current staff or indeed by changes in staff.

The introduction of CR was expected to reduce the high percentage of thoracic spine rejects which were due to incorrect exposure factors. This was achieved and the thoracic spine rejects were reduced from 50.9% of all rejects with Film, to 7.0% with CR and 11.4% with PACS.

Manipulation of the images on the workstations allows a range of densities to be seen in the image unlike a conventional x-ray film image which has a fixed density range. Thus, areas of the body which cannot be seen on an x-ray film might be seen on a workstation with image manipulation. Areas of the body which are difficult to image because of a wide difference in thickness of the body include the

junction of the cervical and thoracic spines which in the lateral projection is obscured by the shoulder girdle. Consequently, it was expected that the use of PACS workstations might reduce some of the rejects due to errors in positioning and technique which accounted for 43% of all cervical spine rejects. Overall the reject rates for the cervical spine remained a reasonably constant proportion of all rejects throughout all three studies (Film 23.8%, CR 23.9% and PACS 19.6%). However, whereas the reject rates due to incorrect exposure factors decreased, (Film 36.7%, CR 3.1% and PACS 2.4%), the reject rates due to incorrect positioning and radiographic technique increased (Film 43.3%, CR 71.9% and PACS 80.6%). Thus the expected reduction in cervical spine rejects overall was not achieved.

It was expected that when PACS was fully operational, the 3% of all rejects which are caused by wet processing faults would be eliminated but that PACS might produce new types of rejects, such as incorrect choice of algorithm. This expectation proved to be true and the new reasons for rejection of CR images, CR technique, incorrect organ code and Digiscan and AC1 faults accounted for 6% of all rejects. In the PACS study 7% of all rejects were caused by CR technique and Digiscan faults. Thus, the introduction of the new techniques produced an overall increase in images rejected because of processing.

The Medical Physicists at Hammersmith have been conducting their own reject analyses and have found no change in the reject rates over all images taken. When data were not recorded by the radiographers, an estimation of the number of images taken per examination was made by the physicist in consultation with the radiographers. The reject rate per images has remained at about 7% but the reasons for rejection of images have changed. These results compare well with the results reported in this study. It would be expected that the reject rate expressed as a percentage of the number of images taken would be less than the reject rate expressed as the percentage of the number of examinations undertaken. In the study reported here, for consistency, the total examinations was taken from the CRIS report for each period. It is accepted that occasionally an examination is mistakenly not entered on CRIS and thus the total examinations may be slightly

lower than they should be, but there is no reason to believe that these errors would have occurred more frequently in any one part of the study than another.

6.5 COMPARISON WITH OTHER STUDIES

The results of the comparison of reject rates when film and CR hard copy images were used compare well with those reported by van der Putten [van der Putten, 1998]. The Hammersmith is a teaching hospital and tertiary referral centre with around 400 beds and van der Putten's study was in a similar type of hospital with 540 beds. Van der Putten reported that when conventional film was used there was a 17% reject rate and 30% of all rejects were due to incorrect exposure factors. When CR was used, the reject rate fell to 7%. In this study it was found that 32.5% of all film rejects were caused by incorrect exposure factors. In both studies the rejects due to incorrect exposure factors were virtually eliminated when CR hard copy images were used.

The results of this study follow the same trend as the results of a contemporaneous comparison of film and PACS images [Peer et al, 1999] but their film repeat rates were higher (15.6), and the PACS rates lower (2.0%). They did not monitor the reject rates for CR hard copy images. Film rejects were monitored for two months in the general department and PACS rejects in the trauma department of the same hospital. Details of the body areas were not given and so it is not possible to determine whether the mix of examinations was similar in both parts of the study or whether it is comparable with the case mix in our study.

6.6 CONCLUSION

Two hypotheses were tested in this study. The first hypothesis that the reject rate of images at the Hammersmith would be reduced after the introduction of phosphor plate technology (CR) was accepted since a statistically significant difference between Film and CR was found. The second hypothesis that the reject rate would be further reduced after the introduction of PACS and soft copy images with manipulation facilities was not accepted because whilst the introduction of PACS was associated with a further reduction in the reject rate, the change was not

shown to be statistically significant.

Table 6.1 Comparison of reject rates when the calculations are based on *the total number of examinations*

Modality	Total plain radiography examinations	Number of rejects involving irradiation	% Reject rate/examination
FILM	3904	385	9.9
CR	4502	365	8.1
PACS	6617	483	7.3

FILM-CR
Difference in proportions = 0.0175
99% Confidence Interval for the difference in proportions is 0.00136 to 0.033,
$p < 0.01$

CR-PACS
Difference in proportions = 0.00808
95% Confidence Interval for the difference in proportions is -0.00206 to 0.0182

FILM-PACS
Difference in proportions = 0.0256
99% Confidence Interval for the difference in proportions is 0.0108 to 0.0404,
$p < 0.01$

Table 6.2 Rejects for plain radiography body areas when the calculations are based on *the total number of examinations*

	Film		CR		PACS	
Body area	Number of exams	Rejects (%)	Total exams	Rejects (%)	Total exams	Rejects (%)
chest	2148	161 (7.5)	2413	105 (4.4)	3653	235 (8.9)
abdomen (no C/M)	231	20 (8.7)	307	26 (8.5)	386	40 (10.4)
skull	132	34 (25.8)	146	53 (36.3)	203	47 (23.2)
cervical spine	126	30 (23.8)	134	32 (23.9)	209	41 (19.6)
thoracic spine	57	29 (50.9)	43	3 (7.0)	79	9 (11.4)
lumbar spine	161	26 (16.1)	223	22 (9.9)	284	38 (13.4)
pelvis	122	17 (13.9)	178	23 (12.9)	219	10 (4.6)
hip	71	8 (11.3)	78	29 (37.2)	137	29 (21.2)
upper limbs & shoulder girdle	403	33 (8.2)	485	45 (9.3)	677	45 (6.7)
lower limbs excluding hips	453	27 (6.0)	495	27 (5.5)	706	31 (4.4)
Total exams	3904	385 (9.9)	4502	365 (8.1)	6617	525* (8.0)

* this total includes 36 rejects which did not involve irradiation of the patient, if these are excluded, the reject rate is 7.3%

Table 6.3 Reasons for rejection of plain radiography images when the calculations are based on *the total number of examinations*

Reason for rejection	FILM Total = 385	CR Total = 365	PACS* Total = 498
patient position, radiographic technique (A)	171 (44.7%)	304 (83.3%)	391 (78.5%)
patient movement (B)	20 (5.2%)	2 (0.55%)	7 (1.4%)
incorrect exposure ©	125 (32.5%)	6 (1.6%)	24 (4.8%)
x-ray equipment fault (D)	12 (3.1%)	0	15 (3.0%)
processing, fogging (E)	15 (3.4%)	n/a	n/a
CR technique (H)	n/a	14 (3.8%)	30 (6.0%)
incorrect organ code (J)	n/a	5 (1.4%)	0
Digiscan fault (K)	n/a	4 (1.1%)	7 (1.4%)
AC1 fault (L)	n/a	0 (0%)	n/a
not required** (F)	12 (3.1%)	3 (0.82%)	16 (3.2%)
miscellaneous (G)	32 (8.3%)	27 (7.4%)	8 (1.6%)

* Some images could not be fetched and viewed, so reasons for rejection could not be identified.

** These rejects DO NOT involve irradiation of the patient

Table 6.4 Reason for rejecting image [number (%) of rejects for body area] FILM

Body area	A	B	C	D	E	F	G	Total rejects for body area
chest	64 (39.8)	11 (6.8)	54 (33.5)	3 (1.9)	6 (3.7)	5 (3.1)	18 (11.2)	161
abdomen (no C/M)	4 (20)	1 (5)	9 (45)	1 (5)	0 (0)	1 (5)	4 (20)	20
skull	22 (64.7)	3 (8.8)	4 (11.8)	0 (0)	2 (5.9)	0 (0)	3 (8.8)	34
c.spine	13 (43.3)	3 (10)	11 (36.7)	2 (6.7)	0 (0)	1 (3.3)	0 (0)	30
t.spine	13 (44.8)	0 (0)	13 (44.8)	2 (6.9)	1 (3.4)	0 (0)	0 (0)	29
l.spine	18 (69.2)	1 (3.8)	4 (15.4)	1 (3.8)	1 (3.8)	1 (3.8)	0 (0)	26
pelvis	5 (29.4)	0 (0)	6 (35.3)	3 (17.6)	1 (5.9)	2 (11.8)	0 (0)	17
hip	6 (75)	0 (0)	2 (25)	0 (0)	0 (0)	0 (0)	0 (0)	8
upper limbs & shoulder girdle	13 (39.4)	1 (3.0)	12 (36.4)	1 (3.0)	1 (3.0)	2 (6.1)	4 (12.1)	33
lower limbs excluding hips	13 (48.1)	0 (0)	10 (37.0)	1 (3.7)	1 (3.7)	0 (0)	3 (11.1)	27

A, patient position, radiographic technique; B, patient movement; C, incorrect exposure; D, X-ray equipment fault; E, processing, fogging; F, not required; G, miscellaneous.

Table 6.5 Reason for rejecting image [number (%) of rejects for body area] CR

Body area	A	B	C	D	H	J	K	L	F	G	Total rejects for body area
chest	88 (83.8)	0 (0)	2 (1.9)	0 (0)	2 (1.9)	2 (1.9)	4 (3.8)	2 (1.9)	0 (0)	5 (4.8)	105
abdomen (no C/M)	21 (80.8)	1 (3.8)	0 (0)	0 (0)	3 (11.5)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3.8)	26
skull	48 (90.1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.9)	0 (0)	0 (0)	0 (0)	4 (7.5)	53
c.spine	23 (71.9)	0 (0)	01 (3.1)	0 (0)	1 (3.1)	0 (0)	0 (0)	0 (0)	0 (0)	7 (21.9)	32
t.spine	2 (66.7)	0 (0)	1 (33.3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3
l.spine	17 (77.3)	0 (0)	2 (9.0)	0 (0)	0 (0)	1 (4.5)	0 (0)	0 (0)	0 (0)	2 (9.0)	22
pelvis	19 (82.6)	0 (0)	0 (0)	0 (0)	1 (4.3)	0 (0)	0 (0)	0 (0)	0 (0)	3 (13.0)	23
hip	27 (93.1)	0 (0)	0 (0)	0 (0)	1 (3.5)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3.5)	29
upper limbs & shoulder girdle	34 (75.5)	2 (4.4)	0 (0)	0 (0)	4 (8.9)	1 (2.2)	0 (0)	0 (0)	0 (0)	4 (8.9)	45
lower limbs excluding hips	25 (92.6)	0 (0)	0 (0)	0 (0)	1 (3.7)	1 (3.7)	0 (0)	0 (0)	0 (0)	0 (0)	27

Total = 365

A, patient position, radiographic technique; B, patient movement; C, incorrect exposure; D, X-ray equipment fault; H, CR technique; J, incorrect organ code; K, Digiscan fault; L, hard copy processor fault; F, not required; G, miscellaneous. Note: code E not applicable

Table 6.6 Reason for rejecting image (% of rejects for body area) PACS

Body area	A	B	C	D	H	K	F*	G	Rejects with unknown reason**	Total rejects for body area
chest	178 (75.7)	4 (1.7)	1 (0.4)	5 (2.1)	7 (3.0)	2 (0.8)	12 (5.6)	5 (2.1)	21	235
abdomen (no C/M)	29 (72.5)	1 (2.5)	1 (2.5)	4 (10.0)	0 (0)	1 (2.5)	4 (10.0)	0 (0)	0	40
skull	41 (87.2)	1 (2.1)	1 (2.1)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4.2)	2	47
c.spine	28 (68.3)	0 (0)	1 (2.4)	0 (0)	4 (9.8)	0 (0)	1 (2.4)	1 (2.4)	5	41
t.spine	6 (66.7)	0 (0)	1 (11.1)	0 (0)	0 (0)	0 (0)	2 (22.2)	0 (0)	0	9
l.spine	25 (65.8)	0 (0)	0 (0)	0 (0)	3 (7.9)	1 (2.6)	8 (21.1)	0 (0)	1	38
pelvis	7 (80.0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (12.5)	0 (0)	2	10
hip	20 (69.0)	0 (0)	3 (10.3)	1 (3.5)	4 (13.8)	0 (0)	0 (0)	0 (0)	2	29
upper limbs & shoulder girdle	22 (48.9)	0 (0)	10 (23.2)	0 (0)	8 (17.8)	1 (2.2)	2 (4.4)	0 (0)	2	45
lower limbs excluding hips	23 (76.7)	0 (0)	0 (0)	1 (3.2)	1 (3.2)	1 (3.2)	1 (3.2)	0 (0)	4	31

Total = 525

* These rejects DO NOT involve irradiation of the patient.

** Images could not be fetched and viewed, so reason for rejection unknown.

A, patient position, radiographic technique; B, patient movement; C, incorrect exposure; D, X-ray equipment fault; H, CR technique; K, Digiscan fault; F, not required; G, miscellaneous. Note codes E, J and L not applicable

Table 6.7 Rejects for plain radiography body areas when the calculations are based on the *total number of images taken*

	Film*		PACS**	
Body area	Number of images	Rejects (%)	Total images	Rejects (%)
chest	2204	161 (7.3)	4502	217 (4.8)
abdomen (no C/M)	429	20 (4.7)	413	29 (7.0)
skull	233	34 (14.6)	444	44 (9.9)
cervical spine	202	30 (14.9)	512	44 (8.6)
thoracic spine	121	29 (24.0)	144	7 (4.9)
lumbar spine	308	26 (8.4)	682	46 (6.7)
pelvis	137	17 (12.4)	262	19 (7.3)
hip	152	8 (5.3)	223	23 (10.3)
upper limbs & shoulder girdle	414	33 (8.0)	926	33 (3.6)
lower limbs excluding hips	685	27 (3.9)	1480	26 (1.8)
Total exams	4885	385 (7.3)	9588	488(5.1)

* These data were collected by the methods detailed in the reject analysis of films.

** Data supplied from PACS system September 1997.

NB. Comparable data on the number of images used during the CR period is not available.

CHAPTER 7

THE IMPACT OF PACS ON UNAVAILABLE IMAGES AND ASSOCIATED PATIENT RADIATION DOSES

7.1 INTRODUCTION

In the preceding chapters observational studies have been described which measured the effect of PACS on the radiation doses to patients undergoing radiographic examinations of the lateral lumbar spine (chapter 4) and the chest (chapter 5) and the change in the number and nature of images which had to be rejected because they were unsatisfactory, necessitating additional radiation doses for patients (chapter 6). This chapter will address the issue of 'lost' or 'unavailable' images which may necessitate repeat examinations and additional patient doses. It has been suggested that *'with a secure and accessible archive of imaging studies (with PACS), the need for repeat exams is reduced, thereby decreasing the amount of unnecessary radiation to the public'* [Belloto, 1997] and, with PACS there is an '*elimination of re-takes due to lost films, which are often necessary in film-based departments'* [Mosser et al, 1994]. Sullivan has claimed that lost images have been eliminated by the use of PACS in part of a hospital in which 20% of images were lost when film was used, and where most of these images were repeated with additional patient doses [Sullivan, 1998]

It is important to define the term 'lost' image as used in this chapter. In the United States the term 'lost' image, or 'lost' examination is used to describe images or examinations which are not available for the radiologist to report on and which represent a loss of income since the radiologist is only paid by the medical insurance companies when the examination has been reported. In the UK, the term 'lost' is sometimes used to describe those images which cannot be traced. If it is known that the images are at another hospital, on a ward or in the reporting room when they are required in an out-patients clinic, those images are not defined as 'lost' because their location is known. In this chapter lost images are defined as 'images which are unavailable when clinically required'. This pragmatic definition has been adopted because it encompasses the concept of the images being required in order to make decisions about the patient's treatment and management, rather than solely an audit of the efficiency of the image tracking system. If the image is not available the clinician may be able to make these decisions based on the x-ray report alone if it is available, but in some situations such as when a fractured bone is to be reduced, and the exact position of the bony parts must be known, the images are essential. By its definition, a hospital wide PACS controls the storage and distribution of radiographic images. It may, in addition handle the reports of the radiographic examinations, but not necessarily and so, the effect of PACS on image availability only will be discussed.

This chapter is presented in three sections

- a quantitative study of lost images for outpatients clinics
- a survey of hospital clinicians to elicit their views on lost images
- an estimation of the magnitude of the effect of lost images on patient doses

7.2 STUDY TO DETERMINE HOW MANY IMAGES ARE 'LOST'

7.2.1 Introduction

Many patients who attend outpatient clinics have already undergone relevant x-ray examinations prior to their clinic appointments. It is therefore important that the clinician who sees the patient in the clinic has access to the previous images so that a decision about the most appropriate management of each patient may be made.

When conventional film images were used they had to be located and taken to the clinic prior to being required with the possibility that the film packets could not be located. As a result, the images were unavailable to the clinicians in the clinic and the clinician had to make the decision whether to order a repeat examination, thus exposing the patient to additional radiation, or to proceed with the patient's treatment without the benefit of the x-ray films. When a whole hospital PACS system is used, in principle, all images should be available to any user on any workstation in the hospital at any time, thus removing the problems caused by unavailable films.

A study was undertaken to assess the size of the problem of film unavailability before PACS was used and then to establish whether, when PACS was operational, all images were available and on line for all patients with booked outpatients appointments.

7.2.2 Methods

The research method used was a before and after comparison of the numbers of patients for whom examinations were unavailable in selected busy outpatient clinics at the Hammersmith Hospital. The busiest clinics were on Thursday mornings and so data were collected for these clinics. However, the method of collection of the data was inevitably different during the two parts of the study.

During the period July 1992 to June 1994, when film was used, data were collected in order to establish a baseline which could be compared with the situation after PACS became operational. Data were collected for a sample of clinics which included fracture clinic and respiratory medicine clinics - the two clinics which generated the most work for filing clerks preparing films for the clinics, and for which the viewing of previous images is of particular importance for the correct management of the patient.

In this period, when film images were being used, the filing clerks received printed clinic lists from the hospital information system (ICHIS) against which they checked

each patient on the radiology information system in order to determine whether the patient had previously been x-rayed at the Hammersmith and, for those patients who had previous examinations, the location of the film packet. The filing staff marked the list with both items of information and then indicated whether they were able to retrieve the film packet. When all possible film envelopes were retrieved, they were taken to the outpatients clinic and the lists, which were no longer required, were discarded. For the purpose of this research, the filing clerks retained the lists and they were used to identify the number of patients for each clinic who had any previous x-ray examinations and for these patients, the number of film packets which could not be retrieved by the filing clerks before the clinic. It was not possible to determine whether the films of interest were actually in the film envelopes, so the data may underestimate the magnitude of the true missing film problem.

After PACS became operational, lists of patients attending outpatient clinics were automatically transferred from the hospital information system (ICHIS) to PACS just after midnight prior to the clinics being held. All examinations which have been taken within the last year and are not already on line i.e. in the short term archive (WSU) and available for immediate viewing, are fetched from the long term archive and transferred to the WSU ready for viewing in the clinics. Older examinations have to be fetched manually which involves a user identifying the appropriate patients and examinations on a PACS work list, highlighting each examination and clicking on 'fetch'. This process takes only a short time for the user and retrieval from the long term archive should take about 3 minutes. At busy times when there is a heavy demand on the system, the fetching process may take longer than 3 minutes before the images can be viewed. However, when PACS is used, all images should be available to users within 3 minutes.

When PACS was used, the patients examinations were automatically fetched from the long term archive so that they were available for viewing in clinic within three seconds. A PACS software programme, written specifically for the purposes of this research project, indicated both the examinations which were 'on line' (in the WSU

and available for immediate viewing), and those which were 'off line' (in the long term archive and not available for immediate viewing), at 8.00am prior to the start of Thursday morning clinics. The time 8.00am[1] was chosen because it was before routine viewing of images occurred and thus the programme did not effect the work of the hospital by slowing down the system. In addition, at 8.00am, it was unlikely that a clinician would have personally fetched an examination, thus all on line examinations would be the result of automatic fetching by PACS.

The ICHIS clinic lists for Thursday mornings were printed for comparison with the PACS lists. The system was piloted for several weeks and the lists were checked before 9.00am to ensure that the programme was operating correctly and identifying examinations which were off line. The programme had to be manually started each week so unfortunately could not be operated at times when the PACS software system administrator was away from the hospital. Thus, data were collected for nine non-consecutive weeks during the period 24th October 1996 to 23rd January 1997.

7.2.3 Results

The number of x-ray film packets requested and the number which were not found by the x-ray filing staff prior to the start of Thursday morning clinics during the film period are shown in Tables 7.1, A2.1 and A2.2. On only one occasion were all the required packets available. For the 70 weeks for which data were available, the mean number of packets requested was 155 (median 169) and of these a mean of

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[1] It was known from the observational study in the fracture clinic [Bryan et al, 1998] that examinations were sometimes off line by the time the patient was seen, even though they may have been on line at the start of the clinic. This often occurred because the patients were seen after the booked appointment times and therefore PACS had automatically removed the examinations from the WSU. An attempt was made to quantify this problem by repeating the running of the PACS programme at 11.30am and 1.00pm on Thursday mornings, in addition to the 8.00am programme run. However, it slowed down the PACS so much that clinical work was affected and the run was aborted and not reattempted. This study was conducted before the WSU was upgraded to the larger capacity ISU and it is acknowledged that there should now be no problems of examinations going off line before they are viewed in clinic. In addition, all examinations for patients attending morning clinics are now protected to remain on the ISU until 2.00 pm so that if the patient's appointment time has passed, the examinations are still immediately available for viewing by clinicians. Similarly, examinations for afternoon clinics are protected until after the end of the clinics.

14% (median 13%) were missing. The fracture clinic requested the highest number of packets (mean 76, median 76) and of these a mean of 12% (median 10%) were unavailable. The respiratory medicine clinics requested fewer packets, (mean 27, median 28) but a higher percentage (mean 15%, median 14%) were missing before the clinic (Figures 7.1-7.3).

When PACS was operational, contrary to expectations, some examinations were off line each week (mean 17%, range 0.3% - 100%), although not always for the fracture and respiratory medicine clinics (Tables 7.2, A2.3 and A2.4). This mean percentage is higher than when film was used because there were two occasions when a high number of examinations were off line and on the first occasion all examinations were off line and on the second occasion 38% of all examinations were off line. For the remaining seven weeks monitored the mean number of images unavailable was 1.7% of those required (Figure 7.4).

7.2.4 Discussion

In the film study, data were collected about the number of film packets which were unavailable. It was assumed for those packets which were found that they contained the relevant x-ray examinations. It was not possible in this study to determine how many examinations were actually missing from the packets. Thus the problem of unavailable images when film was used, may well have been greater than the results of this study indicate. In the PACS study data were collected concerning the number of examinations which were on line and available for immediate viewing before the start of the out patient clinics. It was not known whether the examinations were on line when the clinician wanted to view them, or if the equipment in the consultation rooms was in working order. During the observational study in fracture clinic it was seen that images were often not on line and thus the availability of PACS examinations may be an over estimate of the number which were on line and could be viewed immediately by clinicians.

When film was used, all previous x-rays which were available in the film packets were presented to the clinicians. However, when PACS was used only those

examinations which had been undertaken in the previous year before the appointment were fetched automatically. If the clinicians wished to view older examinations, they had to fetch these from archive themselves. Thus all examinations would be available to clinicians when PACS was operational, but only those within the previous year could be accessed in three seconds, others could take 3 minutes or longer to be fetched from archive.

The availability of PACS examinations was generally very good but on one occasion when the programme was run all the examinations were off line at 8.00am. This was because one of the two archive controllers had failed during the night and no examinations were automatically retrieved from archive. The archive controller was restarted and the examinations fetched manually. In the past such failures of one of the two archive controllers occurred almost every day. If the failure occurred during the normal working day, it was noticed and restarted by the system administrator. However, if the failure occurred during the night, it was normally unnoticed and caused a problem with automatic fetching from archive. The system administrator started work at 7.00am and was able to restart the archive controller if necessary at that time, thus ensuring that all required examinations were fetched and available at the start of morning clinics. In September 1997 a sensor fault was detected and the sensor was replaced. It appeared that this solved the problem of the archive controllers failing to work and there had been no further crashes by November 1997 when the system administrator left and records for this study ceased.

On the second occasion when all examinations were off line for the fracture and respiratory medicine clinics, some, but not all of the examinations required for the other clinics that morning were also off line and a total of 38% of the required examinations were off line. This was not a problem caused by an archive controller failure and its cause remained unknown to the PACS system administrator.

7.3 A SURVEY OF HOSPITAL CLINICIANS TO ELICIT THEIR VIEWS ON LOST IMAGES

7.3.1 Method

A survey was conducted to obtain the views of the users and providers of the radiology services at Hammersmith Hospital and in addition at five comparator hospitals which did not install a PACS but continued to use a conventional film system. One group of staff surveyed were hospital clinicians working in departments which were users of radiological images. The comparator hospitals (Conquest, Norfolk and Norwich, Royal Free, Nottingham City and John Radcliffe) were surveyed so that an impression could be gained about how satisfaction, which could not be related to PACS, changed over time and thus identify whether there was a different pattern of satisfaction at the Hammersmith which might be due to PACS. Clinicians of all grades in these departments were sent a postal survey annually between 1993 and 1996 to elicit their views on the service provided and their satisfaction with that service. If they did not respond to the first questionnaire, a reminder and a second copy of the questionnaire was sent. The clinicians' names did not appear on the questionnaire so that their individual opinions could not be identified.

The questionnaire included a section concerning 'lost' or 'unavailable' images which it defined as 'unavailable when clinically required' so that there could be no confusion about the definition of 'lost' image. It asked whether there was a problem with lost images and if so, subjective estimates of the extent of the problem. In addition the clinicians were asked whether, if the original images were lost, they would order a repeat examination and how often they did this. The exact questions used in the survey are shown in Box 7.1. A copy of the questionnaire is included in Appendix 3 and further details about the survey are included at the end of this thesis in the paper by Bryan et al (1999b).

Box 7.1 Question 21 of Clinician Questionnaire

Question 21

Do you ever order a repeat examination if the original image is lost?

Yes ☐ No ☐

If YES, how many? (please tick)

Less than 1 repeat examination per month	1-2 repeat examinations per month	3-4 repeat examinations per month	More than 4 repeat examinations per month
☐	☐	☐	☐

7.3.2 Results

A total of 4793 questionnaires were sent in four distributions. The mean overall response rate across all hospitals was 54% (range 37% - 71%). The proportion of respondents who considered that there was a problem with lost images of inpatients and outpatients fluctuated over time at all hospitals (Figures 7.5 and 7.6). The largest change was at the Hammersmith where, in 1996 after the implementation of the hospital-wide PACS, there was a significant decrease in the perceived problem of lost images ($p<0.01$). The decrease occurred for both inpatients and outpatients, but was most marked for inpatients.

Although the magnitude of the problem was reduced with PACS, there was some indication that there was still a problem for both in-patients and out-patients, but with only 1% or less being unavailable (Figures 7.7 and 7.7).

Although clinicians were aware that images were unavailable, they rarely ordered repeat examinations. At all hospitals, in all rounds, the majority of respondents said that they ordered less than one repeat examination a month (Tables 7.3 and A2.5 to A2.9).

7.3.3 Discussion

It is possible that the estimates made by the clinicians are higher than the number of examinations which are actually repeated. When film is used, if a clinician writes a request for an examination and states that it is required because the original films are lost, every effort is made to locate the films. On some occasions the films are found and the repeat examination is not undertaken. When PACS is used, images may have been 'lost' because the clinician was not prepared to wait for the examinations to be retrieved from the long term archive. In theory retrieval time should be about 3 minutes, but it was found that at busy times retrieval times were much longer as already discussed in 7.1.5.

7.4 AN ESTIMATION OF THE EFFECT OF LOST IMAGES ON PATIENT DOSES

7.4.1 Method

An estimate has been made of the number of examinations which might be repeated because the previous images were unavailable, and thus to determine the magnitude of the additional radiation dose to the patient populations in the hospitals surveyed.

The number of clinicians in the survey previously described who estimated that they ordered additional examinations, and the estimates of the number of examinations ordered, are shown in Tables 7.3 and A2.5 to A2.9. An estimate of the numbers of repeat examinations ordered was made by taking the maximum number of examinations in each category. So, where the clinicians estimated 'less than one repeat per month', it was taken that one examination was ordered. For '1-2 repeats per month', a value of two repeats was used, where the estimate was '3-4 repeats per month', a value of four repeats was taken, and where the estimate was 'more than 4 repeats per month' a value of four was used. An estimate of the total number of repeat examinations ordered at each site for each round was then calculated. These totals were then expressed as a proportion of the workload of each hospital at that time, using the relevant Korner data as the denominator at each site.

7.4.2 Results

Korner data were available from the NHS Executive for three of the hospitals: Nottingham City, Royal Free and Conquest, and from KH12 returns provided by the Hammersmith Hospital. Similar data were not available for the John Radcliffe and Norfolk and Norwich Hospitals because these hospitals had each formed a Trust with other hospitals during the time period considered and separate hospital data were unavailable. The workloads increased over time at all hospitals each year apart from one small decrease at the Conquest Hospital (Table 7.4).

The estimated number of requests for repeat examinations because the original images were lost, is shown in Table 7.5 and also expressed as the proportion of each hospital's workload. The estimated proportion of the workload which is repeated is remarkably similar at all hospitals except for in 1993 at Hammersmith which is higher than all other estimates, and in 1996 for Hammersmith and Conquest Hospitals where the values are lower than at other sites.

7.4.3 Discussion

The results suggest that the use of PACS in 1996 did reduce the proportion of the workload which needed to be repeated because the original examination was lost. However, in 1996 a similar reduction was seen at Conquest Hospital which did not have a PACS, but was using a film system. Conquest Hospital opened in July 1992 with the intention of being film less. As such there were no film files in the hospital. The files were at another hospital (Bexhill) about 6 km away. The plan was that if it was known that old films were required for an outpatient clinic, the relevant images would be digitized at Bexhill and transmitted via a telephone line to Conquest where they would be available on the hard disk of a predetermined workstation. Workstations were available in Radiology, Accident and Emergency and Orthopaedics. If films were required urgently or unexpectedly, they would be transported by road by hospital transport. The PACS did not work and film was required for all patients with the result that piles of film envelopes accumulated in all parts of the radiology department. By 1996, the situation regarding film storage had become so bad and the PACS had failed to become operational, that the space

within the radiology department was reorganised in order to provide on site storage and filing of old films. This major change in film storage coincided with the decrease in the lost image problem which was seen in the 1996 questionnaire results.

The estimates of the size of the lost image problem at the hospitals surveyed is much lower than those which have been made by others at conferences. One such claim was made by Hruby in 1999 who suggested that 10% of all images undertaken are repeated because they are lost, necessitating a 10% increase in patient doses. [Management in Radiology Conference, Strasbourg 1999].

7.5 CONCLUSIONS

When film was used at the Hammersmith Hospital there was a constant problem with a mean of 14% of films packets being unavailable for clinicians in Out Patient clinics. This problem was not completely eradicated when PACS was used and during this study there were always some examinations (0.3% to 100%) which were off line at the start of the clinics. For two of the nine weeks monitored during the study, no examinations were available for immediate viewing at the start of the respiratory medicine and fracture clinics and the clinicians would have had to retrieve the examinations manually. The cause of the unavailable images for one of these weeks was identified as an archive controller failure which appears to have been repaired, but the cause of the problem on the other week remains unknown.

The subjective opinions of hospital clinicians surveyed were that there were problems with unavailable images at all hospitals. At the Hammersmith Hospital after PACS was used there were still some problems with lost images, although there was a significant reduction in the number of respondents who considered this a problem. The number of repeat examinations was low, predominantly less than one a month at all sites surveyed.

If, when PACS is used all repeats due to lost images could be eliminated, at the hospitals in this study, a mean of 1.4% reduction in patient population radiation dose could be achieved.

Table 7.1 Film packets requested and missing for ALL Thursday morning clinics, including fracture & respiratory medicine clinics, when film was used

	Packet requested	Packets missing	Percent missing
N	70	70	70
Mean	155.4	21.2	14.0
SD	61.0	11.9	7.7
Median	168.5	21	13.1
Range	234 (1-235)	50 (0-50)	57.1 (0-57.1)
Q3-Q1	47	18	7.7

Table 7.2 Examinations requested and on line at the start of Thursday morning out-patient clinics when PACS was fully operational

Date of clinics	Exams required	Exams ON line	Exams OFF line	% Exams OFF line
24.10.96	1248	1211	37	2.97
31.10.96	1086	1083	3	0.28
7.11.96	566	553	13	2.30
14.11.96	406	400	6	1.48
5.12.96	781	777	4	0.51
12.12.96	645	638	7	1.09
19.12.96	626	603	23	3.67
9.01.97	Unknown*	0	ALL	100
23.01.97	1210	749	461	38.10

* No PACS print outs were available

Table 7.3 Hammersmith Hospital - Frequency of repeat examination ordering

	DEC93 (round %)	JUN94 (round %)	JUN95 (round %)	JUN96 (round %)
Less than one repeat per month	62 (60%)	43 (53%)	56 (69%)	60 (88%)
1-2 repeats per month	27 (26%)	29 (36%)	19 (24%)	5 (7%)
3-4 repeats per month	9 (9%)	6 (7%)	5 (6%)	0
More than 4 repeats per month	6 (6%)	3 (4%)	1 (1%)	3 (4%)
Total	104	81	81	68

Table 7.4 Summary of annual (mean monthly) Korner data for Imaging for the period 1992-1996 (excluding Nuclear Medicine and Interventional studies)

Year	Hammersmith	Nottingham City	Royal Free	Conquest
1992-93	69, 990* (5832)	109,981 (9165)	110,730 (9227)	***
1993-94	77,088 (6424)	112,509 (9375)	113,616 (9468)	73,268 (6105)
1994-95	77,835* (6486)	129,873 (10822)	121,719 (10143)	73,119 (6093)
1995-96	79,529** (6627)	141,659 (11805)	123,552 (10296)	82,289 (6857)

* KH12 returns provided by Hammersmith Hospital

** Returns included other hospitals in Hammersmith Hospitals NHS Trust

All other data provided by NHS Executive, Quarry House, Leeds

*** hospital opened in July 1992, so full data not available for the year

NB Comparable data for John Radcliffe and Norfolk & Norwich Hospitals not available because these hospitals formed Trusts with other hospitals and data for individual hospitals were not available

Table 7.5 Estimate of the number of additional examinations (% Korner units) required per month because images were lost

Hospital	1993	1994	1995	1996
Hammersmith	182 (3.1)	84 (1.3)	86 (1.3)	41 (0.6)
Nottingham City	*	96 (1.0)	151 (1.4)	192 (1.6)
Royal Free	*	140 (1.5)	131 (1.2)	163 (1.4)
Conquest	**	84 (1.4)	86 (1.4)	41 (0.6)

* the questionnaires were not distributed to these hospitals in this round

**Korner data unavailable for complete year

Figure 7. 1 Number of film packets requested and number unavailable for ALL Thursday morning Out -Patient Clinics when FILM was used.

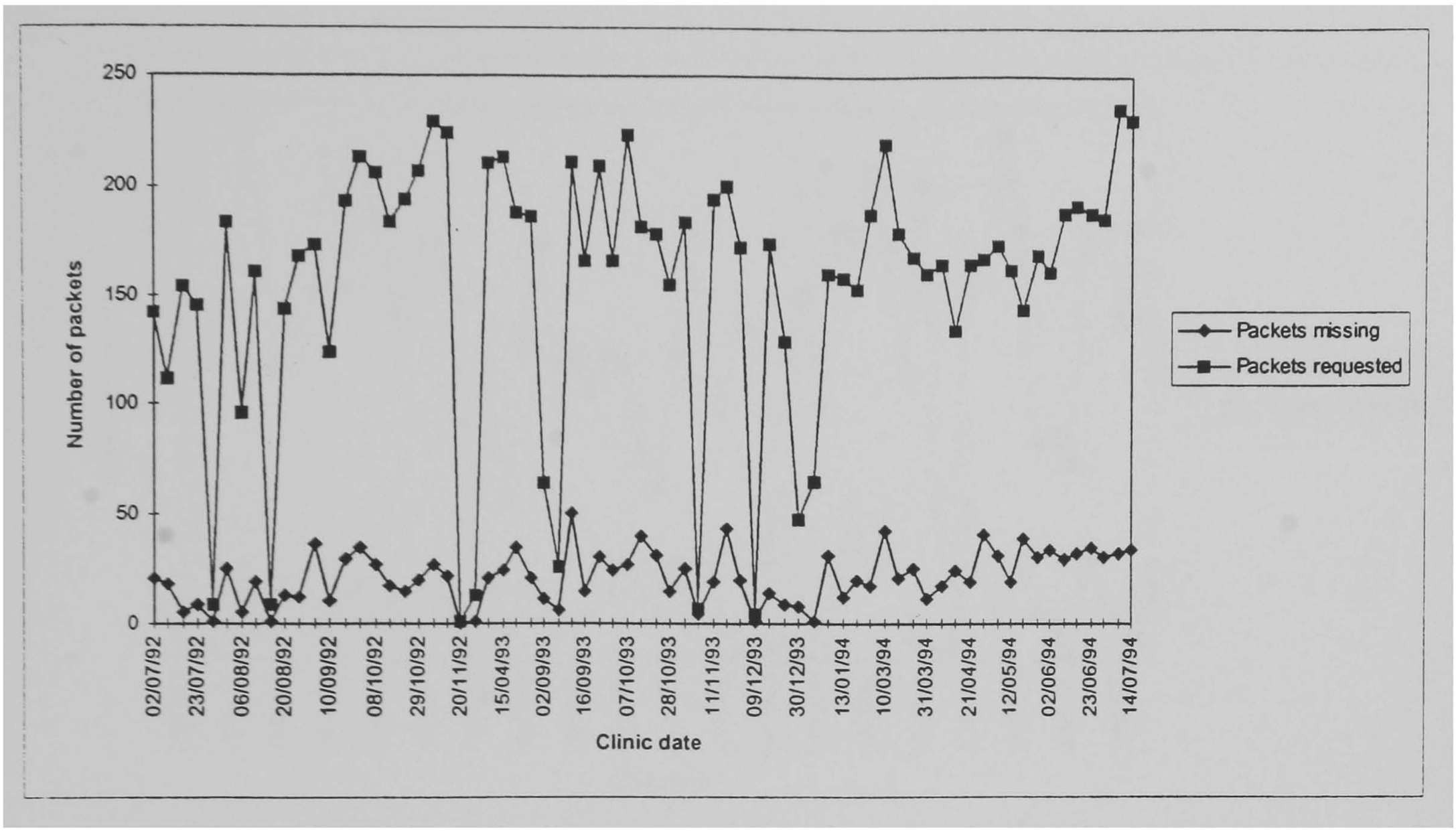


Figure 7.2: Number of film packets requested and number unavailable for Thursday morning Fracture Clinic when FILM was used.

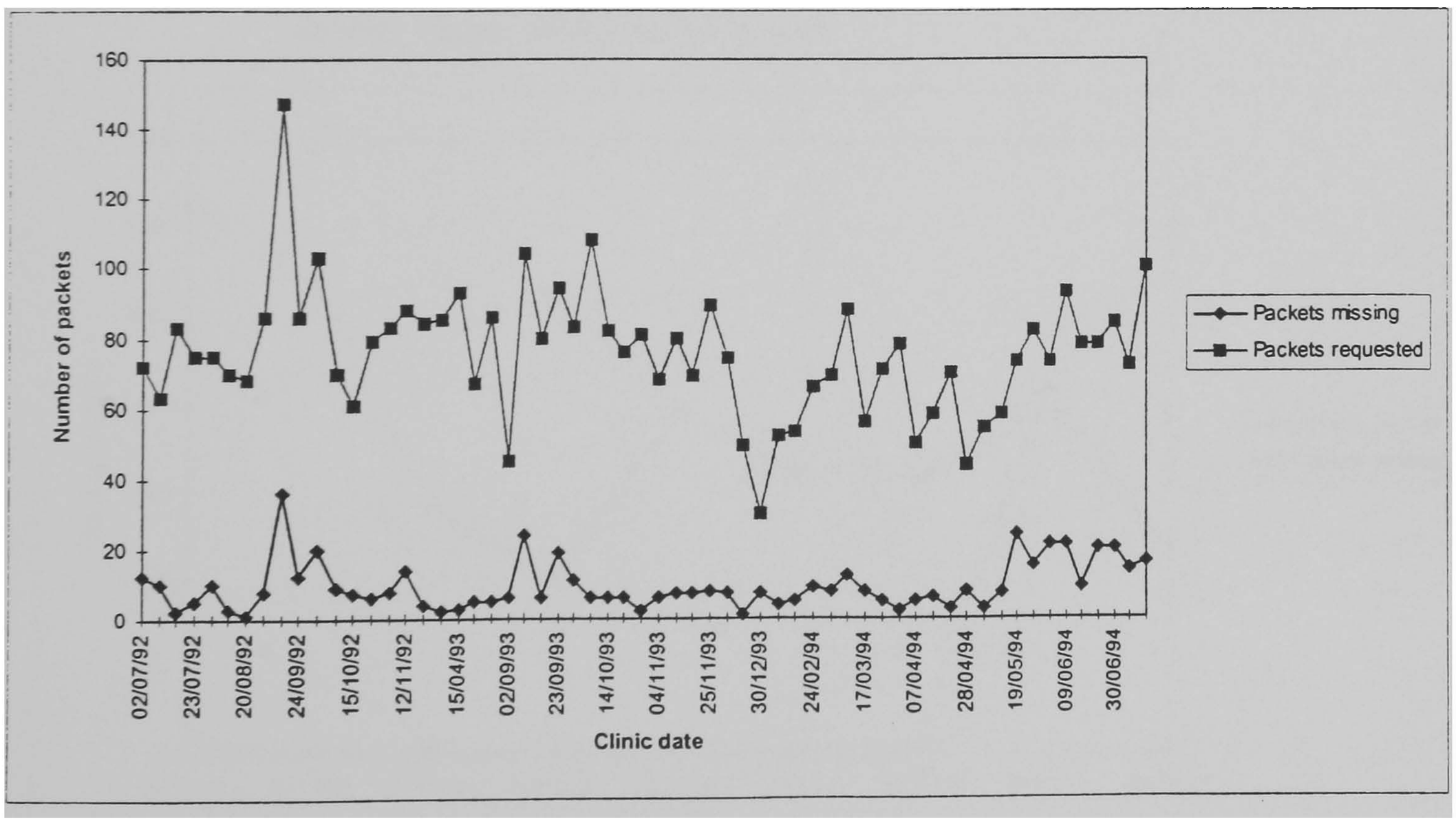


Figure 7.3: Number of film packets requested and number unavailable for Thursday morning Respiratory Medicine Clinics Out -Patient Clinics when FILM was used.

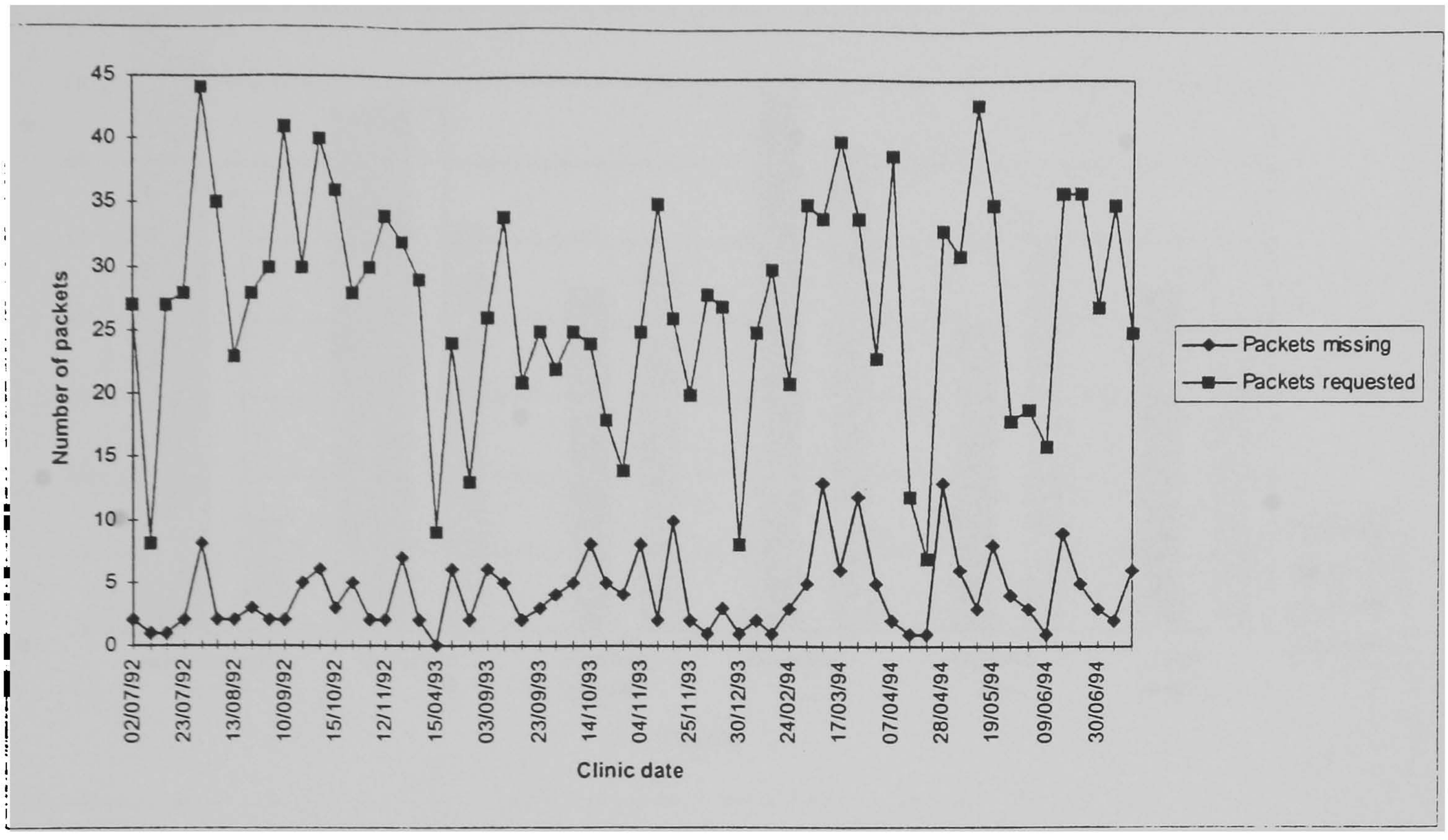
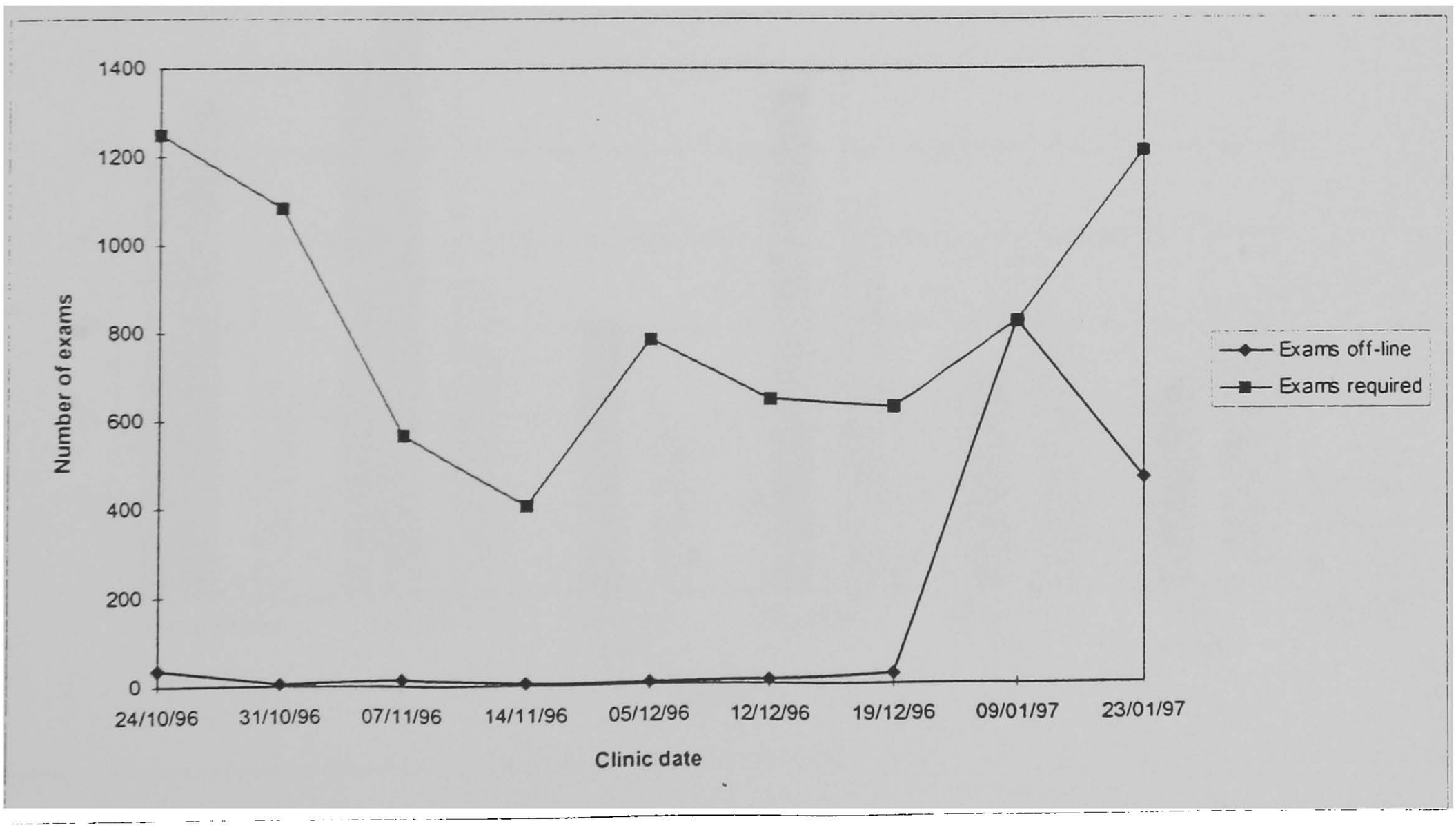


Figure 7.4: X-Ray examinations required and OFF line for ALL Thursday morning Out-Patients Clinics when PACS was used.



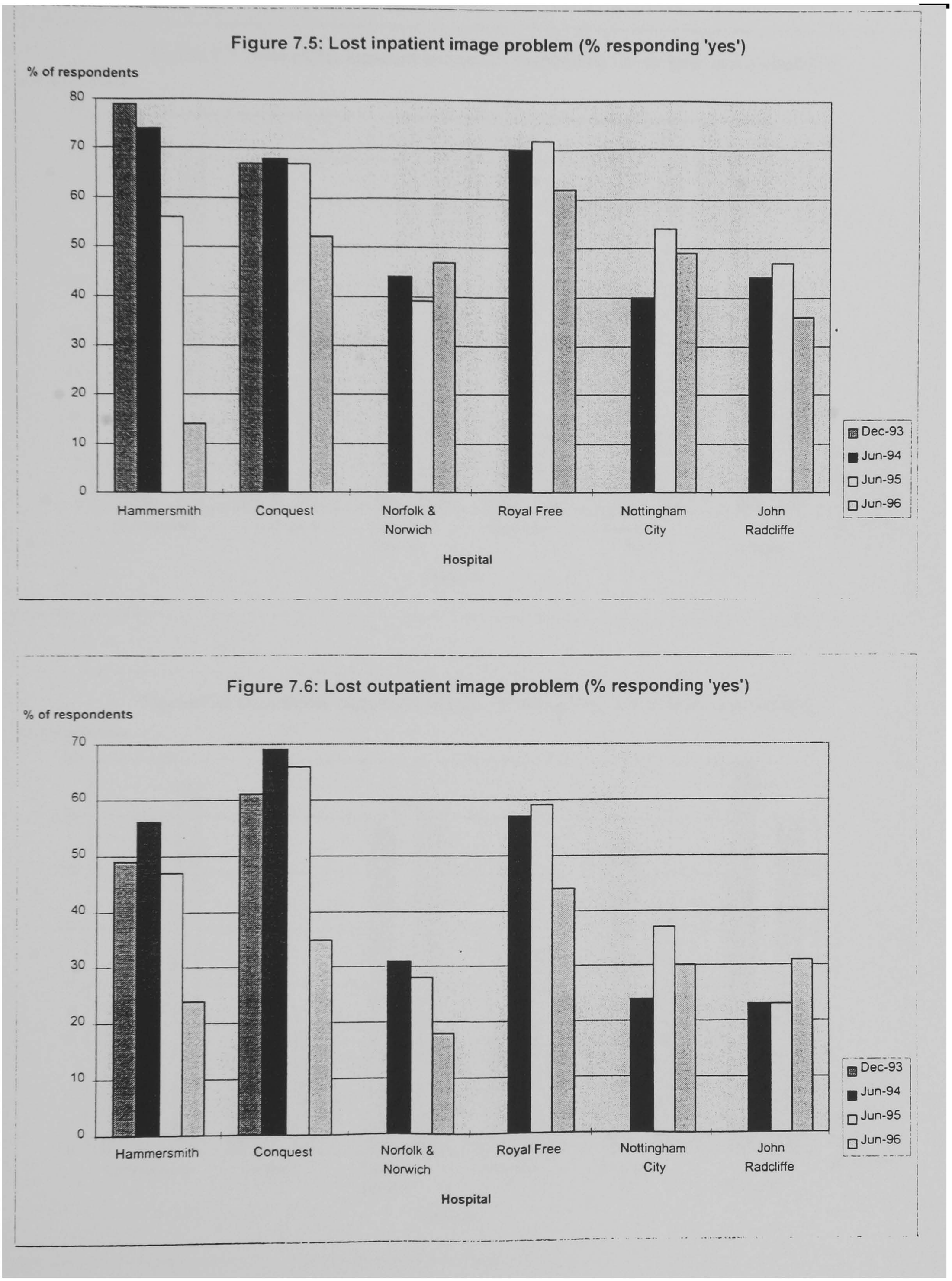


Figure 7.5: Lost inpatient image problem (% responding 'yes')
% of respondents
80
70
60
50
40
30
20
10
0
Hammersmith
Conquest
Norfolk & Norwich
Royal Free
Nottingham City
John Radcliffe
Hospital
Dec-93
Jun-94
Jun-95
Jun-96
Figure 7.6: Lost outpatient image problem (% responding 'yes')
% of respondents
70
60
50
40
30
20
10
0
Hammersmith
Conquest
Norfolk & Norwich
Royal Free
Nottingham City
John Radcliffe
Hospital
Dec-93
Jun-94
Jun-95
Jun-96

Figure 7.7: Unavailable inpatient images (% responding '1% or less' unavailable)

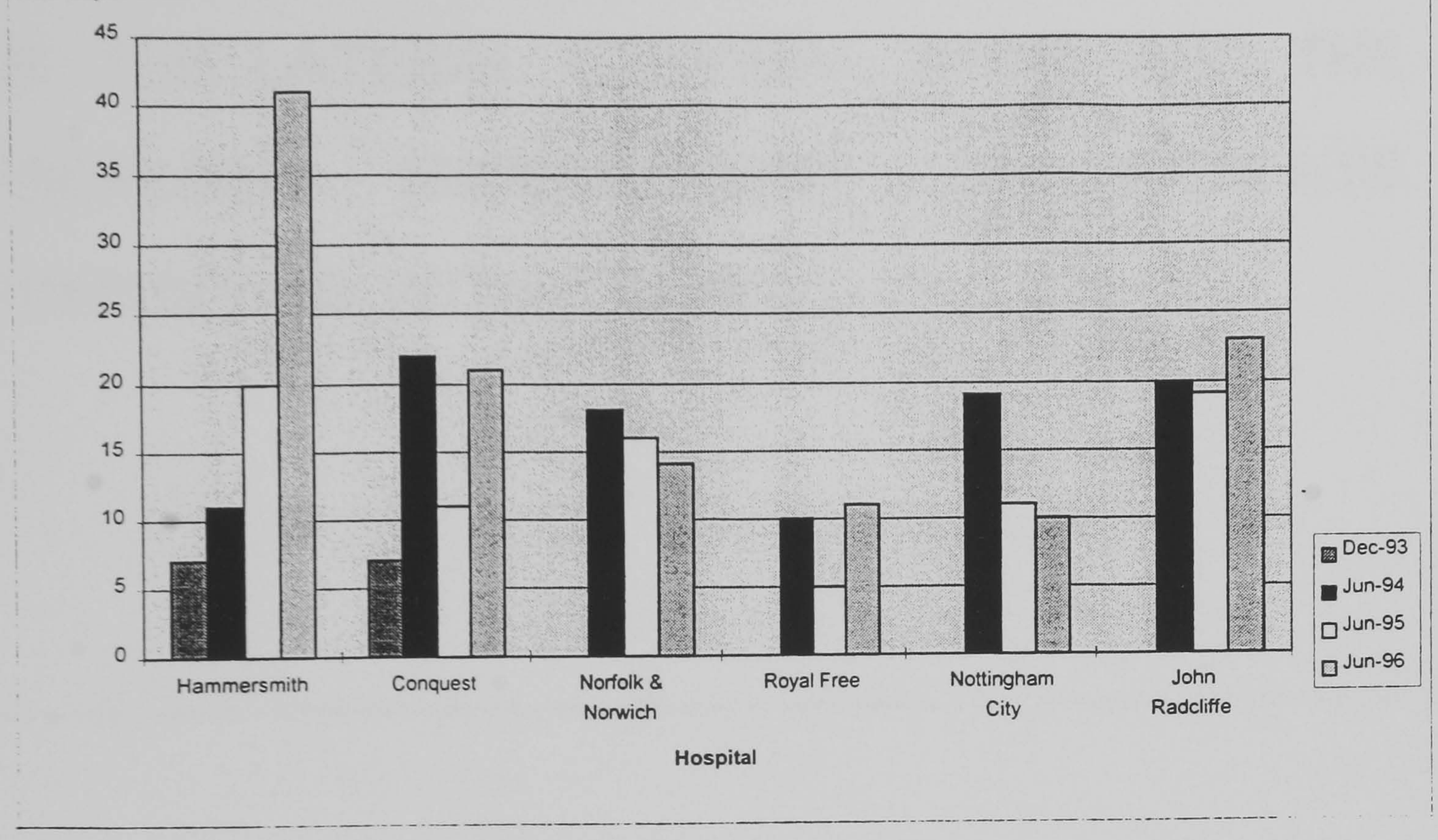
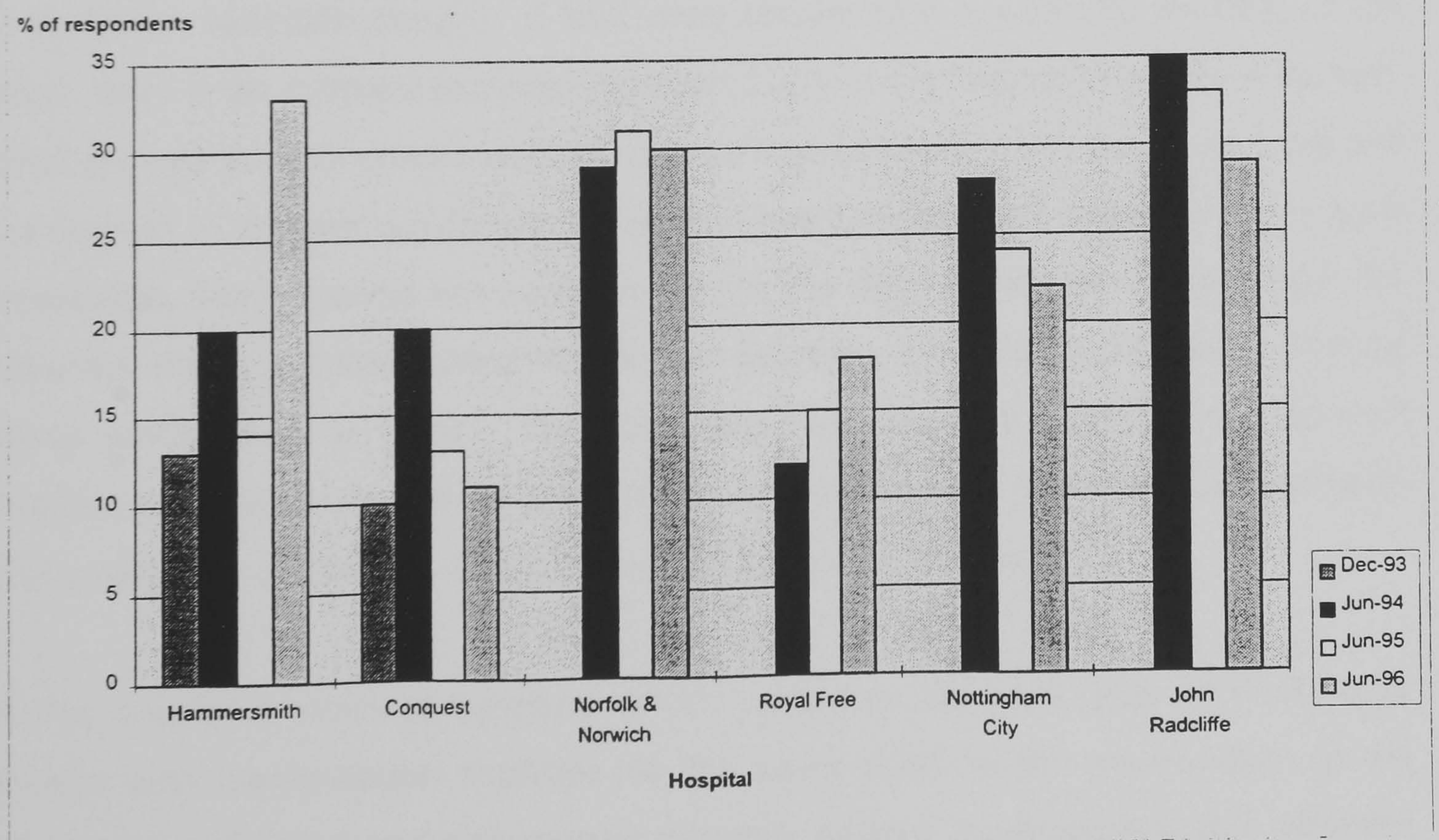


Figure 7.8: Unavailable outpatient images (% responding '1% or less' unavailable)



CHAPTER 8

THE EFFECT OF PACS ON THE VISUALISATION OF THE LATERAL CERVICAL SPINE AND THE PROPOSED MANAGEMENT OF PATIENTS PRESENTING WITH TRAUMA

8.1 INTRODUCTION

The preceding chapters in this thesis have investigated the effect of the introduction of PACS on radiation doses. It has been shown that for mobile imaging of the chest, there is an increase in doses compared with a 400 speed film/screen system. Small savings in dose were identified due to a reduction in both the reject rates and the number of images which had to be repeated because the original images were unavailable, but these did not compensate for the dose increases. Thus overall, for hospitals which use 400 speed film/screen systems, there is an increase in patient doses when PACS is used. The following two chapters consider the issue of whether dose increases can be justified by an improvement in patient management, and whether any changes found could be beneficial to patients.

In this chapter a study is reported which compared CR hard copy and soft copy images with manipulation facilities of the same patients for visualisation of the lateral cervical spine and determined whether patient management was different when the manipulation facilities of PACS were available when the images were

viewed. It was important to compare images which were obtained under identical conditions of exposure and positioning as well as to compare patients who were of similar physique and physical condition. The comparison was therefore made of CR images printed on film and PACS soft copy images of the same images of the same patients.

Many of the trauma patients who present in Accident and Emergency (A&E) departments in the UK have suffered deceleration injuries and in these patients, imaging of the lower cervical spine forms part of their minimum radiological investigation. It is essential that the alignment of the whole of the cervical spine is seen before the patient is moved because if the vertebrae are unstable, the spinal cord could be damaged with paralysis of the patient. The extent of the paralysis depends on the level of the lesion, and is more extensive the lower it occurs. It is often difficult to achieve adequate lateral visualisation of the cervico-thoracic junction because the large muscle bulk of the shoulders obscures the area. Efforts to obtain better images involve traction of the arms or full abduction of the arms in a swimmer (striker) view (Ballinger, 1995). Both may be potentially hazardous and are time consuming. If satisfactory visualisation of the whole of the cervical spine is still not achieved, a CT scan may be undertaken which is costly in terms of time, resources and radiation dose to the patient (Velmahos et al, 1996). For the severely injured patient early diagnosis is of prime importance and is likely to affect the long-term outcome (Trunkey, 1983). Patients with suspected neck injuries are presumed to be injured until the cervical spine is shown to be normal. Nursing care during this phase is labour-intensive. In order to prevent movement of any unstable parts of the spine and damage to the spinal cord, five people are required if the injured patient has to be moved. Thus, improvement in the visualisation of the cervical spine has the potential for improving the long term outcome of the patient as well as a reduction in the cost of treatment.

The principle aim of this study was to determine whether the hospital-wide PACS at the Hammersmith Hospital allows better visualisation of the cervical spine in the lateral projection, compared to hard copy computed radiography (CR) images, and

hence allows appropriate decisions about the management of the patient to be made more rapidly. This study considers 'therapeutic plan' and therefore falls within Level 3 of Fineberg's Hierarchy for assessing imaging systems and Level 4 of the hierarchy later suggested by Fryback and Thornbury [Fryback & Thornbury 1991, Thornbury 1994].

8.2 METHODS

8.2.1 Data Collection

For several months during 1995 the Hammersmith Hospital operated an A&E radiology service whereby both hard copy CR images (with edge enhancement) from a Fuji A/C-1 unit and soft copy PACS images were produced routinely. This setting allowed comparison to be made of CR hard copy and soft copy PACS images of the cervical spine. Such images were obtained for a sample of 100 patients. All study patients were referred to Radiology for a cervical spine examination by the A&E Department, between May and October 1995, having presented with a history of trauma. All study patients were adults, aged over 16 years, selected at random but stratified to reflect the national ratio of men to women (62%:38%) who present with trauma (Parliamentary Advisory Council on Transport Safety, 1992). All patients were radiographed using the same equipment in the X-ray room dedicated to A&E examinations and both hard and soft copy images produced at the time when the CR plate was processed. Thus, it was not necessary for patients to undergo two separate examinations, and the exposure conditions and patient position were the same for the PACS and CR images.

For the viewing process, PACS images were retrieved from the long-term archive, with 10:1 compression. All images were annotated with a study number by which the image was identified by the viewers. The PACS images were transferred to two academic PACS folders, each with 50 images, which did not display the patients' demographic details. The hard copy images were placed into two groups each containing 50 films. Each film was numbered for identification by the viewers. All hard copy images were viewed prior to the soft copy images being viewed. The hard copy images were not displayed in the same order as the soft copy images.

The order in which the soft copy images were retrieved from archive and displayed, varied for each viewer. The viewers were given complete discretion to choose the order in which they viewed the hard copy images.

Viewers were presented with only one cervical spine image for each modality for each study patient and this was not necessarily the complete lateral examination of the cervical spine. In some cases additional images had been produced at the time of the patient's presentation in A&E. Thus the level of the cervical spine which could be seen in these images does not necessarily reflect the level which was seen in the full radiographic examination of the patient. However, where more than one lateral projection was available, the viewers were presented with the same single view for each modality.

All images were read and scored by five viewers. The viewers were all members of the A&E Department since these are the staff who undertake the initial viewing of the radiographic images and often have to make decisions about the management of the patients without the opportunity of seeking advice from a radiologist. The viewers had a range of levels of experience reflecting the staffing of the department: one consultant, one registrar, one clinical assistant and two senior house officers. All PACS images were viewed on a Siemens work station (a 1152x870 pixel ' lite box') in the A&E seminar room and the viewers were allowed to use all the facilities available such as windowing and magnification. All the hard copy images were viewed on conventional light boxes in the same department seminar room. The room has no windows.

Each image was given a score indicating the level of visualisation of the cervical spine and how the proposed management of the patient would proceed (Figure 8.1). For PACS images only, additional information was obtained about whether PACS tools such as magnification and windowing were used.

8.2.2 Data analysis

Data from the questionnaires were entered into SAS (data management and analysis

system) and then entered a second time so that the two data sets could be compared. Any inconsistencies between the two data sets were checked and rectified. Data analysis was carried out using SAS/STAT software (SAS Institute, 1994). The three main factors considered in the analysis were:

- the level of the cervical spine which could be seen on the image (AREA);
- the proposed clinical management of the patient which would have been undertaken as a result of viewing the image; and
- the impact of PACS image manipulation on visualisation of the cervical spine.

The analysis of these data had to take into account the non-independence of the observations in the study. There were 10 observations for each patient, two of these for each viewer, (one relating to CR and one relating to PACS) and thus the observations were not independent.

8.2.2.1 Visualisation of the cervical spine

The approach taken in the analysis of the scores for AREA was to examine the scores for each viewer separately. In the first part of the analysis, treating AREA as a continuous variable, the mean differences in score between the two modalities were calculated. The statistical significance of the mean difference for each viewer was tested using a paired t-test. The overall mean score on AREA for each modality, across the five viewers, was then calculated. This was done by taking the mean score on AREA for each patient, across the five viewers, and calculating the overall mean difference between modalities. The overall mean difference was tested using a t-test.

The second part of the analysis examining AREA involved re-coding the scores for AREA to form a binary categorical variable (C7/T1). This was done by dividing the data into two groups: those observations where the viewer had been able to view the C7/T1 junction or lower in the spine (scoring 8 or more), and those where they had not been able to view the C7/T1 junction (scoring 7 or less). The relationship between the modality and the viewers' ability to see the C7/T1 junction was examined using separate Chi^2 tests for each viewer. For the analysis of the

variables AREA and C7/T1 the threshold level for statistical significance was defined as 5%.

8.2.2.2 *Proposed clinical management after viewing image*

The second factor considered in the analysis was the impact of the modality (PACS or CR) on the proposed clinical management of the patient following the viewing of the image. The association between the modality and the proposed clinical management by each viewer was investigated using Chi^2 tests, thus accounting for non-independence. Fisher's Exact Test was carried out when there were small numbers of observations in each group to be compared. The threshold for statistical significance was defined as 1% because multiple testing was undertaken.

8.2.2.3 *Impact of PACS image manipulation on visualisation of C7/T1 junction*

For PACS images only, the effect of manipulating the PACS image on the visualisation of the C7/T1 junction was also examined. Chi^2 tests were used to investigate the association between visualisation of the C7/T1 junction and the use of manipulative tools such as windowing and magnification. The categorical variable C7/T1 was used for this analysis. The threshold level for statistical significance was defined as 5%.

8.3 RESULTS

Complete data were available on 978 observations, 482 relating to PACS and 496 relating to CR. There were 22 missing observations. The reason for the 18 missing observations of images in the PACS group was that the study images were in PACS academic folders which have the lowest priority in the retrieval and storage protocol of the PACS short term storage unit (Working Storage Unit) and some images were therefore not available on-line during the viewing session. The images that were not viewed were different for different viewers because the images were fetched by PACS in random viewing order for the study. The four missing CR observations were due to the incorrect duplicate recording of the same image number by the viewer. Each viewer should have had only one observation for each image number.

If two observations for one viewer had the same image number but they clearly did not relate to the same image (i.e. the forms were scored differently), it was not possible to know which observation was correctly numbered and both observations were treated as missing.

8.3.1 Visualisation of the cervical spine

The results for the comparison of the two modalities in terms of the continuous variable AREA are summarised in Table 8.1. The mean difference was calculated by taking the CR score from the PACS score for each patient and calculating the overall mean difference for each viewer. It can be seen from Table 8.1 that significant differences in mean scores were found for viewers B, D and E; in favour of PACS for viewer B and in favour of CR for viewers D and E. No significant differences were detected for viewers A and C. The results indicate that between modality differences exist for some, but not all viewers in this study. The data from all viewers (Table 8.2) reveal no significant difference between modalities.

Table 8.3 shows the results of the comparison between the two modalities using the categorical variable C7/T1. The results are similar to those shown using the continuous variable AREA (Table 8.1), in that viewer B could more often visualise the C7/T1 junction or lower with PACS than with CR (i.e. visualisation with PACS is better) whilst viewer E could visualise the C7/T1 junction less often with PACS. No significant difference was detected between the modalities for any of the other viewers, including viewer D who showed a significant difference in modalities when the variable AREA was used.

8.3.2 Proposed clinical management after viewing image

The results for the comparison of the two modalities in terms of the clinical management that would have been undertaken following the viewing of the image are reported in Tables 8.4 to 8.8. The results show that there were some statistically significant differences in proposed clinical management between the modalities for viewers D and E. Viewers D and E both requested a greater number of further images when viewing CR than PACS (Table 8.5). A significant difference

between modalities was also found for viewer E in terms of collar removal (Table 8.4). Following the viewing of the image, viewer E asked for the neck collar to be removed in 46% of CR images and in 64% of PACS images, despite significantly better visualisation of CR images (Table 8.1).

8.3.3 Impact of PACS image manipulation on visualisation of C7/T1 junction

Whilst viewing an image on the PACS system it is possible to use tools such as windowing and magnification, to manipulate the image and potentially extract additional information. Windowing adjusts the grey scale contrast within a set area and magnification increases the size and resolution of part of the image, in this case from 1K to 2K pixels. Tools were used when viewing 39% (187) of the PACS images. Magnification was used in 15% (70) of images and windowing in 27% (130). In 3% of images both windowing and magnification were used to alter visualisation. When the association between tool use and visualisation of C7/T1 was investigated, it was found to significantly improve visualisation for viewer B but reduced visualisation for viewer D (Table 8.9). This may substantiate the finding (Table 8.1) that viewer B obtained better visualisation scores for AREA when viewing PACS and viewer D gained better scores for AREA when viewing CR images.

8.4 DISCUSSION

It is interesting that although viewers D and E both visualised the cervical spine better with CR than with PACS, they both requested 'further images' more frequently for CR than for PACS observations, and viewer E made the decision to 'remove the collar' more frequently after viewing PACS images. These findings imply, for viewers D and E, a lower clinician confidence following the viewing of CR images, even though the visualisation of the cervical spine was better with CR. There are several possible explanations for this. First, it may be that, although these clinicians did not see more of the cervical spine with PACS, they may have seen more information relating to soft tissue structures which could have aided in their diagnosis and led to differences in proposed management. Second, it may be that PACS was seen to represent one of the latest high technology developments in

radiology and this in itself may have contributed to giving clinicians more confidence in their decision-making following the viewing of PACS images. Third, it may have been that the clinicians were more confident because, with PACS, they were able to manipulate the images personally rather than, as with film, having to rely on the expertise of the radiographer.

The results of this study show interesting between viewer differences . Viewer B was the most senior clinician amongst the viewers and was one of the first clinicians in the hospital to be trained to use PACS. This viewer was a firm supporter of PACS and was of the opinion that it was a superior imaging system. Viewer E had many years clinical experience but was not enthusiastic about the PACS system during the period this study was undertaken. Whilst the number of viewers in this study is clearly quite small, one might, nevertheless, hypothesize on the basis of the results that user motivation is an important factor in determining user effectiveness. This case has been argued by others in relation to information technology more generally (Davis, 1993). If this hypothesis is correct then there are important implications for the training requirements of PACS users.

Comparison can be made with the results of a similar study undertaken by Leckie and colleagues (Leckie et al, 1993). Their study involved 2 radiologists viewing 100 PACS images and 100 CR hard copy images obtained routinely during the implementation of a PACS system. The PACS images had 10:1 lossy compression. They reported that, on average, an additional half vertebra was demonstrated by PACS images compared with hard copy CR images. The study did not investigate the effect of improved visualisation on patient management. There are, however, important differences between the studies. In the study reported in this paper, the PACS images were displayed on a 1152x870 (1K) PACS lite box. In the study by Leckie et al, the comparison involved PACS images displayed on 2K PACS monitors. Thus, in the Leckie et al study the PACS images were displayed on workstations which have been shown to be superior for diagnosis of similar conditions (Wegryn et al, 1990).

8.5 CONCLUSION

This study has not shown an overall difference between CR hard copy and PACS in the level of visualisation of the lateral cervical spine in patients presenting with trauma to the Accident and Emergency department of Hammersmith Hospital. The results suggest that confidence levels amongst two of the five clinicians, in terms of whether 'further images' were required of the cervical spine, were higher following the viewing of PACS images, and that one viewer was more confident in removing the neck collar after viewing PACS images. This is important because any reduction in the time taken to diagnose the extent of the injury in trauma patients has the potential to improve the long term outcome of the patient. It was assumed that this was the correct decision, but if the clinicians have unjustified confidence in proceeding to remove neck collars, adverse effects on the patients could be produced. In this study, which used a retrospective sample of images, the viewers gave hypothetical opinions about proposed management of the patients after viewing a single lateral cervical spine image. They did not have access to other images and did not have any influence on the way the patients were been managed. In a real situation they may have acted differently when faced with the responsibility of making a real decision.

Table 8.1 Paired t-tests comparing PACS and CR mean differences in score for AREA

Viewer	Number of image pairs	Mean difference*	Std Dev	95% CI	Prob>T
A	93	-0.0107	1.108	-0.239 to 0.217	0.93
B	89	0.3596	0.908	0.168 to 0.551	<0.01
C	96	0.0625	1.141	-0.169 to 0.294	0.59
D	98	-0.2041	0.973	-0.399 to -0.009	0.04
E	99	-0.3737	0.899	-0.553 to -0.194	<0.01

* *The difference was calculated by taking CR scores from PACS scores so positive mean values indicate better visualisation for PACS and negative mean values indicate better visualisation for CR.*

Table 8.2 Comparison of PACS and CR overall mean differences in scores for AREA

Number of image pairs	Mean difference*	Std Dev	95% CI	Prob >T
78	-0.02	0.637	-0.164 to 0.123	0.78

* *The difference was calculated by taking CR scores from PACS scores so positive mean values indicate better visualisation for PACS and negative mean values indicate better visualisation for CR.*

Table 8.3 Ability to visualise C7/T1 junction of cervical spine for each modality

Viewer	Sample Size	CR Hard Copy	PACS Soft Copy	Chi ^{2} Prob
A	195	22	23	0.90
B	189	40	51	0.03
C	196	29	31	0.61
D	198	46	40	0.46
E	200	22	10	0.02

Table 8.4 Collar removal: number of times requested for each modality

Viewer	Sample Size	CR Hard Copy	PACS Soft Copy	Chi ^{2} Prob
A	195	42	50	0.28
B	189	38	47	0.06
C	196	19	15	0.53
D	198	0	0	n/a
E	200	46	64	0.01

Table 8.5 Request further images: number of times requested for each modality

Viewer	Sample Size	CR Hard Copy	PACS Soft Copy	Chi ^{2} Prob
A	195	22	12	0.06
B	189	4	1	0.37*
C	196	26	27	0.74
D	198	99	63	<0.01
E	200	38	13	<0.01

** indicates use of Fisher's Exact Test*

Table 8.6 Swimmer/striker view: number of times requested for each modality

Viewer	Sample Size	CR Hard Copy	PACS Soft Copy	Chi ^{2} Prob
A	195	7	11	0.33
B	189	0	0	n/a
C	196	0	0	n/a
D	198	0	0	n/a
E	200	1	0	1.00*

** indicates use of Fisher's Exact Test*

Table 8.7 Lateral view: number of times requested for each modality

Viewer	Sample Size	CR Hard Copy	PACS Soft Copy	Chi ^{2} Prob
A	195	11	12	0.85
B	189	59	40	0.04
C	196	55	54	0.86
D	198	31	33	0.69
E	200	0	0	n/a

Table 8.8 CT scan: number of times requested for each modality

Viewer	Sample Size	CR Hard Copy	PACS Soft Copy	Chi ^{2} Prob
A	195	4	2	0.45*
B	189	0	0	n/a
C	196	0	0	n/a
D	198	1	2	0.62*
E	200	0	0	n/a

** indicates use of Fisher's Exact Test*

Table 8.9 Number of PACS observations where viewer could and could not visualise C7/T1, with and without tools

		Can see C7/T1		Cannot see C7/T1		
Viewer	Sample Size	Tools	No tools	Tools	No tools	Chi^2 Prob
A	98	11	12	23	52	0.13
B	90	40	11	38	1	<0.01
C	96	0	31	1	64	1.00*
D	98	9	31	37	21	<0.01
E	100	4	6	24	66	0.46*

** indicates use of Fisher's Exact Test*

Figure 8.1 Part of the data sheet for scoring the images

Please indicate your level of visualisation of the cervical spine from C1 to the upper thoracic levels

Please circle ONE number

Area Seen

1 - No useful information gained from radiograph 1
2 - Visualisation of C4 and above - alignment only 2
3 - Visualisation of C4 and above - with bony detail 3
4 - Visualisation of C6 and above - alignment only 4
5 - Visualisation of C6 and above - with bony detail 5
6 - Visualisation of C7 - upper border only 6
7 - Visualisation of C7 - whole vertebra 7
8 - Visualisation of C7/T1 junction 8
9 - Visualisation of whole C7 and T1 vertebra 9
10 - Perfect visualisation of alignment, vertebral shape and structure 10

From the information you have seen on the film please indicate how you would proceed with the patient's management.
Please tick the appropriate boxes

Remove collar . . . . . ☐

Request further images . . . . . ☐

Request a swimmer's view . . . . . ☐

Request a lateral view with shoulders pulled down by a doctor (with traction) . . ☐

Request a CT scan . . . . . ☐

Other (please specify)_____ . . . . . ☐

CHAPTER 9

THE EFFECT OF PACS ON 'DIAGNOSTIC PERFORMANCE' IN THE ACCIDENT AND EMERGENCY DEPARTMENT

9.1 INTRODUCTION

This chapter describes the second study which was undertaken in the Accident and Emergency Department at the Hammersmith Hospital in order to determine whether the use of a hospital-wide PACS contributed to an improvement in patient management. Unlike the study in the previous chapter, this study compared real decisions which A&E clinicians had made at the time when the patients presented for treatment in A&E when film and PACS images were used.

In the Accident and Emergency (A&E) Department x-ray images are used to assist in the initial diagnosis and management of the patient. Misdiagnosis by A&E clinicians is an apparently common and potentially serious problem, and previous studies have shown that misdiagnosis rates by A&E staff range from 0.6% to 7% (Galasko & Monahan, 1971; de Lacey *et al*, 1980; Selzer *et al*, 1981; Carew-McColl, 1983; Mucci, 1983; Guly, 1984; Wardrope & Chennels, 1985; Robson *et al*, 1985; Berman *et al*, 1985; Tachakra & Beckett, 1985; Gleadhill *et al*, 1987; Beggs & Davidson, 1990; Thomas *et al*, 1992).

Most junior medical staff working in an A&E Department have very limited radiological training or experience but normally have to interpret images without a radiologist's report for 16 hours per day from Monday to Friday, and 24 hours per day over weekends. At the Hammersmith Hospital a 'safety-net' exists whereby all images of A&E patients are subsequently reported on by a radiologist and, where the radiologist identifies an abnormality, that report is compared with the A&E clinician's interpretations. In cases of a difference in diagnosis which may have resulted in the patient being given inappropriate treatment which requires revision, the patient is recalled. PACS might be expected to improve this situation by enabling A&E clinicians to 'manipulate' PACS images and, thus, potentially improve their diagnostic performance. Image manipulation facilities include variation in the grey scale and contrast, and zooming to magnify part of the image and increase its resolution. In order to assess whether this benefit was realized at Hammersmith, a case-study was undertaken which monitored the diagnostic performance of A&E clinicians before and after the PACS implementation.

9.2 METHODS

The hypothesis that was tested in this study was that the use of PACS would reduce the number of misdiagnoses by A&E clinicians, compared with diagnoses made using either film or hard copy computed radiography (CR) images. Thus, the aim of this study was to monitor the incidence, and consequences, of misdiagnoses in the A&E Department at the Hammersmith Hospital, over three periods: when conventional hard copy film images were used, when CR hard copy images were used and when PACS was in use[1]. Data were collected on all images reported as positive (abnormality present) by the radiologist but seen as negative (no abnormality present) by the A&E clinician. As a matter of routine audit, the senior

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The collection of data during the period when CR hard copy images were used was intermittent and unreliable due to the lack of cooperation by one member of the A&E staff involved in auditing the radiologists' reports. When this clinician took responsibility for the audit procedure, no record was kept of discrepancies between the A&E reports and the Radiology reports despite repeated requests for this to be done. Thus, no data can be reported for the intermediate period between a conventional and a Radiology department when diagnosis was made from CR hard copy images.

A&E clinician compared the radiologist's reports with the findings of the casualty officer. If it appeared that the correct diagnosis had not been made by the A&E clinician, the auditing clinician decided whether the patient's treatment should be changed. If a change of treatment was considered necessary then a decision was made on how urgent such a change was and whether the patient should be recalled for further treatment. This information was recorded on a data sheet by the auditing clinician. By this method potential false negative findings on x-ray images by A&E clinicians were identified. These cases were classified by the seriousness of the condition and any action recommended was also recorded. The classification is given in Table 8.1. The audit procedure in operation at the Hammersmith did not similarly monitor all positive x-ray findings by A&E clinicians and so an investigation of false positive findings could not be undertaken. Thus, the term misdiagnosis' is used in this chapter to refer to false negative cases only, where the gold standard is taken as the radiologist's report[2]. This study is another example of a Fineberg Level 3 comparison which considers 'therapeutic plan' for the patients [Fineberg et al 1977].

Data were collected first while conventional film (analogue) images were used, and then when the hospital became filmless and soft copy PACS images were used. The film data collection took place for a 6 month period from 31st March 1992 to 30th September 1992. The Hammersmith Hospital became 'filmless' at the end of March 1996 and the post PACS data collection period was from 1st April 1996 to 30th September 1996. The common timing of the 'before' and 'after' periods was designed to increase the chance that the mix of patients would be similar for the two periods, in terms of their injuries and conditions. The common timing for data

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In order to determine whether the radiologist or the A&E clinician was correct, patient notes were reviewed during the film data collection phase. The term 'misdiagnosis' is used here to refer to false negative findings, where the A&E clinician found no abnormality but the radiologist did. It was only possible to obtain a definitive diagnosis in 9 of the 39 cases reviewed since many patients failed to attend their follow up appointments, several were told to attend a hospital nearer their home if they required any further treatment or the patient's notes were missing. Thus, in thirty cases it was not known whether the radiologist's report or the A&E clinician's report was correct. Given these difficulties, the process was not repeated for misdiagnosis cases found when PACS was in use.

collection also ensured that the junior A&E staff, who work in A&E for six months commencing either at the beginning of February or August, were of the same experience in both studies. Although the PACS study commenced as soon as the Hospital became filmless, both the A&E clinicians and the radiologists had been using PACS images for some considerable time and had familiarized themselves with the new system.

Data on the total number of A&E[3] patients x-rayed during each study period were obtained from the Radiology Information System (RIS). The details of every radiological examination were routinely recorded on RIS either by the radiographer or by the X-Ray receptionist when a patient attended for an examination. It should be noted that some patients had more than one x-ray examination and, thus, the total number of examinations was greater than the total number of patients x-rayed. Data on the number of patients attending the A&E department during each study period were obtained from routine data taken from the A&E Register. These data included both new and follow up attenders.

The two rounds of data collection were initially compared in terms of the characteristics of patients attending the A&E department. Data were available on the number of patients presenting with a new problem and the number of follow-up attenders. Data were also available on the number of A&E attenders who were x-rayed, and the body areas of the x-ray examination. The data from each round were compared by calculating differences in proportions of patients and 95% confidence intervals around the differences.

The overall misdiagnosis rates for the film and PACS periods were then compared. The rates were first calculated using the total number of A&E attenders as the denominator and then re-calculated using the number of A&E attenders who were x-rayed as the denominator. The misdiagnosis rates for the film and PACS rounds

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The A&E department serves as a receiving area for Medical and Surgical patients who have been referred to these Directorates for admission to the hospital. These patients, who are not treated by the A&E clinicians, were not included in the survey.

were then compared separately for adults (defined as being 16 years of age or older) and children (defined as being less than 16 years of age). Again, these comparisons were made by calculating 95% confidence intervals around the differences in proportions. Finally, data were reported on the distribution of misdiagnoses by body area.

9.3 RESULTS

The results for the comparison of film and PACS periods in terms of patient characteristics is given in Tables 8.2 and 8.3. During the film period 14,256 patients attended the Hammersmith A&E, of whom 2,588 (18.15%) were x-rayed. During the PACS period 17,071 patients were seen in A&E of whom 5,345 (31.31%) were x-rayed. The mix of patients presenting at the A&E department appears to have been significantly different between the two periods, in two important respects. First, a significantly smaller proportion of patients attending in 1996 were follow-up patients and, thus, a significantly greater proportion were attenders presenting with a new problem (Table 8.2). Second, a significantly larger proportion of patients attending in 1996 received an x-ray examination (Table 8.3). Apart from examinations of an upper limb, for all categories of x-ray examinations, a larger proportion of patients received the examination in 1996. This increase was particularly marked for examinations of the chest. In 1992, approximately 6% of all A&E attenders received a chest x-ray, whereas in 1996, approximately 12% of attenders had a chest x-ray. The findings on the use of x-ray examinations can be interpreted either as a change in the characteristics of patients seen in the A&E department or as a change in the behaviour of A&E clinicians. There may be a causal link between the larger proportion of patients receiving an x-ray examination in 1996 and the larger proportion of patients presenting with a new problem.

The results for the overall comparison of the film and PACS data collection periods, in terms of misdiagnosis rates, are shown in Table 8.4. During the film period a total of 39 patients were misdiagnosed when film was being used, giving an overall misdiagnosis rate of 1.5% in those patients who were x-rayed. The number of patients who were recalled for review (misdiagnosis categories 1 to 3) was 16.

During the PACS period a total of 35 patients were misdiagnosed when PACS was being used, giving an overall misdiagnosis rate of 0.66% in those patients who were x-rayed. The number of patients in the PACS period who were recalled (misdiagnosis categories 1 to 3) was 18.

The proportion of misdiagnoses among A&E attenders who were x-rayed was statistically significantly lower in the period when PACS was being used compared to the period when film was used. However, the proportion of serious misdiagnoses among A&E attenders who were x-rayed was not significantly different between the two periods. Similarly, the proportion of misdiagnoses among all A&E attenders did not differ significantly between the two periods. When the data were analyzed separately for adults and children (Tables 8.5 and 8.6), similar results were found for the adult sub-sample. For adults, there was a significantly lower proportion of misdiagnoses overall when PACS was used. However, the rate of serious misdiagnoses, requiring patient recall, was the same for the two periods. For children, the misdiagnosis rates, both overall and for serious misdiagnoses, were the same for the PACS and film periods.

Tables 8.7 to 8.10 show the misdiagnoses were distributed between body areas, for both adults and children. The results indicate that the misdiagnoses tended to relate, principally, to examinations of an upper or lower limb or skull examinations. There are no pronounced differences in the distributions between the film and PACS periods.

9.4 DISCUSSION

The number of misdiagnoses by A&E staff identified in this study was very low, for both film and PACS. The rates identified here compare favourably with those reported in other studies. The overall rate of misdiagnoses per x-rayed patient was significantly lower in the PACS period, compared to the film period, but the rate of serious misdiagnoses involving patient recall was not different.

In the PACS data collection period three of the misdiagnosed cases were graded as 4 (no change of treatment required) only because the time between the patient being x-rayed and the radiologist's report being produced was too long to be able to affect the management of the patient. If the radiologists' reports for these 3 patients had been received earlier, they would have been graded as 3 or less (requiring recall for review). However, this would not have changed the result that there were no significant differences between the film and PACS periods in terms of the rates of serious misdiagnoses.

There are several factors which may have contributed to the results that have been obtained in this study, other than the change of imaging technology. There was a time delay of over two years between the end of the film study and the start of the PACS study. During this time many of the A&E clinicians and radiologists changed and there may have been a change in the patient population attending the A&E department. In 1992 the new SHOs in A&E had 'in house' induction training at the start of their jobs. By 1996 the training had become more extensive and thus the two groups of SHOs may not be strictly comparable. Compared to 1992, in 1996 there were more 'middle grade' doctors during normal working hours who are available to give advice. However, outside normal working hours, including weekends, there was no change in the grade of doctor available. For the first data collection period, patients were x-rayed in the general (old) x-ray department on the floor immediately above A&E. In 1996 there was a dedicated x-ray room for A&E patients within the A&E department which was run by a superintendent radiographer with responsibility for A&E work. The close proximity of a dedicated A&E x-ray room may have prompted more requests for x-ray examinations during the PACS period. During the PACS study, the close proximity of an experienced A&E Superintendent radiographer who was able to give an opinion on x-ray images may have contributed to the lower rate of misdiagnosis during this period. PACS provided the potential for images to be viewed simultaneously in A&E and Radiology. This may have led, in 1996, to the A&E doctors consulting radiologists by phone for an opinion more frequently than in 1992. In 1996 the A&E staff reported that the written radiologists' reports took longer to arrive than in the past.

This may have caused them to rely less on radiology and instead seek the opinion of senior clinicians outside of the radiology department. The accuracy of the RIS information on the numbers of patients x-rayed must be treated with caution. On some occasions a patient's details appear not to have been entered on RIS even though the patient has been x-rayed and the images are available. Thus, the numbers of patients x-rayed may be lower than the actual number and the percentage of misdiagnoses may be inflated. This is a known inaccuracy in the data which could not be controlled by the researchers. However, there is no reason to believe that mistakes would have been made more often in one part of the study than the other.

9.5 CONCLUSIONS

When PACS was used, there were fewer misdiagnoses of images by A&E clinicians, but there was no statistically significant difference in the number of patients whose treatment was changed after the missed diagnosis was detected.

Table 9.1 Classification of misdiagnosis

LEVEL OF MISDIAGNOSIS	GRADE
Serious, urgent action required	1
Serious, action within 5 days required	2
Requires recall for review	3
Abnormality present, no change of treatment required	4
Questionable misdiagnosis	5

Table 9.2 Patient characteristics: comparison in terms of new and follow-up A&E attenders

	FILM (% of all A&E attenders)	PACS (% of all A&E attenders)
Number of new A&E attenders	12,619 (88.52)	15,990 (93.67)
Number of follow-up A&E attenders	1,637 (11.48)	1,081 (6.33)
Total number of A&E attenders	14,256	17,071

Proportion of all A&E attenders that were new cases:
Observed difference between proportions = -0.0515
95%CI for difference between the proportions is -0.0579 to -0.0451

Table 9.3 Patient characteristics: comparison in terms of body areas examined using x-ray images

Body area	FILM (% of all A&E attenders)	PACS (% of all A&E attenders)
Upper limb	1,106 (7.76)	1,202 (7.04)
Lower limb	786 (5.51)	1,040 (6.09)
Chest	875 (6.14)	2,191 (12.83)
Skull	303 (2.13)	509 (2.98)
Abdomen	163 (1.14)	635 (3.72)
Pelvis	61 (0.43)	128 (0.75)
Total number of x-ray examinations	3,294	5,705
Total number of patients x-rayed	2,588 (18.15)	5,345 (31.31)
Total number of A&E attenders	14,256	17,071

Proportion of A&E attenders x-rayed:
Observed difference between proportions = 0.132
95%CI for difference between the proportions is 0.122 to 0.141

Proportion of A&E attenders receiving an upper limb x-ray:
Observed difference between proportions =- 0.00717
95%CI for difference between the proportions is - 0.0130 to -.00134

Proportion of A&E attenders receiving a lower limb x-ray:
Observed difference between proportions = 0.00579
95%CI for difference between the proportions is 0.0006 to 0.0110

Proportion of A&E attenders receiving a chest x-ray:
Observed difference between proportions = 0.0670
95%CI for difference between the proportions is 0.0606 to 0.0733

Proportion of A&E attenders receiving a skull x-ray:
Observed difference between proportions = 0.00856
95%CI for difference between the proportions is 0.00508 to 0.0120

Proportion of A&E attenders receiving an abdomen x-ray:
Observed difference between proportions = 0.0258
95%CI for difference between the proportions is 0.0224 to 0.0291

Proportion of A&E attenders receiving a pelvis x-ray:
Observed difference between proportions = 0.00322
95%CI for difference between the proportions is 0.00154 to 0.00490

Table 9.4 Misdiagnosis rates: overall comparisons

	FILM	PACS
Number of misdiagnoses	39	35
Number of misdiagnoses requiring patient recall	16	20
Number of A&E attenders	14,256	17,071
Number of patients x-rayed	2,588	5,345

All misdiagnoses per A&E attender:
Observed difference between proportions = -0.000685
95%CI for difference between the proportions is -0.00178 to 0.000408

All misdiagnoses per x-rayed patient:
Observed difference between proportions = -0.0085
95% CI for difference between the proportions is -0.0137 to -0.00335

Misdiagnoses requiring recall per A&E attender:
Observed difference between proportions = 0.0000492
95%CI for difference between the proportions is -0.000703 to 0.000801

Misdiagnoses requiring recall per x-rayed patient:
Observed difference between proportions = -0.00374
95% CI for difference between the proportions is -0.00588 to 0.000994

Table 9.5 Misdiagnosis rates: adults (16 years of age and over)

	FILM	PACS
Number of misdiagnoses	30	28
Number of misdiagnoses requiring patient recall	12	15
Number of adults x-rayed	2,155	4,474

All misdiagnoses per adult x-rayed:
Observed difference between proportions = -0.00766
95% CI for difference between the proportions is -0.0131 to -0.0022

Misdiagnoses requiring recall per adult x-rayed:
Observed difference between proportions = -0.00222
95% CI for difference between the proportions is -0.00579 to 0.00135

Table 9.6 Misdiagnosis rates: children (under 16 years of age)

	FILM	PACS
Number of misdiagnoses	9	7
Number of misdiagnoses requiring patient recall	4	5
Number of children x-rayed	433	871

All misdiagnoses per child x-rayed:
Observed difference between proportions = -0.0127
95% CI for difference between the proportions is -0.0274 to 0.00194

Misdiagnoses requiring recall per child x-rayed:
Observed difference between proportions = -0.0035
95% CI for difference between the proportions is -0.00138 to 0.00682

Table 9.7 Misdiagnoses during the film period: adults

Body area	Total x-rayed	Number of misdiagnoses (%)
Upper limb	804	15 (1.87)
Lower limb	687	7 (1.02)
Chest	794	2 (0.25)
Skull	303	4 (1.32)
Abdomen	163	1 (0.61)
Pelvis	61	1 (1.64)
Number of adults x-rayed	2,155	30 (1.39)

Table 9.8 Misdiagnoses during the film period: children

Body area	**Total x-rayed**	**Number of misdiagnoses (%)**
Upper limb	302	6 (1.99)
Lower limb	99	2 (2.02)
Chest	81	1 (1.23)
Skull	102	0 (0)
Number of children x-rayed	433	9 (2.08)

Table 9.9 Misdiagnoses during the PACS period: adults

Body area	Total x-rayed	Number of misdiagnoses (%)
Upper limb	845	10 (1.18)
Lower limb	838	12 (1.43)
Chest	2,045	4 (0.20)
Skull	376	2 (0.53)
Abdomen	598	0 (0)
Pelvis	128	0 (0)
Number of adults x-rayed	4,474	28 (0.63)

Table 9.10 Misdiagnoses during the PACS period: children

Body area	Total x-rayed	Number of misdiagnoses (%)
Upper limb	357	3 (0.84)
Lower limb	202	2 (0.99)
Chest	146	0 (0)
Skull	131	2 (1.53)
Number of children x-rayed	871	7 (0.80)

CHAPTER 10

SUMMARY AND DISCUSSION

10.1 INTRODUCTION

The aim of this thesis has been to determine what effect, if any, the introduction of Picture Archiving and Communications Systems, which utilise phosphor plate image acquisition, have on patient doses, and whether any increase in dose could be justified by improvements in patient management.

10.2 SUMMARY OF FINDINGS OF THE THESIS

10.2.1 Summary of Chapter 2

Chapter 2 considered the evidence which is already available in the literature concerning the effect of the use of PACS on patient doses. Evidence was sought for dose changes due to change in the doses for individual images, to change in reject rates which might reduce the additional doses due to repeat exposures, and the change in the number of lost images which may necessitate additional images (with additional patient doses) being undertaken.

No papers were found which described comparative studies relating to changes in dose when film was replaced with PACS imaging. Some studies compared film and CR hard copy imaging, but there was no consensus of opinion about the direction and magnitude of changes in dose. At the time when the original studies which are

reported in this thesis were planned, there were only two relevant publications and these related to CR doses and not PACS doses. One paper reported two studies one of which used two human volunteers and phantoms. In the other study patients had been imaged twice, once with film, and once with CR but no statistical analysis of results was described. The second paper, which reported an ROC analysis, compared the doses for the images of phantoms. The methodology used in these two early papers was good, but in neither paper had doses been measured. Thus at the start of the work reported in this thesis, there had been no comprehensive studies and it was unknown how the use of PACS would affect patient doses. A further 14 publications post date the planning and design of the material in this thesis, but no studies have been within a randomised controlled trial. All studies have assumed that any differences in dose identified were due to the change to CR imaging. There have been no use of regression techniques to identify the influence of CR and other factors on dose.

Similarly, at the start of the work reported in this thesis there were no publications which reported comparisons of image reject rates for film and PACS. One paper has been recently published which compared reject rates when film and PACS were used [Peer et al 1999] and the work described in chapter 6 which compared reject rates when film, CR hard copy and PACS soft copy images were used [Weatherburn et al 1999] has now been published. No publications were found which compared the number of images lost and necessitating potential repeat images when film and CR or PACS were used.

10.2.2 Summary of Chapter 3

This chapter described three comparisons of film, CR hard copy and PACS soft copy images using test objects. The comparisons were of the technical output of each of the systems and as such were at Level 1 of the hierarchy suggested by Fineberg et al for the assessment of the clinical effectiveness of a diagnostic procedure [Fineberg et al, 1977].

The first test was to reproduce a comparison of film and CR for high contrast

resolution using the grid in the TOR (CDR) test object to count the number of line pairs detected per mm. The results were comparable with those published in the literature for CR [Cowan et al 1993, Workman et al 1995, Newton 1995, Huda et al 1995, Seibert 1996]. In addition a comparison was made with these images and PACS soft copy images and it was found that there was no significant difference between the PACS soft copy and the CR hard copy images.

The second test used the Faxil TO20 test object, in a way for which it was not designed, to compare the threshold contrast detail detectability of film, CR hard copy and PACS soft copy images. Contrast detail curves were plotted for the three types of images and the curves compared well.

In the third test, the same test object was used to determine how the contrast detail curves for film, CR and PACS compared at different mAs values from the lowest possible (1mAs) to 800 mAS. Contrast detail curves were produced for each system at each value of mAs where this was possible. The wider exposure latitude of both CR hard copy and PACS soft copy images was significantly greater than that of film but the increased latitude occurred at exposure values above the optimum film exposure rather than below. At lower exposures, mottle was seen in the digital images but as the exposure increased, more information was seen in these images. The manipulation of the soft copy images did not provide additional information compared with the CR hard copy images.

The chapter concluded with the recommendation that manufacturers of PACS equipment should provide information on the default soft copy images which gives some indication of the patient dose associated with the production of the image. After publication of the paper based on the material in this chapter [Weatherburn & Davies, 1999], at least one equipment manufacture has attempted to adapt its equipment in the way suggested.

10.2.3 Summary of Chapter 4

Chapter 4 described another Level 1 [Fineberg et al 1977] comparison of imaging systems. An observational study was undertaken to measure and compare patient doses for examination of the lateral lumbar spine when a 300 speed film/screen system and PACS were used at the Hammersmith Hospital for the examinations of 100 and 96 patients respectively. The strength of the methodology of this study was that very comprehensive data were collected for all exposures and the same radiographic equipment was used for all examinations. The characteristics of the patients were measured and compared to see if the two groups of patients were comparable for age, sex, height, weight, and thickness at the centring point. Individual entry doses and dose area product readings were measured for all images taken for each patient and the effective doses were calculated. The doses for all images to demonstrate the whole of the lumbar spine L1-5, the lumbo-sacral junction L5/S1 and all repeat images were measured.

It was found that the two groups of patients were generally well matched. For individual images of the whole of the lumbar spine there was no statistically significant differences in the entry or effective doses. The DAP readings during the PACS period were significantly lower which could be explained by a significant increase in focus to film distance; the intensity of the beam being inversely proportional to the square of the focus to film distance. For the single images of the lumbo-sacral junction no significant differences in doses were found. It is important to note that almost all entry doses for the L1-5 and L5/S1 views were less than the National Reference Values recommended by the NRPB (30mGy and 40mGy, respectively) for these body areas, when both film and PACS were used.

The examination dose for each patient was found by finding the sum of the individual doses for all the images, including L1-5, L5/S1 and repeat images, which were needed for satisfactory visualisation of the whole of the lateral lumbar spine. It was found that the examination doses when PACS was used were significantly lower than when film was used. This difference in doses was not explained by a significant difference in the number of images required for the examination.

Similarly, the doses for the examination submitted for reporting, excluding rejected images, were significantly lower when PACS was used.

Regression models were produced to explore the relationship between PACS and entry dose, effective dose and DAP readings for the whole examination of the total sample of patients, including rejects and the examination submitted for reporting (satisfactory images only). The models showed that PACS made a significant contribution to reduced patient doses compared with when film was used. However the models for the examination doses could include only those independent variables which were the same for all images of each patient and thus the exposure factors could not be included. Thus the models, although significant, explain only about half of the factors which affected patient doses.

The film/screen system used at the Hammersmith Hospital had a speed of 300, and as such was not typical of the majority of hospitals in the UK. The 1995 Review of patient doses [Hart et al, 1996] showed that for the period 1988-1995, 60% of hospitals used film/screen combinations which had speeds greater than 400. By 1994 the number had increased to 75% [Hart, personal communication].

10.2.4 Summary of Chapter 5

The study which is reported in chapter 5 compared doses when PACS was used with those in a hospital which used a 400 speed film/screen system, and was therefore more typical of UK hospitals than the previous study. The PACS was a small system which linked the radiology department with the Intensive Therapy Unit (ITU) only. Almost all the radiographic examinations on ITU are of the chest in the anterior-posterior (AP) position and so doses were measured and compared for these examinations when film and PACS was used. Since the PACS was not hospital wide, the conventional film system was also in use and so it was possible to undertake a contemporaneous comparison of film and PACS doses, removing some of the problems of confounding factors which were encountered in the dose study undertaken at the Hammersmith Hospital. Surface entry doses were measured, from which effective doses were calculated, and examination techniques noted and

compared as part of a randomised controlled trial [Weatherburn et al, in press]. As far as I am aware this is the only study where doses have been measured and compared as part of an RCT.

It was found that there was a significant increase in doses when PACS was used. The median entry doses for the first examination of each patient increased by 31%, and the median effective dose increased by 36% when PACS was used. There was also a significant reduction in the number of repeat images which were required when PACS was used.

This study was again Level 1 of the hierarchy of Fineberg et al [1977] but had a stronger methodology being a contemporaneous comparison within an RCT rather than a before and after comparison as described in chapter 4. Both studies were pragmatic studies which compared what actually happened in clinical practice rather than in an artificial research setting. The results of these two studies provide the same result: that PACS using phosphor plate technology for image acquisition has a speed equivalent to a 300 speed film/screen system.

10.2.5 Summary of Chapter 6

Chapter 6 considered the issue of images which are unsatisfactory and have to be repeated necessitating additional patient radiation doses, and the effect, if any, of PACS on image reject rates. The study which has been described investigated the number of images which were rejected because they were unsatisfactory, the body areas involved and the reasons for the image being rejected.

It has been suggested in the literature that the wider latitude of the phosphor plates eliminates image rejects which are due to the use of incorrect exposure factors. Phosphor plate imaging is used in most PACS, but in addition, the manipulation facilities which are available for the soft copy PACS images may further reduce rejects rates. This study aimed to test this hypothesis, and in addition, to determine whether the manipulation facilities which are available for the soft copy PACS images, further reduced the reject rates. Rejects at the Hammersmith Hospital were

monitored in three separate periods. In the first period conventional film was used, in the second period hard copy PACS images were used and in the third period, soft copy PACS images were used. Comparisons were made between the images rejected in these three periods in order to determine whether there were fewer rejects when PACS was used.

The reject rates for each period were expressed as the percentages of the total number of examinations undertaken during the period since these data could be obtained, from the same source, for all three periods. It was found that there was a significant reduction in reject rates when CR was used compared to when film was used, but no further significant reduction when PACS was used. However, since reject rates are normally expressed as the percentage of all images taken, an estimate was made of the total number of images used in each period and the reject rates calculated. The percentage of images rejected were 6.6% for film, 5.5% for CR and 5.5% for PACS.

It was confirmed that the rejects due to incorrect exposure factors were significantly reduced when the digital images were used. However, there were new reasons for rejection of the digital images which had not been seen with film, so that the reject rates did not fall as much as expected. As far as I am aware, this is the only study which has comprehensively investigated changes in reject rates when these three types of images were used for normal clinical practice.

10.2.6 Summary of Chapter 7

Chapter 7 considered the issue of images which are unavailable when clinically required or 'lost' and which may necessitate additional examinations and patient doses. The chapter considered three sources of information: a quantitative study of lost images for outpatients clinics, a survey of clinicians to elicit their views on lost images, and an estimation of the effect of lost images on patient doses.

A study was described which, over a two year period, monitored the number of film packets which were requested, the number which were unavailable, and thus the

percentage 'lost' when film was used at the start of the morning when the largest number of outpatient clinics were held at the Hammersmith Hospital. The equivalent process was undertaken when PACS was used and the number of examinations requested and the number which were 'off line' and unavailable for viewing from the short term archive were monitored by a PACS programme which was designed for this study. It was found that when film was used, the mean number of films missing was 14% and when PACS was used the mean number of examinations missing was 17%. The higher mean value for PACS was because on two occasions there were high numbers of images off line when there were equipment faults. On one occasion all images were off line and on the other, 38% were off line. For the remaining seven weeks monitored the mean number of images which were off line and unavailable was 1.7% of those required. Thus for most of the time there were fewer images 'lost' when PACS was used than when film was used, but the problem of lost images had not been eliminated and was worse when the PACS equipment failed to work correctly. Unfortunately the period for monitoring during the use of PACS was much shorter than when film was used because the PACS systems operator who ran the programme had to return to work in the United States and the study had to be curtailed. Ideally PACS would have been monitored for the same period as film, and if this study were repeated it would be important to try to achieve similar lengths of periods for comparison. It would be useful to repeat the PACS part of the study periodically in order to determine its performance when more images had been stored. In addition, since other hospitals do not have the equipment manufacturer's PACS expert permanently on hand, as the Hammersmith did, it would be useful to repeat the PACS study when no systems operator was based in the hospital to check that the equipment was functioning correctly.

Hospital clinicians who used the radiology department were surveyed by annual questionnaires over a four year period in order to elicit their views on the lost image problem. They were asked if they thought that there was a problem with lost images in their hospital, and if so, to provide an estimate of the extent of the problem. The same questionnaires were sent to clinicians at the Hammersmith

Hospital and to clinicians in five comparator hospitals. There was a 54% response rate to the questionnaires. There was a significant decrease in the number of clinicians at the Hammersmith who considered that there was a lost image problem when PACS was used, compared to when film was used. A similar decrease was not seen in any of the comparator hospitals. Although the clinicians considered that there was a problem with lost images, they rarely ordered a repeat examination. At all hospitals, in all rounds, the majority of respondents said that they ordered less than one repeat examination a month.

The results of the questionnaire were used with routine Korner data in order to estimate how many images were actually repeated in each hospital because the original was lost and to determine whether there was any change when PACS was used at the Hammersmith which was not seen when film was used elsewhere. It was seen that the estimated number of additional examinations was similar across all hospitals (mean 1.4%) but was lower at the Hammersmith when PACS was used (0.6%). It was estimated that if PACS could solve the problem of images having to be repeated because the original was lost, about 1.4% reduction in the patient population dose could be achieved.

10.2.7 Conclusions of Chapters 3 to 7

When a PACS with phosphor plates image acquisition replaces a conventional film/ screen system,

- there is no change in the entry and effective doses for individual images of the lateral lumbar spine when the speed of the film/screen system is 300

- there is an increase in entry (31%) and effective (36%) doses for AP mobile chest examinations when the film/screen speed is 400

- Reject rates, expressed as the percentage of all images undertaken, are reduced by 1.1%

- the number of images which are unavailable when clinically required or 'lost,' and which may require a repeat patient examination with an additional patient dose, are reduced, with a potential dose saving to the patient population of 1.4%.

Thus, for hospitals replacing 300 speed film/ screen systems, the use of PACS with phosphor plate image acquisition could give an overall dose reduction for adult patients of 2.5%. In hospitals replacing 400 speed film/screen systems, adult doses would be likely to increase by almost 30% when PACS is used. In the UK 75% of hospitals use film/screen combinations which have speeds greater than 300, and thus the use of PACS would cause an increase in dose to the adult population of the country. In order to justify the use of higher doses for diagnostic imaging investigations, it must be shown either that the use of PACS reduces costs and thus makes resources available for other purposes which could benefit the patients, or that the patients benefit from additional information which is available in the images. It has already been established that PACS has added to costs [Bryan et al, 1999b] the studies in the next two chapters therefore aimed to produce evidence that the use of PACS improved patient management. Both studies were undertaken at the Hammersmith Hospital.

10.2.8 Summary of Chapter 8

The study which was described in chapter 8 compared the visualisation of the lateral cervical spine of 100 trauma patients when CR hard copy and PACS soft copy images were used, and the management decisions which were made by five clinicians in the Accident and Emergency Department and based on the viewing of the images. When radiographs of the lateral cervical spine are undertaken, the area of the lateral cervical spine which is the most difficult to demonstrate is the cervical-thoracic junction (C7/T1), because the bulk of the shoulders overshadows the area of interest. If this landmark is not seen clearly, additional images are undertaken which may include the 'Swimmer' or 'Striker' views and CT scans.

It was found that there was no significant difference in the level of the cervical

spine seen when PACS was used, but two out of five viewers requested fewer additional images compared with when film images were viewed. One of these two viewers was more confident in removing the neck collar after viewing PACS images. This result is important because any reduction in the time taken to diagnose the location and extent of injury in trauma patients has the potential to improve the long term outcome of the patient.

This study considered how the management of each patient should proceed after the images had been viewed and whether the different types of images changed patient management and was within Level 3 of Fineberg's Model [Fineberg et al, 1977] and Level 4 of the subsequent model suggested by Fryback and Thornbury [Fryback & Thornbury, 1991] for the evaluation of imaging systems.

10.2.9 Summary of Chapter 9

In chapter 9 a second study involving patients from the Accident and Emergency department was described which was also at Fineberg's Level 3 and Thornbury's Level 4 for technology assessment. The 'misdiagnosis' rates of radiographic images by A&E clinicians compared with the radiologists' reports were compared when film and PACS were used. False negative A&E reports were investigated and classified according to the severity of the difference in diagnoses and in particular to identify those patients where a change in management was indicated. It was found that the proportion of misdiagnoses among A&E attenders who were x-rayed was statistically significantly lower in the period when PACS was being used compared with to the period when film was used. However, the proportion of serious misdiagnoses which required a change in patient management, was not significantly different between the two periods.

10.2.10 Overall conclusions of Chapters 8 and 9

When PACS was used instead of a film based imaging system,

- there was no significant difference in the level of the lateral cervical spine visualised
- two viewers out of five made fewer requests for additional images and one

indicated more frequently that the neck collar could be removed without further investigations.

- there were fewer misdiagnoses of radiographic images by A&E clinicians
- there was no significant difference in the number of patients whose treatment had to be changed after a misdiagnosis was detected.

10.3 DISCUSSION OF THE RESULTS OF THE THESIS

10.3.1 Discussion of the methodology used in this thesis

10.3.1.1 *Methodological limitations*

The methodology which was utilised in the original studies reported in this thesis was limited by constraints which were imposed by the nature of the implementation of the PACS equipment, the decision to use data from clinical patient examinations rather than artificial experimental settings and the need for the cooperation of hospital staff.

At the Hammersmith Hospital the intention was to use a 'Big Bang' implementation for PACS so that one day film would be used, and the next PACS would be operational and the hospital would operate in a film-less environment. Thus there was no possibility of undertaking a contemporaneous comparison methodology for any of the studies. The 'Big Bang' implementation did not materialise, but instead, the PACS operated within Radiology first, and then went to a limited number of departments at a time, until it was operating hospital-wide. The methodology for the studies at the Hammersmith therefore had to be 'before PACS' and 'after PACS' comparisons without the knowledge of exactly when the 'after' phase would begin. There was thus a major problem about other factors which changed between the two periods (which were separated by as much as four years), and control for these confounding factors was a major consideration when the studies were designed and the results were interpreted.

Many of the problems associated with the work relating to the Hammersmith Hospital which is reported in this thesis, were a result of the positive decision to undertake pragmatic studies to measure what actually happened when film, CR and

PACS images were used in the hospital, rather than in an experimental setting. As explained at the beginning of this thesis, these studies were components of a very large study which was undertaken to measure the costs and benefits of the introduction of a hospital-wide PACS. Where possible, the data were collected personally but there were times when this was not feasible since data for some studies were required 24 hours every day. The staff in the hospital were asked to participate in many parts of the study, and thus an effort was made to ensure that they were not overloaded with data collection activities which would be detrimental to their clinical commitments. A very careful balance had to be achieved between the amount of effort which the staff could be expected to make and the total number of studies which were required. However, the radiographers in the hospitals were generally very cooperative and recorded data using the protocols provided.

The timing of the studies at the Hammersmith Hospital were determined by the hospital staff. The baseline periods using film had to be completed before the work of the radiology department moved to the new department because conventional film images would cease to be produced. In all post film studies it was important that the initial problems associated with the staff in radiology and the rest of the hospital using unfamiliar equipment had been overcome before data were collected. For all studies, the hospital staff indicated when they were ready to undertake studies in which the new technology was used.

10.3.1.2 Innovative methodology

The methodology for the comparison of doses at the Hammersmith had to be a before PACS and after PACS comparison in different radiology departments. It was fortunate that it was known that the equipment from one X-Ray room would be transferred from the old department to the new department and it was possible to encourage the radiographers to undertake lumbar spine examinations in that room on the days when data were being collected and measurements were made of patient doses, height and weight. Since it is time consuming to collect all this data and clinical staff are unable to take the time required to undertake such comprehensive data collection exercises, the study reported in chapter 4 includes

a lot of information which is not normally available. Since there were no previous comparison of film and PACS doses, the nature of any changes was unknown and so doses were measured by both TLD and DAP. The Hammersmith staff had intended collecting only DAP readings and to compare these to see if there was a shift in population doses. If DAP readings only had been collected, there would have been the false impression that doses for each image were reduced. By also collecting surface entry doses and variables relating to the exposure conditions, it was possible to show that entry doses did not change and that it was changes in the focus to film distances and size of the area irradiated which changed the DAP readings. In addition, no other studies have been identified which use regression analysis to determine the factors which affect changes in doses when PACS is used.

The measurement of doses within an RCT at Glan Clwyd Hospital was possible because the PACS was not hospital-wide and both film and PACS were used in the hospital simultaneously. This provided the opportunity to undertake dose measurements on patients who were randomised to have all images undertaken by either film or PACS. It was possible to obtain a good sized sample of patients and to produce statistically valid results that the PACS patients received higher doses than the film patients (chapter 5). It is believed that there are no other studies which have compared radiation doses within an RCT.

The delayed implementation of PACS at the Hammersmith Hospital was advantageous because while parts of the hospital used film and part used PACS, film images had to be available for those clinicians who did not have PACS images and so as an interim measure, both CR hard copy and PACS soft copy images were produced. This gave the unexpected opportunity for a three-way comparison to be undertaken: film, CR hard copy and PACS soft copy, and to provide additional information about what changes might be expected on moving from film to CR and from CR to PACS. Three-way comparisons are not usually undertaken and so these results are of particular relevance to those hospitals which are already using CR and producing hard copy images who will be interested to determine what changes they

might expect using PACS. Three-way comparisons were undertaken of contrast detail using images of test objects (chapter 3), and reject rates (chapter 6).

The comparison of cervical spine images in chapter 8 was one of the studies which was made possible because, for some time, both CR hard copy and soft copy images were produced for all Accident and Emergency patients. Thus two images were available which had been produced simultaneously with exactly the same exposure factors and conditions and the same patient position. It is unlikely that if two separate images had been taken of these patients who presented with trauma, they would have been produced under identical conditions. Indeed it is unlikely that the radiographers would have taken the time to undertake an additional exposure for each of 100 trauma patients. The comparative study of the extent of the cervical spine which could be visualised is a Level 1 study in Fineberg's Hierarchy [Fineberg et al, 1977] and has also been undertaken by Leckie at al [1993]. However the study described in chapter 8 additionally asked clinicians to make a judgement on the subsequent appropriate clinical management of each patient which is classified as a Fineberg Level 3 study (Level 4 in Thornbury's hierarchy [Thornbury, 1994]). The second A&E study was also a Fineberg Level 3/Thornbury Level 4 study which aimed to identify whether the use of PACS improved patient management by reducing the number of times the A&E staff failed to detect radiographic abnormalities and proceeded with treatment which was inappropriate for the missed abnormality. No similar studies which have compared patient management as a result of viewing hard and soft copy images have been found.

10.3.1.3 Suggestions for further research

There were two problems associated with the A&E study which is described in chapter 9. Firstly, it was assumed that the radiologist's interpretation of the images was the correct diagnosis. It has been demonstrated that the diagnosis made by the A&E clinician who sees the patient as well as the images may be more accurate than that of the radiologist [Tachakra et al, 1998]. For various reasons, it was not possible to locate the follow up notes of all those patients where a difference in diagnosis was identified and to determine who made the correct

diagnosis. Secondly, between the periods when the data were collected the hospital services in West London were reorganised, and it is possible that the type of patients attending the Hammersmith Hospital A&E department, changed. There were no records of the numbers of patients who had presented themselves at the department and the number brought in by ambulance, and so no comparisons could be made. The study could be improved if data were available to ensure that the true diagnoses were identified and the patient mix was known. Further research in this area would be useful.

One of the major confounding factors which could not be controlled for at the Hammersmith was the issue of staff changes. This was a disadvantage of the comparisons of the systems since new staff might have different skills for producing the images (chapter 4) or different standards for accepting and rejecting images (chapter 6). The radiographers did not want to be identified and since their cooperation was an essential component for the studies, this problem could not be resolved. An ideal further study would collect details of the radiographers' identity which could then be included in a regression analysis to determine whether a change in staff influenced results.

The final study relating to patient doses was to determine the additional doses which were required because the original images were lost. There are many unsubstantiated claims that when PACS is used no images are lost, but there have been no other studies which have measured and compared the 'lost' image problem when film and PACS are used. The nature of the data collection exercise for the out patient clinic study was of necessity different when film and PACS were used. During the film component data were collected over a two year period but the PACS period was much shorter. The PACS programme had to be run manually and was limited to those days when the PACS system operator was available and by the end of the project. After the completion of this study it was identified that there was an equipment fault which prevented the automatic fetching of images from the long term to the short term archive and this fault was rectified. In addition the short term working storage unit was replaced with one with larger capacity. It was not

possible to repeat the PACS part of this study after the alterations had been made, but further research in this area would be useful to determine whether all problems have been resolved.

10.3.2 Policy implications

The combined results of the seven sub-studies reported in this thesis are that for hospitals which currently use a film/screen combination with a speed greater than 300, if PACS with phosphor plate imaging is introduced, and images comparable to those produced by conventional film systems are required [Todd-Pokropek et al, 1997], there will be an overall increase in current adult doses of about 30% with very little evidence of improvement in patient management which could justify the increased dose to the population.

The 1999 Review of Radiation Exposure of the UK Population [Hughes, 1999] found that

'From 1984 to 1995 there was an overall reduction in dose per radiograph of about 30%. One of the main factors contributing to this reduction was the more extensive use of faster film/screen combinations. Average exposures are well below the reference doses. It has been estimated that, during the years 1984 to 1995, these efforts to restrict exposures has achieved an annual reduction in patient collective dose of about 4,700 man Sv'.

Assuming that the number and type of radiographic images has not changed, the effect of the widespread introduction of PACS with phosphor plate image acquisition would appear to be to return the population dose to that of the early 1980s with an annual increase in collective dose in excess of the 4,700 man Sv saving which was achieved between 1984 and 1995. A recent American study has suggested that since the use of PACS makes images and reports available more speedily, clinicians are requesting more radiological examinations [Reiner et al, 2000]. The authors state that at the hospital which used PACS, the number of examinations per outpatient visit increased by 21% while those at a similar hospital increased by only 1% and those nationally decreased by 19%. If a similar trend in

the number of examinations per patient is seen at all hospitals which use PACS, the population dose will increase even if there is no change in the dose for individual images.

The risks associated with low doses of radiation (such as those used for general diagnostic examinations) are still under discussion [Nussbaum 1998, Mossman 1998, Sinclair WK 1998]. A study in an 800 bedded hospital in Greece [Okkalides and Fotakis, 1994] estimated that the total effective dose for patients undergoing plain radiographic examinations has an average annual risk of producing about three malignancies. In addition the authors extrapolated their results to the whole of Greece, and based on the number of examinations undertaken in 1989, they estimated that each year there would be 300 fatal malignancies and 55 cases of severe hereditary disorders due to doses from plain radiography.

The Joint Working Party of the RCR and the NRPB has stated
'The paucity of direct evidence for detrimental effects from low levels of radiation has led some radiologists to question the need for any concerns. The following quotation from a recent paper on radiology for back pain highlights this opinion. "A restriction or alteration of radiological investigations is often suggested to avoid possible radiation hazards: however, the world literature does not contain a single report of a patient injured by modern diagnostic radiography of the lumbar spine no matter how complex or repeated and it borders on the absurd to argue that this should restrict the patient's investigation [Butt W, 1989]"' The JWP disagreed with this statement and estimated that between 100 and 250 cancer fatalities each year could be due to unnecessary diagnostic radiology [NRPB, 1990].

The increase of more than 4,700 man Sv in annual exposure due to the use of CR plates instead of 400 speed film systems, represents an additional risk to the general (not paediatric) population of about 165 patients developing a fatal cancer, other cancer or other serious defect including hereditary effects, over the course of their lives [ICRP, 1990]. The cost of this additional risk is estimated as £235m [NRPB, 1993] for the general population. If the population was composed of older

patients, the cost would be reduced by 50% to £117.5m, and if the population was paediatric, the cost would increase to £470m. However, in this thesis the issue of paediatric doses has not been addressed and so no comment can be made on the effect of PACS on paediatric doses.

The body areas for which doses have been measured and which are reported in this thesis are the lateral lumbar spine and the chest. The lumbar spine was chosen for detailed study because it was the single area which made the greatest contribution (15%) to the collective dose in the UK, and was second only to CT examinations which contributed 23% [NRPB, 1990]. The lateral views were selected because they accounted for the major part of the dose for each examination. The NRPB has estimated the average 'lifetime risk of fatal cancer' per million people of all ages and both sexes to be 30 - 100 for lumbar spine examinations [NRPB, 1990]. The estimated probability of a hereditary effect occurring after the mother has had a lumbar spine examination is 16 per million and 0.2 per million after irradiation of the father for the same examination. The effect on the fetus was estimated to be 200 per million for childhood cancer, and 1560 per million for mental retardation when the exposure occurred at 8 to 15 weeks gestation [NRPB, 1990]. The chest is the single area most frequently examined but has a risk 50 times lower than for the lumbar spine (0.7 - 2 per million), and contributes to only 2% of the annual collective dose. The NRPB have not quoted estimates for the effects on a fetus of parental irradiation of a chest examination.

The NRPB comments *'It must be remembered that the effects of radiation are cumulative and that many patients undergo intensive periods of radiological examination during the course of their medical treatment. The risk of inducing fatal cancer from a series of X-ray examinations required in the course of a long- standing illness or severe trauma may well accumulate to a level of one in only a few hundred or so, particularly if the patient is young'* [NRPB, 1990]. In the study which was reported in chapter 5 one patient, who was originally admitted for trauma, had more than 80 mobile chest examinations while on the ITU.

Some authors have reported that doses for examinations of extremities can be reduced when CR is used, while maintaining image information comparable to film [van der Jagt et al, 2000]. However, since extremity examinations require good detail, slow speed films and screens are used. The speed used in the van der Jagt study was not given, but mammography films and screens were used which would have a low combined speed. The risk associated with extremity examinations is low compared with examinations of the thorax and abdomen. Shrimpton has calculated the period of natural radiation which is equivalent to specific radiological examinations [Shrimpton, personal communication]. An extremity examination is equivalent to a period of less than 1.5 days exposure to natural radiation, while a lumbar spine examination is equivalent to a year's exposure and a chest examination to a week's exposure. Thus the risk to the patient from examinations of the extremities is comparatively low.

In 1980 Capp predicted that all film would be eliminated and all radiology departments would be electronic by the year 2000 [Capp, 1981]. Five years later he amended his prediction and suggested that the change would occur 5 to 10 years earlier [Capp, 1985]. In 1989 Fraser et al [Fraser et al, 1989] predicted that by the turn of the century 50% of large teaching hospitals would be using digital radiography for chest images, and that by 2020 all chest images in large centres would be digital. They also suggested that '*the potential overall impact (of PACS) on digital imaging cannot be avoided. ..... Further, assuming that PACS is an inevitable trend as a means of improving organisation and communication within both the radiology department and hospital as a whole, full-scale digital imaging is the first step in this development*'. In 1997 it was reported that there were 3000 computed radiography installations in the world with 600 in Europe, 580 in America and 85 in Germany [Braunschweig et al, 1997]. This implies that the patients in these hospitals are receiving higher doses than if film screen systems with speeds greater than 300 were used.

The number of PACS in hospitals in the world is increasing but has not been as rapid as Fraser suggested. Surveys have shown that there was an increase in the number

of large scale PACS from 13[1] in 1993 [Bauman, 1994] to 23[2] in 1995 [Bauman et al 1996a, Bauman et al 1996b]. There is currently only one hospital in the UK which has a hospital-wide PACS and this is the Hammersmith Hospital. There are also several hospitals in the UK which have small scale systems and others which are moving towards a full system. There is therefore still time for lower dose digital acquisition systems to be refined and incorporated into PACS.

10.4 RECENT TECHNOLOGICAL DEVELOPMENTS AND IMPLICATIONS FOR FURTHER RESEARCH

The use of PACS does not itself necessarily increase radiation doses. If images are acquired by a fast film/screen system and then digitised into PACS, the overall doses should be reduced due to the saving in repeat exposures due to lost images. However, it is time consuming to digitise films. An improvement in the manufacture of phosphor plates or detectors might reduce doses. An alternative is to use another method of obtaining the images which produces images which are acceptable for diagnosis at lower doses. Direct Radiography (DR) systems are being developed which save radiographer time because the detectors do not have to be removed from the site of exposure for processing. The evidence is currently inconclusive whether DR will allow lower doses to be used for acceptable image quality for clinical patient examinations [Van Heesewijk et al 1996, Bury et al 1998, Strotzer et al 1998, Fay 1998].

Bury et al [Bury et al 1998] used the Leeds Test Object, TO20 (as used in chapter 3), to measure and plot curves of the threshold detection index of each system. They found that the curves for the DR system were better than those for the CR system, even at lower exposures, suggesting that lower doses by a factor of two or three could be used with the DR system for clinical work, with no reduction in image quality. Conversely, the same exposures could be used which would produce

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[1] the PACS had to be in daily clinical use, include three or more modalities, and have images available inside and outside radiology.

[2] in addition to the 1993 requirements, these PACS had to handle a minimum of 20,000 exams annually.

significant improvement in the quality of the images They reported that initial results of using DR for clinical work was encouraging, and that a clinical evaluation programme had already begun. However, the field size of the DR system used was 20 cm x 20 cm (too small for many examinations). Further comparative research needs to be undertaken when larger sizes of detector are available.

Strotzer et al have undertaken a comparison of DR and a 400 speed film/screen system and shown dose reductions up to 75% for skeletal radiography [Strotzer et al 1998]. Unfortunately these authors also encountered methodological problems due to the small size of the DR system. They obtained images of the same patients with both systems but used different field sizes. Since the areas of the images were not identical, strict comparisons cannot be made but the results are encouraging and suggest that dose reductions may be possible with such systems while maintaining adequate image quality. Again, further research is required in this area.

More recent unpublished work from Bremen (Hamers, personal communication, 2000) suggests that a more recent DR system with a field size of 43cm x 43cm produces images which are of comparable quality to 400 speed film/screen images with significantly reduced doses. Two studies have been undertaken which will be submitted for publication. In the first study, 31 pairs of bone images including skull, lumbar spine and upper femur, were compared side by side by six radiologists. Six criteria were used for the comparisons (image latitude, soft tissue rendition, cortical bone, cancellous bone and pathology including the visibility of lesions) and the viewers used a 5 point scale to indicate their image preference for each of the criteria. All radiologists preferred the DR images for all criteria except visibility of lesions and for these, the results were less clear. In the second study phantoms were used. Sixty bovine humeri with simulated lesions, subdivided into four regions, were used to compare film/screen, two CR systems and DR images for contrast resolution. The results indicate that the DR system compares well with the other systems. Further details will be available when the papers are published.

Siegel and Reiner suggested that '*although not fully tested clinically, DR additionally promises the potential to maintain or increase spatial resolution depending on the system used, increase contrast resolution, and, in some cases, increase detected quantum efficiency resulting in decreased radiation exposures.*' [Siegel & Reiner, 1999]. The VA Hospital in Baltimore has been working with equipment manufacturers and has tested a DR unit. They report that there are problems associated with incorporating DR into a PACS which require the production of new software and these problems have not yet been fully resolved. These results confirm the statement by Professor Osteaux, former President of EuroPACS, that manufacturers have been promising DR for the last 6 years and 'we are still waiting' [Osteaux, Invited Lecture 'PACS at 1998: What should be expected', EuroPACS 1998]. In addition, a Working Party of the Royal College of Radiologists has pointed out that although DR systems may permit the use of lower doses, they are currently unsuitable for mobile images for which phosphor plate imaging will need to be used [Royal College of Radiologists, 1999].

10.5 THE NEED FOR DIGITAL IMAGES

Stewart has suggested that '*the driver for film less radiology is not anticipated cost or film library space savings, but the economic imperative of practicing medicine, and specifically radiology, at a distance, as well as providing prompt service to physician customers for use in decision making*' [Stewart, 1999]. In order to operate a teleradiology service the images much be in digital format and PACS fits well into this digital environment. In the United States there are already well established businesses which run teleradiology services and the number is increasing rapidly [Thrall & Boland, 1998]. At present there are limited teleradiology systems in the UK, however, since these fit well into the environment of providing health care at a distance under the umbrella of 'Telemedicine' they are encouraged within the Government's Information Strategy [NHS Executive, 1998].

10.6 CONCLUDING COMMENTS

A lot of attention is being paid to looking at PACS in terms of its cost implications and to justify business cases for its purchase . This thesis has not considered cost but has focussed on the more fundamental issue of patient radiation doses and the 'value in use' of the resultant radiological images.

It has been shown that with current PACS, there are dose increases compared with those which are achievable in the majority of UK hospitals. Unless CR systems within PACS can be replaced by image acquisition systems which provide the required quality of image at lower radiation doses there will be an increase in the collective dose to the adult population. The work reported in this thesis found very little evidence of improvements in patient outcomes when PACS was used which can justify the use of higher radiation doses. Each hospital considering purchasing a PACS must therefore make a judgement about whether the organisational benefits associated with easier access to radiological images can justify the additional radiation doses and associated risks to patients.

APPENDICES

APPENDIX 1 ADDITIONAL TABLES RELATING TO CHAPTER 4

DATA RELATING TO CHARACTERISTICS OF ALL PATIENTS IN THE STUDY.

Table A1.1 SEX

	FILM (N = 100)	PACS (N = 96)
MALE	46	46
FEMALE	54	50

Chi^2 test p = 0.79

Table A1.2 AGE (years)

	FILM (N = 100)	PACS (N = 96)
mean	49.82	49.74
SD	17.19	15.87
Median	48.47	48.04
Range	70.385 (88.37-17.988)	60.599 (19.69-80.29)
Q3-Q1	31.086	25.77

Mann - Whitney test p = 0.99

Table A1.3 WEIGHT (kg)

	FILM (N = 99*)	PACS (N = 95*)
mean	72.77	74.33
SD	15.21	16.14
Median	70.5	73
Range	74.5 (41-115.5)	83 (43-126)
Q3-Q1	17.5	18.5

Mann - Whitney test p = 0.51

*two patients were unable to stand to be weighed

Table A1.4 HEIGHT (cms)

	FILM (N = 99*)	PACS (N = 95*)
mean	167.52	166.85
SD	11.00	9.54
Median	167	167
Range	45 (151-196)	44 (148-192)
Q3-Q1	15	14

Mann - Whitney test p = 0.96

*two patients were unable to stand to be measured

RESULTS FOR DATA RELATING TO GROUP 3 - SINGLE VIEWS OF THE WHOLE OF THE LUMBAR SPINE, L1-5.

Table A1.5 THICK (cms)

	FILM (N = 100)	PACS (N = 96)
mean	28.02	27.16
SD	3.04	2.42
Median	28	27
Range	18 (20-38)	14 (22-36)
Q3-Q1	3	3

T-Test p = 0.025

RESULTS FOR DATA RELATING TO PATIENTS CHARACTERISTICS OF GROUP 4 FOR L1-5 EXAMINATIONS. (PATIENTS WITH WEIGHT 65-75 KILOGRAMS).

Table A1.6 Variable SEX of patient

	FILM (N = 34)	PACS (N = 26)
MALE	11	9
FEMALE	23	17

Chisq test p = 0.85

Table A1.7 Variable AGE of patient (years)

	FILM (N = 34)	PACS (N = 26)
mean	54.01	51.16
SD	16.71	14.02
Median	57.72	51.28
Range	69.03 (19.34-88.37)	48.66 (29.1-77.76)
Q3-Q1	25.10	19.73

Mann-Whitney test p = 0.44
T-Test p = 0.4454

Table A1.8 Variable WEIGHT of patient (kg)

	FILM (N = 34)	PACS (N = 26)
mean	69.51	69.54
SD	2.77	3.33
Median	69.5	68.75
Range	9.5 (65-74.5)	10 (65-75)
Q3-Q1	4	6

Mann-Whitney test p = 0.88
T-Test p = 0.8815

Table A1.9 Variable HEIGHT of patient (cms)

	FILM (N = 34)	PACS (N = 26)
mean	164.35	164.38
SD	7.82	8.07
Median	164	164.5
Range	28 (151-179)	32(149-181)
Q3-Q1	14	13

T-test p = 0.86

Table A1.10 Variable THICK - thickness of patient at centring point (cms)

	FILM (N = 34)	PACS (N = 26)
mean	27.81	26.56
SD	1.8	1.64
Median	27.5	27
Range	9.5 (22.5-32)	6 (24-30)
Q3-Q1	1.5	3

T-Test p = 0.63

RESULTS FOR DATA RELATING TO GROUP 5 - SINGLE VIEWS OF THE LUMBO-SACRAL JOINT (L5/S1) N = 38 total

Table A1.11 Variable SEX of patient

	FILM (N = 26)	PACS (N = 12)
MALE	5	3
FEMALE	21	9

Chisq test p = 0.69

Table A1.12 Variable AGE of patient (years)

	FILM (N = 26)	PACS (N = 12)
mean	52.34	57.31
SD	14.29	15.45
Median	52.77	59.79
Range	45.98 (27.25-73.22)	43.42(34.98-78.40)
Q3-Q1	24.25	27.95

T-test p = 0.71

Table A1.13 Variable WEIGHT of patient (kg)

	FILM (N = 26)	PACS (N = 12)
mean	74.23	78.49
SD	13.46	20.53
Median	71.75	78
Range	48.5 (51.5-100)	81.5(44.5-126)
Q3-Q1	12	19.5

T-test p = 0.08

Table A1.14 Variable HEIGHT of patient (cms)

	FILM (N = 26)	PACS (N = 12)
mean	165.58	162.75
SD	7.80	10.39
Median	164.5	161
Range	30 (151-181)	35(148-183)
Q3-Q1	12	12

T-test p = 0.23

Table A1.15 Variable THICK - thickness of patient at centring point (cms)

	FILM (N = 24*)	PACS (N = 12)
mean	32.38	32.04
SD	2.21	2.38
Median	32	32
Range	11 (28-39)	7.5 (29-36.5)
Q3-Q1	2	4

T-Test p = 0.74

* patients were moved before measurements could be made.

REGRESSION MODELS

Group 1 Patients

Table A1.16 Model 1: total effective dose per examination (dependent variable, LOGSUMEFF; N = 194)

Independent variable	Regression coefficient	p value
PACSDUM	-0.182148	0.0047
SEXDUM	-0.447340	0.0001
JUNCTDUM	0.300033	0.5020
BMI	0.056269	0.0001
AGE	-0.006532	0.0010
FREQ	0.746506	0.0001

Table A1.17 Model 2: total entry dose per examination (dependent variable, LOGSUMENT; N = 194)

Independent variable	Regression coefficient	p value
PACSDUM	-0.233663	0.0009
SEXDUM	-0.414043	0.0001
BMI	0.050542	0.0001
AGE	-0.006188	0.0041
Junctdum	0.662622	0.1746
FREQ	1.033102	0.0001

Table A1.18 Model 3: total dose area product per examination (dependent variable, LOGSUMDAP; N = 169)

Independent variable	Regression coefficient	p value
PACSDUM	-0.324977	0.0001
JUNCTDUM	-0.057709	0.9120
FREQ	0.585073	0.0001
BMI	0.059681	0.0001
AGE	-0.005751	0.0176

Group 2 Patients

Table A1.19 Model 4: total effective dose per examination reported (dependent variable, LOGSUMEFF: N = 194)

Independent variable	Regression coefficient	p value
PACSDUM	-0.289472	0.0003
SEXDUM	-0.287902	0.0003
BMI	0.060831	0.0001
AGE	-0.004961	0.0400

Table A1.20 Model 5: total entry dose per examination (dependent variable, LOGSUMENT: N = 194)

Independent variable	Regression coefficient	p value
PACSDUM	-0.379555	0.0001
SEXDUM	-0.190609	0.0477
BMI	0.058629	0.0001
AGE	-0.003945	0.1832

Table A1.21 Model 6: total dose area product per examination (dependent variable, LOGSUMDAP: N = 169)

Independent variable	Regression coefficient	p value
PACSDUM	-0.450002	0.0001
SEXDUM	-0.231657	0.0065
BMI	0.063510	0.0001
AGE	-0.003879	0.1281

Group 3 Patients

Table A1.22 Model 7: dose for L1-5 images (dependent variable, LOGEFF, N = 179)

Independent variable	Regression coefficient	p value
PACSDUM	-0.067352	0.0932
THICK	0.100273	0.0001
MAS	0.006248	0.0001
PATAREA	0.000321	0.0504
CONSTANT	-4.714801	0.0001

Table A1.23 Model 8: dose for L1-5 images (dependent variable, LOGENT N = 175*)

Independent variable	Regression coefficient	p value
PACSDUM	0.082018	0.0831
THICK	0.077600	0.0001
FFD	-0.014946	0.0001
MAS	0.008117	0.0001
AGE	-0.002378	0.0167
PATAREA	0.000213	0.1265
CONSTANT	1.460586	0.0001

*Some observations produced influential data points and were not included on the grounds of the Cook's D-statistic.

Table A1.24 Model 9: dose for L1-5 images (dependent variable, LOGDAP, N = 163*)

Independent variable	Regression coefficient	p value
PACSDUM	-0.269802	0.0001
THICK	0.048220	0.0001
KV	0.004435	0.2262
MAS	0.008533	0.0001
PATAREA	0.001217	0.0001
CONSTANT	32.538927	0.0001

* some DAP readings unavailable because the diamentor was not working/installed, and two observations were excluded owing to influential data points

Group 4 Patients

Table A1.25 Model 10: dose for L1-5 images for patients within the National Protocol weight range (dependent variable, LOGEFF: N = 58)

Independent variable	Regression coefficient	p value
PACSDUM	0.067508	0.4217
SEXDUM	-0.046382	0.5356
THICK	0.048141	0.0351
PATAREA	-0.000134	0.5987
AGE	-0.003811	0.0282
KV	0.025245	0.0042
MAS	0.014225	0.0001
FFD	-0.016104	0.0007
BMI	0.007899	0.5068
CONSTANT	-4.009004	0.0001

Table A1.26 Model 11: dose for L1-5 images for patients within National Protocol weight range (dependent variable, LOGENT; N = 59)

Independent variable	Regression coefficient	p value
PACSDUM	0.068429	0.4151
SEXDUM	-0.045303	0.5448
AGE	-0.003809	0.0281
BMI	0.008105	0.4956
THICK	0.047882	0.0359
KV	0.013091	0.1256
MAS	0.014327	0.0001
FFD	-0.016236	0.0006
PATAREA	-0.000132	0.6044
CONSTANT	1.006096	0.2857

Table A1.27 Model 12: dose for L1-5 images for patients within the National Protocol weight range (dependent variable, LOGDAP; N = 58)

Independent variable	Regression coefficient	p value
PACSDUM	-0.281863	0.0186
SEXDUM	-0.185824	0.0655
THICK	0.011848	0.6913
PATAREA	0.000608	0.0826
AGE	0.001379	0.5410
KV	-0.008459	0.5232
MAS	0.010940	0.0003
FFD	-0.003644	0.5513
BMI	0.026935	0.0890
CONSTANT	4.8963693	0.0011

APPENDIX 2 ADDITIONAL TABLES RELATING TO CHAPTER 7

Table A2.1 Film packets requested and missing for Thursday morning fracture clinics when film was used

	Packet requested	Packets missing	Percent missing
N	60	60	60
Mean	75.6	9.3	12.0
SD	18.1	6.9	7.2
Median	75.5	7	10.2
Range	117 (30-147)	35 (1-36)	31.4 (1.5-32.9)
Q3-Q1	17	7	8.8

Table A2.2 Film packets requested and missing for Thursday morning respiratory medicine clinics when film was used

	Packet requested	Packets missing	Percent missing
N	60	60	60
Mean	27.1	4.1	15.3
SD	8.9	3.1	9.8
Median	27.5	3	14.1
Range	37 (7-44)	13 (0-13)	39.4 (0-39.4)
Q3-Q1	11.5	4	14.7

Table A2.3 Examinations requested and on line at the start of Thursday morning fracture Clinics when PACS was fully operational

Date	Number of patients with previous exams in last year	Number of patients with unavailable exams at start of clinic	% patients with unavailable exams at start of clinic
24.10.96	24	0	0
31.10.96	23	0	0
7.11.96	19	0	0
14.11.96	12	0	0
12.12.96	17	0	0
19.12.96	12	0	0
9.01.97	Unknown*	ALL	100
23.01.97	20	20	100

* No PACS print outs were available

NB: The Department of Orthopaedics moved from Hammersmith Hospital to Charing Cross Hospital after the film study and before the PACS study. The number of patients attending fracture clinic each week was therefore lower for the PACS study

Table A2.4 Examinations requested and on line at the start of Thursday morning respiratory medicine clinics when PACS was fully operational

Date	Number of patients with previous exams in last year	Number of patients with unavailable exams at start of clinic	% patients with unavailable exams at start of clinic
24.10.96	27	0	0
31.10.96	24	0	0
7.11.96	22	0	0
14.11.96	21	0	0
12.12.96	15	0	0
19.12.96	8	0	0
9.01.97	Unknown*	ALL	100
23.01.97	14	14	100

* No PACS print outs were available

Table A2.5 Conquest Hospital - Frequency of repeat examination ordering

	DEC93 (round %)	JUN94 (round %)	JUN95 (round %)	JUN96 (round %)
Less than one repeat per month	26 (50%)	21 (50%)	30 (63%)	23 (74%)
1-2 repeats per month	15 (29%)	13 (31%)	11 (23%)	7 (23%)
3-4 repeats per month	3 (6%)	3 (7%)	1 (2%)	1 (3%)
More than 4 repeats per month	8 (15%)	5 (15%)	6 (13%)	0
Total	52	42	48	31

Table A2.6 Norfolk and Norwich Hospital - Frequency of repeat examination ordering

	JUN94 (round %)	JUN95 (round %)	JUN96 (round %)
Less than one repeat per month	81 (76%)	70 (79%)	105 (82%)
1-2 repeats per month	19 (18%)	17 (19%)	19 (15%)
3-4 repeats per month	7 (7%)	1 (1%)	4 (3%)
More than 4 repeats per month	0 (0%)	1 (1%)	0 (3%)
Total	107	89	128

Table A2.7 Royal Free Hospital - Frequency of repeat examination ordering

	JUN94 (round %)	JUN95 (round %)	JUN96 (round %)
Less than one repeat per month	66 (71%)	65 (73%)	75 (71%)
1-2 repeats per month	17 (18%)	16 (18%)	20 (19%)
3-4 repeats per month	10 (10%)	6 (7%)	7 (7%)
More than 4 repeats per month	0 (0%)	2 (2%)	4 (4%)
Total	93	89	106

Table A2.8 Nottingham City Hospital - Frequency of repeat examination ordering

	JUN94 (round %)	JUN95 (round %)	JUN96 (round %)
Less than one repeat per month	72 (86%)	85 (75%)	104 (75%)
1-2 repeats per month	12 (14%)	25 (22%)	26 (19%)
3-4 repeats per month	0 (0%)	4 (4%)	4 (3%)
More than 4 repeats per month	0 (0%)	0 (0%)	4 (3%)
Total	84	114	138

Table A2.9 John Radcliffe Hospital - Frequency of repeat examination ordering

	JUN94 (round %)	JUN95 (round %)	JUN96 (round %)
Less than one repeat per month	70 (71%)	83 (78%)	76 (84%)
1-2 repeats per month	22 (22%)	16 (15%)	12 (13%)
3-4 repeats per month	5 (5%)	5 (5%)	2 (2%)
More than 4 repeats per month	1 (1%)	2 (2%)	1 (1%)
Total	98	106	91

HEALTH ECONOMICS RESEARCH GROUP

Brunel
THE UNIVERSITY OF WEST LONDON

EVALUATION OF RADIOLOGY ARCHIVING AND COMMUNICATION SYSTEMS

Hammersmith Hospital

Clinician Questionnaire

The questions which follow will only take a few minutes to answer. They are being distributed every six months. Therefore, some of the questions may not appear to be relevant at present, but please bear with us and complete the questionnaire.

Professor David Allison would like you to know that this questionnaire is being distributed with his full approval. However, the individual responses will be dealt with in strict confidence by staff at Brunel University.

Thank you for your time and co-operation.

1 AUG 1994

Distribution date: ~~June 1994~~ Please return by: ~~Friday 1st July 1994~~

Health Economics Research Group, Brunel University, Uxbridge, Middlesex, UB8 3PH, UK.
(Tel: 0895 203331).

SECTION I

We would like first to ask you about your routine use of the radiography and radiology service in your hospital.

1 In general, how satisfied are you with the quality of the images that you receive? (please tick each line)

	Very Satisfied	Satisfied	Neutral	Dissat-isfied	Very Dissat-isfied	Not Relevant To Me
Clinical Purposes						
a) inpatient	☐	☐	☐	☐	☐	☐
b) outpatient*	☐	☐	☐	☐	☐	☐
Teaching Purposes	☐	☐	☐	☐	☐	☐
Research Purposes	☐	☐	☐	☐	☐	☐

* including A&E attenders

2. If you are dissatisfied in any way with the quality of the images you receive, please identify the reason(s) and any particular modality/body area.

	Reason	(please tick)	Modality/body area
A	Labelling	☐	_____
B	Lack of image detail	☐	_____
C	Poor exposure	☐	_____
D	Incorrect patient position	☐	_____
E	Images too small	☐	_____
F	Incorrect choice of views	☐	_____
G	Other, please specify	☐	_____

Please identify the major cause of your dissatisfaction; circle ONE letter below.

A B C D E F G

3. In general, how satisfied are you with the **written** reporting service that you receive? (please tick each line)

'Written' reporting includes any of 4 instances when a radiologist i) dictates to a dictaphone for subsequent typing, ii) dictates directly to a typist, iii) hand writes a report and iv) records the report directly on to a computer.

	Very Satisfied	Satisfied	Neutral	Dissat-isfied	Very Dissat-isfied	Not Relevant To Me
Clinical Purposes						
a) inpatient	☐	☐	☐	☐	☐	☐
b) outpatient*	☐	☐	☐	☐	☐	☐
Teaching Purposes	☐	☐	☐	☐	☐	☐
Research Purposes	☐	☐	☐	☐	☐	☐

* including A&E attenders

4. If you are dissatisfied in any way with the **written** reporting service, please identify the reason(s) and any particular modality/area.

	Reason	(please tick)	Modality/area
A	Time delay in report production	☐	_____
B	Not available when clinically required	☐	_____
C	Restrictions in reporting service	☐	_____
D	Report inaccuracies	☐	_____
E	Incomplete reports	☐	_____
F	Computer related problems	☐	_____
G	Other, please specify	☐	_____

Please identify the major cause of your dissatisfaction; circle ONE letter below.

A B C D E F G

5. In general, how long after imaging do you receive a **written** report on the images? (please tick each line)

	Within 1 day	Within 3 days	Within 7 days	Within 2 weeks	Within 2-4 weeks	Longer than 4 weeks	Not relevant to me
Clinical Purposes							
a) inpatient	☐	☐	☐	☐	☐	☐	☐
b) outpatient*	☐	☐	☐	☐	☐	☐	☐
Teaching Purposes	☐	☐	☐	☐	☐	☐	☐
Research Purposes	☐	☐	☐	☐	☐	☐	☐

* including A&E attenders

6. In general, how satisfied are you with the quality of the **verbal** reporting service that you receive? (please tick each line).

'Verbal' reports/opinions are defined as the situation where a referring clinician asks the radiologist to comment on an image in an informal setting either in person or by telephone.

	Very Satisfied	Satisfied	Neutral	Dissat-isfied	Very Dissat-isfied	Not Relevant To Me
a) inpatient	☐	☐	☐	☐	☐	☐
b) outpatient*	☐	☐	☐	☐	☐	☐

* including A&E attenders

7. If you are dissatisfied in any way with the verbal reporting service please indicate below (please tick as appropriate).

A	Service not available	☐
B	Radiologist rarely available to give verbal opinion	☐
C	Time involved in visiting Radiology Department to see radiologist	☐
D	Difficulty in getting through by phone	☐
E	Inadequate/inaccurate opinions provided	☐
F	Variation in quality of service depending on which radiologist is available	☐
G	Other, please specify	☐

Please indicate the greatest cause of your dissatisfaction; circle ONE letter below.

A B C D E F G

8. Approximately how much time do you spend, on average, in informal case discussions with radiologists each week?

..... hrs per week

9. Approximately how much time do you spend, on average, in routine meetings, eg clinico-radiological sessions, with radiologists each week?

..... hrs per week

10. What aspect of the current radiology service do you find least satisfactory?

_____

_____

11. Which of the following images do you use? (please tick each line)

	Frequently	Occasionally	Rarely	Never
Computed Tomography (C/T).....	☐	☐	☐	☐
Digital Subtraction Angiography (DSA)	☐	☐	☐	☐
Ultrasound (US).....	☐	☐	☐	☐
Nuclear Medicine (N/M).....	☐	☐	☐	☐
Magnetic Resonance (MRI).....	☐	☐	☐	☐
X-rays: head/neck.....	☐	☐	☐	☐
chest.....	☐	☐	☐	☐
abdomen.....	☐	☐	☐	☐
limbs.....	☐	☐	☐	☐
screening eg barriums	☐	☐	☐	☐
A & E	☐	☐	☐	☐
mobiles on wards	☐	☐	☐	☐
mobiles in theatres	☐	☐	☐	☐
mammography.....	☐	☐	☐	☐
IVP/IVU.....	☐	☐	☐	☐
Others.....	☐	☐	☐	☐
.....	☐	☐	☐	☐

SECTION II

We would now like to ask you some questions about the time you spend looking for and viewing images of ward patients and outpatients, and the impact this has on your work.

Ward Patients

12. If applicable, could you estimate the time you personally spend, on average, locating and viewing images for:-

    a ward round ..... hrs

13. Could you estimate what proportion of images of ward patients are typically unavailable? (please tick one range)

1% or less	2-5%	6-10%	11-15%	16-20%	21-50%
☐	☐	☐	☐	☐	☐

14. Do you feel that there is a problem with **lost ward patient images** at your hospital?

    'Lost' images are defined as those which are not available when clinically required.

    Yes ☐ No ☐

    If YES, what impact does this have on your clinical practice? (please tick appropriate boxes).

A	Clinical decisions are delayed	☐
B	There is less time for patient care	☐
C	Ward rounds are disrupted	☐
D	Operations are delayed	☐
E	Patient's hospital stay is longer	☐
F	Medico-legal implications	☐
G	No major effect	☐
H	Other, please specify	☐

    Please identify the major impact on your clinical practice; circle ONE letter below.

    A B C D E F G H

Outpatients

15. If applicable, could you estimate the time you **personally** spend, on average, locating and viewing images for:

    an outpatient clinic ..... hrs

16. Could you estimate what proportion of images of outpatients are typically unavailable? (please tick one range)

1% or less	2-5%	6-10%	11-15%	16-20%	21-50%
☐	☐	☐	☐	☐	☐

17. Do you feel that there is a problem with lost **outpatient images** at your hospital?

Yes ☐ No ☐

If YES, what impact does this have on your clinical practice? (please tick appropriate boxes)

A	Clinical decisions are delayed	☐
B	There is less time for patient care	☐
C	Patient's outpatient visit is longer	☐
D	Patient requires additional outpatient visit	☐
E	Disrupts outpatient clinic	☐
F	Medico-legal implications	☐
G	No major effect	☐
H	Other, please specify	☐

Please identify the major impact on your clinical practice; circle ONE letter below.

A B C D E F G H

18. If you consider that "**lost**" images are a problem, where do you think the problem lies? (please tick more than one box if appropriate)

A	Misfiling/incorrect labelling	☐
B	Multi-packs (separate packets for each modality, ie. film, C/T, MRI, N/M, US, mammos, angios)	☐
C	Images awaiting reports	☐
D	Images kept on wards	☐
E	Images not kept on wards	☐
F	Split-site hospitals	☐
G	Patients referred from other hospitals	☐
H	Archiving time too short	☐
I	Images being retained by previous user/doctor	☐
J	Other, please specify	☐

Please identify the major cause of the problem; circle ONE letter below.

A B C D E F G H I J

19. If an image was "lost" would you **personally** search for it?

Yes ☐ No ☐

If YES, could you estimate the **average time** that you **personally** spend searching in a week?

..... hrs

20. Do you routinely delegate this task to someone else?

Yes ☐ No ☐

If YES, to whom? (please tick more than one box if appropriate)

Junior doctor	☐
Ward clerk	☐
Medical secretary	☐
Nurse	☐
X-ray department staff	☐
OP Clerk/Receptionist	☐
Auxiliary	☐
Medical student	☐
Other	☐

If "other", please specify

_____

21. Do you ever order a repeat examination if the original image is lost?

Yes ☐ No ☐

If YES, how many? (Please tick).

Less than 1 repeat examination per month	1-2 repeat examinations per month	3-4 repeat examinations per month	More than 4 repeat examinations per month
☐	☐	☐	☐

SECTION III

Finally, we would like you to consider all PACS-related activities that you have participated in, and the impact that your time commitment to these activities has had on your work.

22. Please estimate the total amount of time you have spent on formal and informal PACS-related training over the last six months.

Time undergoing training yourself ..... hrs

Time spent on the training of others ..... hrs

23. Please estimate the time you have spent on other PACS-related activities in the last six months, eg. meetings/committees.

..... hrs

..... hrs

24. Since the start of the PACS Project, have you had to forgo any activities which you had previously undertaken at work?

Yes ☐ No ☐

If YES, what are the activities you have forgone?
(Please quantify if possible, and indicate if a locum has ever had to be employed.)

_____

_____

_____

_____

_____

25. Since the start of the PACS Project have your total working hours increased due to involvement with the Project?

Yes ☐ No ☐

26. How, in general do you feel about PACS and the demands it places on your time?

_____

_____

_____

_____

_____

_____

_____

Thank you for taking the time to complete this questionnaire. Please return it in the envelope provided by ~~Friday 1st July 1994.~~

Professor Martin Buxton, Health Economics Research Group,
Brunel University, Uxbridge, Middlesex UB8 3PH.

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