

PORTABLE FLUOROSCOPIC DEVICES — THE LIXISCOPE —

a report by the

NATIONAL

HEALTH

TECHNOLOGY

ADVISORY

PANEL

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PORTABLE FLUOROSCOPIC DEVICES - THE LIXISCOPE

A REPORT BY THE
NATIONAL HEALTH TECHNOLOGY ADVISORY PANEL

Any comments or information relevant to the subject matter of this report would be welcome. Correspondence should be directed to:

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PORTABLE FLUOROSCOPIC DEVICES - THE LIXISCOPE

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THE NATIONAL HEALTH TECHNOLOGY ADVISORY PANEL

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- | | |
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EXECUTIVE SUMMARY

- . The Lixiscope is a portable, hand-held, fluoroscopic X-ray unit. The device incorporates an iodine-125 X-ray source and a small battery powered image intensifier.
- . The landed cost of the Lixiscope (duty free) in Australia is about \$18,000. Each replacement of the radioisotope (whose useful life is about 4 months) costs approximately \$2,000. Annual renewal costs are therefore \$6,000. These costs may be substantially reduced in the future by introduction of longer lived sources.
- . Although there are areas of concern, the Australian Radiation Laboratory has concluded that the use of the Lixiscope by a competent operator would not create a radiation hazard to the patient or operator.
- . The literature on this device reports uses in sports medicine, accident and emergency rooms, podiatry and orthopaedics.
- . The Panel has concerns that the nature, size and quality of the image could lead to misdiagnoses. For example, hairline fractures could be missed. Misdiagnoses could occur also if the device is used by persons untrained in radiological practice.
- . The Panel concludes that the effectiveness of the Lixiscope as a diagnostic tool has not been established, and considers that widespread use of this device is not justified.
- . Other portable fluoroscopic devices are being developed and marketed overseas. The questions raised in respect of the Lixiscope should be similarly considered with these devices before any decisions are made on their distribution and use. In particular they should meet the following criteria:
 - the image should have adequate spatial and contrast resolution for the applications for which the device is intended.
 - the image should neither be inverted nor reversed.
 - scatter radiation reaching the patient and the user should be negligible.
 - permanent records of images should be readily obtainable.

The Panel recommends that:

- the use of the Lixiscope and other portable imaging devices should be restricted to medical practitioners who have the appropriate licenses and expertise in radiation safety;
- guidelines should be developed by users to ensure good radiological practice and security against theft and unauthorized use.
- reimbursement for use of the Lixiscope should not be considered.

INTRODUCTION

In March 1985 the Commonwealth Department of Health asked the NHTAP to provide advice on the effectiveness of the Lixiscope, a hand-held fluoroscopic device which can be used to X-ray the extremities. This request followed an approach to the Department of Health concerning possible reimbursement for services using this device.

At that time there were no Lixiscopes approved for medical use in Australia, and assessment did not proceed pending a review of safety and performance of the device by the Australian Radiation Laboratory (ARL). A Lixiscope was subsequently provided to the ARL in June 1986 for evaluation for radiation safety.

In the course of its study of this technology the Panel became aware that other manufacturers were producing portable fluoroscopic devices. The Panel's report, whilst concerned mainly with the Lixiscope, also arrives at some general principles for the assessment of the wider range of portable fluoroscopic devices entering the medical imaging market.

DESCRIPTION OF THE LIXISCOPE

The name for this device is in part an acronym for low intensity X-ray imaging. The Lixiscope is based on a device developed in the course of the United States space program, for the detection of low intensity radiation from deep space. It is manufactured by Lixi Inc, Illinois, USA, under licence from NASA.

The Lixiscope comprises a sealed radiation source, detector, image intensifier, and 50 mm fluorescent viewing screen. The source is usually iodine-125 (which has a half-life of 60 days and a disintegration energy of 28 keV) with a choice of activities from 3.7GBq to 18.5GBq. The literature on this device also describes an americium - 241 source.

The object being observed is placed between the source and the detector, which are linked by a fixed arm. There is a choice of arms that allow the source-to-detector distance to be varied from 50-200 mm. The detector is a scintillator which converts X-rays from the source to a visible light image. This image is intensified by a high-gain microchannel plate electron multiplier which produces an average gain of about 4×10^4 . The output is then directly visualized on a fluorescent screen. Two 1.5V size "C" batteries are required to charge the microchannel plate. The basic unit weighs 3kg.

Imaging is initiated by depressing a spring loaded trigger located at the hand grip which aligns the radiation source with an aperture in its stainless steel capsule. The action allows a collimated beam to be directed towards the scintillator. Releasing the trigger allows a spring mechanism to return the source to its covered position.

The Lixiscope can be supplied with an optional video display system incorporating a camera that magnifies the 50 mm image and displays it on a monitor. Also included is a special stand with a flex arm that makes it easier to focus on the area of interest. The system is floor-activated for easier use during operation.

The manufacturer's literature on the Lixiscope does not mention the need for any special safety precautions such as use of radiation badges or protective gear (for example lead aprons or shielding) when operating the device.

APPLICATIONS

Removal of foreign Bodies

The Lixiscope has been reported to be useful in the location and removal of radiopaque foreign bodies from the extremities. It has been reported that the entry wound could be explored with minimal dissection, and the object removed with reduced trauma to the surrounding tissue (1).

Sports Medicine

The use of the Lixiscope in sports medicine to diagnose injuries of the hand, foot, ankle, wrist and elbow has been reported (2). The Lixiscope was said to have the advantages that immediate diagnosis could be carried out at the scene of the injury, enabling a physician to differentiate quickly between sprains and fractures.

The Panel was informed that the Lixiscope was made available to the medical staff of the USA Olympic Team during the Summer Olympic Games in 1984. The Panel was advised that overall the Lixiscope was found to be very useful (3) but no quantitative data were provided on the extent of usage. It aided on-the-spot initial evaluation of distal extremity trauma but was subject to limitations in the level of detail it could provide and could not be applied to larger anatomic regions (3).

Accident and Emergency Rooms

Reports have been published on short-term evaluations (one-two weeks) of the Lixiscope in Accident and Emergency Departments, at Northampton General Hospital (4), King's College Hospital (5) and Plymouth General Hospital (6) in the UK. The Lixiscope

was generally perceived as a useful diagnostic tool in these settings. It could be applied in diagnosing or excluding fractures (4, 6) checking fracture reduction, bone alignment, and requirements for manipulation (4, 5, 6), positioning screws and wires during fracture fixation (4), and removing foreign bodies (4, 5).

However, assessors noted several limitations of the device. The anatomical areas to which the Lixiscope could be applied were limited by declining image clarity with increasing soft tissue thickness (6). At King's College Hospital it was found that for adults, the Lixiscope could be used to examine only the hands, forearms, toes, metatarsals and heels (5). It was difficult to visualise details through plaster casts (5, 6). Owing to its weight, the Lixiscope was difficult to hold for any length of time, particularly if one hand was used to position the patient (5, 6).

At King's College Hospital, where the device was operated by casualty officers, the Lixiscope was used to examine 71 patients out of a total of 1139 seen in the Accident and Emergency Department over a 7 day period. All Lixiscope examinations were followed by conventional X-ray examination. In 13 cases the Lixiscope diagnosis was not supported by the conventional X-ray examination.

Podiatry

Several papers have reported on the applications of the Lixiscope in podiatry, as a diagnostic tool, a monitor of operative procedures and for post-operative assessment (1, 7-9). The Lixiscope was seen to have the advantages of providing images in real time, allowing the examination of an object from a number of different angles, and because of its capacity for continuous imaging, permitting observation of movement, restrictions on motion and points of impingement (1). It has been pointed out to the Panel that because of the small field of view the movement being observed could only be of one joint at a time (10). Clinically it is desirable to see the relationships between all joints simultaneously to assess function as a unit (10). The Lixiscope is reported to facilitate the application of minimal incision surgery, which has benefits such as the use of local rather than general anaesthesia, less pain and faster healing (1).

Orthopaedics

Orthopaedic applications were described at the first symposium on the medical uses of the Lixiscope (11). It was suggested that it could be an important screening device.

The Lixiscope has been used in the examination and evaluation of geometry-dependent flaws in osseous structures as well as in the evaluation of both range and quality of motion of joints (1, 12). Other uses have included visualising the manipulation

of dislocations and fractures in real time, location of percutaneous fixation devices immobilizing fractures, and timing of their removal and real time visualisation of finger, hand, wrist and ankle arthrograms. This is reported to allow the flow of dye to be visualized while it is being injected, a procedure which is claimed to facilitate identification and location of any abnormality.

The Australian Society of Orthopaedic Surgeons has commented that the image provided by the Lixiscope of bones is mediocre but that a technique such as this could have a place in the management of simple fractures, such as those of the hand or wrist, provided that there is no significant radiation problem for the user or the patient (13).

Dentistry

Dental applications were discussed at the first symposium on the medical uses of the Lixiscope (14). It was noted that the resolution may not be fine enough to detect hairline fractures, small apical abscesses and other common dental pathology for which a resolution of more than 10 line pairs per mm (lp/mm) is required. The Panel is unaware of any extensive use in dentistry.

SAFETY ASPECTS

Safety Features of the Device

Safety features have been included in the design of the Lixiscope to reduce radiation exposure to both the patient and the operator. When the Lixiscope is not being used an automatic shutoff device shields the I-125 source. When the device is used a beeping sound is heard every ten seconds to alert the user that the source is exposed. Unauthorised use can be minimised by applying a locking device which prevents alignment of the source with the aperture. The sealed source cannot be removed from its shielded capsule without special tools. The device is expected by the manufacturers to withstand any accidents that may be likely to occur during transportation, storage or use.

Overseas Assessments of Safety

The US Nuclear Regulatory Commission (NRC) approved the Lixiscope for licensing purposes in April 1981 (15). In discussing its safety features, the NRC stated that it was unlikely that any person would be exposed to excess doses of radiation. An in-depth review of leakage or scatter of ionizing radiation found it to be well within NRC standards. It was noted that, like most other devices with isotope sources, each Lixiscope should be leak tested by an individual or company licensed to do such testing, at intervals not to

exceed six months (15). The NRC data on health physics was evaluated by the US Food and Drug Administration (FDA) and considered to be adequate to allow approval of the device for medical use. The FDA permitted marketing of the Lixiscope as a medical device in 1982.

An assessment of the device has also been undertaken by the United Kingdom National Radiological Protection Board (16). The assessment was carried out primarily with regard to the hazard to the user, and the consequent operating requirements which may be imposed on the user. The report concluded that the radiation was adequately confined to the equipment housing. A typical surface dose rate to the skin of a patient was measured but the report did not comment on total dose delivered to a patient during an examination, which would be determined by clinical considerations. The report recommended that in accordance with the basic principle in radiological protection that all exposures should be kept as low as reasonably achievable, care should be taken that the Lixiscope is not used to gain information which could have been satisfactorily ascertained by the use of existing non-radiological means. The report also recommended that only persons who have undergone suitable training should use the Lixiscope.

In September 1985 the Department of Health and Social Security, UK issued an assessment report on the Lixiscope (5). The report stated that the device met the requirements of the Code of Practice for the Protection of Persons against Ionizing Radiation in respect of radiation dose to designated personnel, but that its use would require local regulations to be imposed by the responsible authority.

In July 1986 the National Radiation Laboratory (NRL) of the New Zealand Department of Health tested the device for dose rate, image quality and personal protection (17). Because of the low X-ray output and small field size, the radiation hazard from the Lixiscope was found to be very low. The NRL was of the opinion that the device should be restricted to use by licensed operators. Conditions for such a license would need to be decided in each case.

During the trial in the Accident and Emergency Department at Northhampton General Hospital, Denman and Evans (18) tested the radiation safety of the Lixiscope on 118 patients. They found that the dose to the operator's eye was so low as to be unmeasurable and the dose to the trigger finger was similarly very low. The operator's free hand, which was often used for manipulation of the patient, was found to be most at risk.

The authors commented that as the Lixiscope was so simple to use, there was a possibility that it could be used more widely than conventional radiography. Indeed, at the end of the tests, 58% of the patients examined by the Lixiscope received less radiation dose as a consequence of using the device, 16% received more and 26% received radiation when under standard conditions none would have been given. Denman and Evans suggested local rules for its use as follows:

- . The device should only be used by Accident and Emergency doctors, and kept locked at all other times.
- . Screening time should be restricted to the minimum suitable for adequate diagnosis, and it is recommended that the screening time should never exceed one minute for each patient.
- . When the device is used on pregnant patients, a lead apron covering the patient's body should be used.
- . When positioning the patient during screening care must be taken to ensure that hands are kept well away from the main beam.
- . The largest amount of scattered radiation is directed in an arc back towards the source. It is therefore essential that patient and operator are positioned so that no part of their bodies are within 10cm of the Lixiscope in this area.

Australian Assessments of Safety

In 1986 the ARL undertook a radiation safety evaluation of two models of the Lixiscope.

The evaluation was concerned primarily with assessing the radiation doses to the user and patient. The report of the evaluation (19) concluded that competent use of the instrument would not create a radiation hazard to the patient or operator. Nevertheless the ARL identified the following areas of concern:

- . Size of the beam:

The diameter of the beam is substantially greater than required to cover the receptor area. The collimation of the source needs to be corrected so that the diameter of the beam does not exceed by more than 2 mm that necessary to fill the field of view.

- . Small source to skin distance (SSD):

The exposure rate from the source increases substantially as the SSD is reduced. In the interest of reducing patient dose (and improving image definition) medical examinations

should be undertaken with the limb positioned against the image intensifier of the unit. The minimum SSD does not comply with the minimum distance requirements of two Australian standards for X-ray equipment, AS 2814 and AS 3205). Owing to the design of the source housing, there is nothing to prevent the skin being placed as close as 1 cm from the source.

Levels of scattered radiation dose to the hands of the user:

It was found that the dose rate to the user due to scattered radiation, in particular to the hands, varied substantially with respect to the geometry of the scattering arrangement and the scattering material. Using a water phantom placed near to the source it was possible to measure dose rates at the location of the user's hands of approximately $180 \mu\text{Gy}\cdot\text{hr}^{-1}$. Although this dose rate is not high, particularly when averaged over a normal working week and assuming intermittent usage, it is substantially higher than those for most standard radiographic procedures which are generally near to normal background levels.

The dose to the user may be reduced to levels near those of standard radiography by using scatter shields and lead rubber gloves. These precautions are recommended. Finger monitoring is also recommended when using the unit.

The ARL also noted that as the Lixiscope is small, very portable and simple to use, the potential for misuse or theft cannot be ignored. If left unattended, for example, at a sports medicine clinic or casualty department of a hospital, the temptation for self-use or unauthorized use would be high.

IMAGE QUALITY

The spatial resolution of the image produced by the Lixiscope is about 3-4 lp/mm with a 18.5GBq source. By comparison, the resolution of an industrial television monitor is of the order of 8 lp/mm.

The Lixiscope provides a small field of view which could be inconvenient for examining total extremity structures or long bones. In addition, the device produces a reversed and inverted image which can prove confusing to the operator. Daniels and Mason have commented that orientation was found to be especially difficult when screening the carpal and tarsal bones (4). The ARL has suggested that the nature of this image combined with the small field of view means that the user will require a period of orientation which will prolong the diagnostic/exposure period and hence the radiation dose to the

user and the patient (19). The ARL further commented that due to the divergence of the beam, the actual size of the object required to fill the field of view can be very much less than 50 mm (10).

There has been some concern expressed regarding the quality of the image produced by the Lixiscope. The National Institutes of Health have advised the US Office of Health Technology Assessment that before the technology is used on a wide scale better data are needed regarding image quality (15). Similar comments were made by the American Academy of Orthopaedic Surgeons (15). The Veterans Administration also expressed concerns about the possibility of misdiagnoses due to the diagnostic limitations of the device. It was noted that the image quality deteriorates as the operator examines thicker parts of limbs, thereby raising the possibility of mistaken diagnosis (15).

In its evaluation of the device the ARL noted that, compared to standard radiographic methods the image appears relatively grainy and of low contrast (19). The ARL commented that the poorer the image, the longer will be the period required to reach a diagnosis. The electronic circuitry within the unit includes an "automatic gain control" so that the brightness does not reduce as the source activity decays. However as the source reduces in activity the image quality falls (19).

The ARL considered that the Lixiscope should not be recommended for use in preference to standard radiographic methods unless it can be demonstrated that the procedure cannot be performed readily using standard radiography or other appropriate method.

The Royal Australasian College of Radiologists (RACR) has commented that as a general principle a real time image obtained with an image intensifier is useful in the study of dynamic processes (20). However, real time imaging is not appropriate for the diagnosis of bone and soft tissue injuries because their use produces the possibility of an unacceptably high radiation exposure. If an abnormality is difficult to visualize the operator is likely to require a long exposure time to make a satisfactory diagnosis.

The New Zealand National Radiation Laboratory (17) found that the image quality of the device was reasonable, but its low contrast performance was not as good as conventional image intensifiers or film screen combinations, while detectability of small objects was superior to conventional image intensifiers and comparable with medium speed film screen systems. Fine grain film screen combinations typically used for extremity and joint radiography were superior to the Lixiscope on all counts.

The RACR has undertaken a limited assessment of image quality of the Lixiscope (20). Images were found to be of only moderate quality, with both contrast and spatial resolution inferior to a film/screen combination. It was therefore likely that a fine fracture line could be missed by the Lixiscope. The field of view (50 mm) was found to be extremely small making it difficult and time consuming to study an injured limb. This also made assessment of fracture alignment unsatisfactory.

The RACR concluded that there were only rare indications for the use of the Lixiscope because a minor injury in which no fracture was detected by the device would need a further X-ray to exclude the possibility of a hairline fracture, whilst serious injuries with significant fractures would have a deformity which is obvious clinically and would not require the Lixiscope for a diagnosis. Subsequent X-ray examinations would always be carried out in this group of patients. The use of the Lixiscope in the above situations was considered to be unnecessary, and would result in extra radiation exposure to patients (20).

COSTS

The landed cost of the Lixiscope (duty free) in Australia was estimated to be about \$18,000 in August 1986. Each replacement of the radioisotope (whose useful life is about 4 months) costs approximately \$2,000. Annual isotope renewal costs are therefore about \$6,000. These costs (capital and renewal) will vary with movements in foreign exchange rates.

ASSESSMENTS OF EFFECTIVENESS

In a recent assessment of the Lixiscope the US Office of Health Technology Assessment (OHTA) of the National Center for Health Services Research and Health Care Technology Assessment noted that there were no controlled clinical trials comparing the device with other imaging devices (15). There were, however, reports of its use in various clinical situations.

Daniels and Mason considered the cost effectiveness of the Lixiscope during the trial at the Northhampton General Hospital (4). During that period 2392 patients were treated of whom 854 (36%) were X-rayed. A total of 118 patients were screened with the Lixiscope. During the second week of the trial 394 X-rays were ordered by the Accident and Emergency Department. A further 46 (10.5%) would have been requested had the device not been available. The authors estimated that the Lixiscope saved the National Health Service a minimum of £ 230 in that week, projected to £ 11,960 per year. The capital cost of the device at that time could on the basis of this performance, be recovered in less than 9 months.

In its report on the Lixiscope, the UK Department of Health and Social Security (5) commented that in its present form the device was expected only to have limited application in the UK National Health Service. The report noted however that the proposed use of a radioactive isotope of twice the half life and half the cost of the existing source would overcome most of the objections to the device.

In its report on the Lixiscope, the New Zealand NRL agreed with written reports received from two radiologists in New Zealand hospitals on the clinical usefulness of the device (17). Both reports expressed the view that the Lixiscope would be of use in restricted circumstances such as fracture reduction, when in the hands of an experienced operator. Doubt was expressed about its use for initial diagnosis of fractures, and about its use by inexperienced medical staff. Its use by untrained staff was opposed. The NRL commented that these opinions generally agreed with those expressed in other reports it had received.

Although the Lixiscope has been licensed for use in Canada there appears to be little demand for it (21). The West German Federal Department of Health has not licensed the device on the grounds of limited image quality, ready access of normal X-ray diagnostic equipment to the radiologist, and restricted range of application (21).

The cost effectiveness of the Lixiscope in sports medicine would depend in part on the frequency of injuries for which it would be relevant. Dicker et al (22) recently reported on the results of a three-year study on the site and nature of injuries in Australian Rules Football players (in the Victorian Football League). A total of 1408 injuries were recorded comprising mainly sprains and strains (39%) and haematomas (34%). Fractures of the upper and lower limbs represented 4% of the total injuries and dislocations 4%. Of lower limb fractures, 25% (6 cases), occurred in the foot. In upper limb fractures 74% (20 cases), occurred in the hand or wrist. Another Australian Rules study by Hoy and Kennedy over one year revealed a comparable distribution of type and site of injury (23). An earlier study examined Australian Rules injuries presenting to the casualty department of a district hospital during a 25 week period (24). A much higher percentage of more serious injuries were reported. Fractures of the upper and lower limbs represented 22% of total injuries and dislocations 6%. Hoy has suggested that these results more likely reflect the type of injuries that are selectively referred to casualty departments (23).

These figures suggest that in contact sports such as Australian Rules, the frequency of injuries which are likely to be diagnosed by the Lixiscope would not be high. However a portable device would be useful if it were efficient enough to rule out fractures reliably.

The Australian Institute of Sport has advised the Panel that 30% of all injuries seen at the Institute are in the extremities (25). Some of these injuries would be hairline or stress fractures arising from the repetitive nature of the training undertaken by athletes. As discussed in the earlier sections of this report, the Lixiscope would be unsuitable in the diagnosis of such fractures.

DEVELOPMENT OF OTHER PORTABLE FLUOROSCOPIC DEVICES

The Panel has been informed that portable instruments, similar to the Lixiscope, but using X-ray tubes rather than a radioactive source, are likely to be marketed in the near future and that a model is being designed for dental use (21). Two companies, other than Lixi, are known to be active in the same market. More detailed information on the instruments was not available to the Panel at the time of publication of this report.

CONCLUSIONS

The Panel considers that portable real-time imaging devices could be clinically useful in a limited number of fields, such as emergency services, sports medicine and orthopaedics. However, their usefulness would depend on satisfactory technical performance, radiation safety and operator competence.

In the case of the Lixiscope, a number of technical problems have been identified. In particular, the low resolution of the image severely limits its range of applications. The small, inverted and reversed image causes difficulties for the operator and could contribute to prolonged exposure for the patient. The radiation dose to the operator's hand is a matter for concern. A permanent record of an image can only be obtained by photographing it, which may not always be convenient.

The Panel suggests that the scope for clinical applications of portable imaging devices could be considerably expanded if efforts were made to optimise image quality, minimise scattered radiation and provide a simple mechanism for obtaining a permanent record.

There are also non-technical problems associated with the Lixiscope which could apply to all portable imaging devices. Their simplicity could lead to use by persons untrained in the interpretation of radiographic images, which would result in misdiagnoses. Their portability makes them vulnerable to theft or use by unauthorised persons. It is suggested that institutions using portable imaging devices should formulate rules for their use in order to minimise these problems.

The Panel notes that there have been no substantial clinical trials of the Lixiscope, and literature reports on its use generally refer to trials based on a short time period or a limited number of patients. It is difficult to conclude, therefore, that its usefulness as a diagnostic tool has been established. While it may have a limited role, for example in accident and emergency services, the Panel is not certain that its capital and operating costs would be justified even in these cases.

The Panel concludes that there is insufficient evidence of cost-effectiveness at the present time to justify reimbursement of services using this device, or for encouraging its widespread use. Where it is used, it should be operated only by medical practitioners with some experience in the interpretation of radiographic images and a knowledge of radiation safety.

It is suggested that as other portable imaging devices become available in Australia, they should be examined in the light of the issues raised in this report before decisions are made on their distribution and use.

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