N80-12384

NASA Conference Publication 2112

PRELIMINARY APPLICATIONS
AND EVALUATION RESULTS

BINDERY SHELF

LIXISCOPE

Proceedings
of the
Lixiscope Conference

MAR 1 9 2000

A Conference held at the
Goddard Space Flight Center
Greenbelt, Maryland
on July 27 and 28, 1978

July 1978

GODDARD SPACE FLIGHT CENTER
GREENBELT, MARYLAND

NASA-CP-2112

Preliminary Applications
and Evaluation Results

Lixiscope

Proceedings of the
Lixiscope Conference

A conference held at the
Goddard Space Flight Center
Greenbelt, Maryland
on July 27 and 28, 1978

Goddard Space Flight Center
Greenbelt, Maryland

ACKNOWLEDGMENTS

Page intentionally left blank

CONTENTS

I. INTRODUCTION

Dr. George F. Pieper
Director of Sciences
Goddard Space Flight Center

Some time ago, it became apparent to scientists at the Goddard Space Flight Center that the ability to make images of celestial objects in the X-ray and gamma ray regions of the spectrum would be important to astronomy in the future, much as the ability to make an image in the visible region using ordinary photographic techniques is important today. It was this interest in the imaging of hard X-rays and soft gamma rays that led to the development of a low intensity X-ray imaging device, known as the Lixiscope, by Dr. Lo I Yin of Goddard's Science Staff.

Soon after Dr. Yin began its development, it became clear that the Lixiscope would have uses beyond the purely scientific. Recognizing these potential uses, he first presented the Lixiscope concept at the American Nuclear Society meeting in San Francisco in November 1977. Since that time, interest in the device has been very strong in areas of non-space applications.

During the past year, a number of highly qualified medical institutions have conducted preliminary evaluations of the Lixiscope to determine the usefulness of the device in various applications. These applications include:
- Orthopedics
- Dental Research
- Podiatry
- Maxillo-Facial Diagnosis
- Pediatrics
- Veterinary Medicine

On July 27 and 28, 1978, a conference was held at the Goddard Space Flight Center to present the preliminary results of these evaluations. The conference provided an opportunity for the discussion of future possibilities, future improvements, and future applications.

In the following paragraphs, summary descriptions of these preliminary results are given, along with a discussion of the concept of the Lixiscope; its comparison with other X-ray imaging devices; information regarding the use of the device, patent policy and licensing, and radiological regulations; and some contemplated improvements to the prototype Lixiscope.

Page intentionally left blank

II. THE LIXISCOPE

A. THE LIXISCOPE CONCEPT

Dr. Lo I Yin
Laboratory for Astronomy and Solar Physics
Goddard Space Flight Center

The principle of the Lixiscope is extremely simple. (Figure 1) It is based on a modular approach toward X-ray imaging where the three major components are physically independent entities, and therefore easily replaceable and interchangeable. The three major components are: the X-ray source, the converter phosphor or scintillator, and the microchannel plate visible-light image intensifier. The X-ray image of an object formed by the X-ray source falls onto the converter phosphor or scintillator which converts the X-ray image into a visible-light image. This visible-light image is then intensified by a factor of 10^5 or more by a high-gain microchannel plate visible-light image intensifier whose output can be viewed directly, photographed, or coupled to other imaging devices. Because of the high gain of the microchannel plate image intensifier, it is possible in some applications to use a radioactive source instead of an X-ray machine. In this manner, the whole X-ray imaging device becomes completely portable.

In the Lixiscope prototype, a "point" radioactive source is inside a shielded source holder. (Figure 2) A finger-controlled mechanism unshields the source to collimate the radiation onto a converter phosphor which is shielded from ambient light, but is optically coupled to the night vision image intensifier. Because of the source collimation and two layers of lead glass in the intensifier, no significant radiation above natural background reaches the viewer. The Lixiscope is powered by a single 2.7 volt battery in the handle.

Since its inception, there has been a large interest in the Lixiscope. Because of its small size and portability, there are many potential medical and
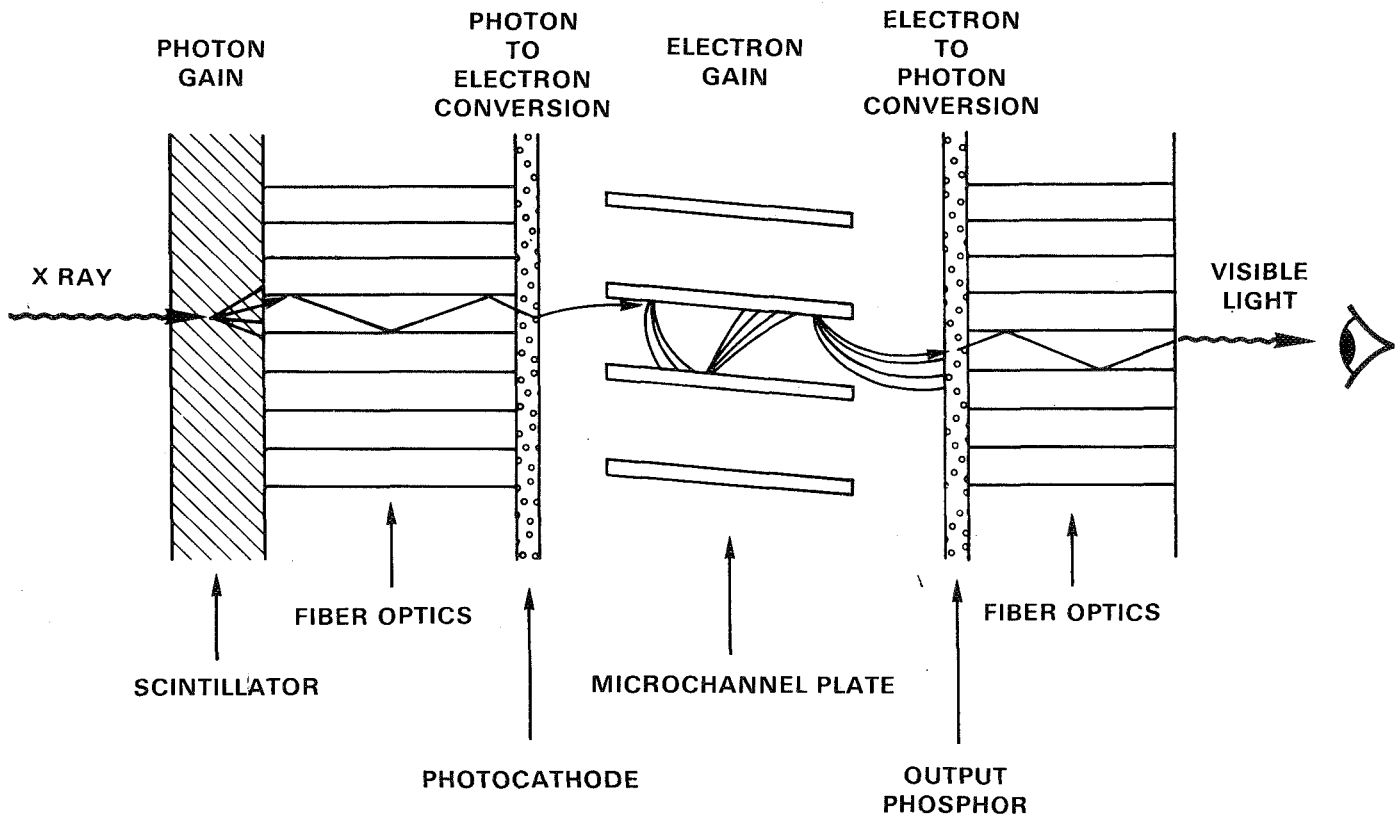
Figure 1. Principle of the Lixiscope
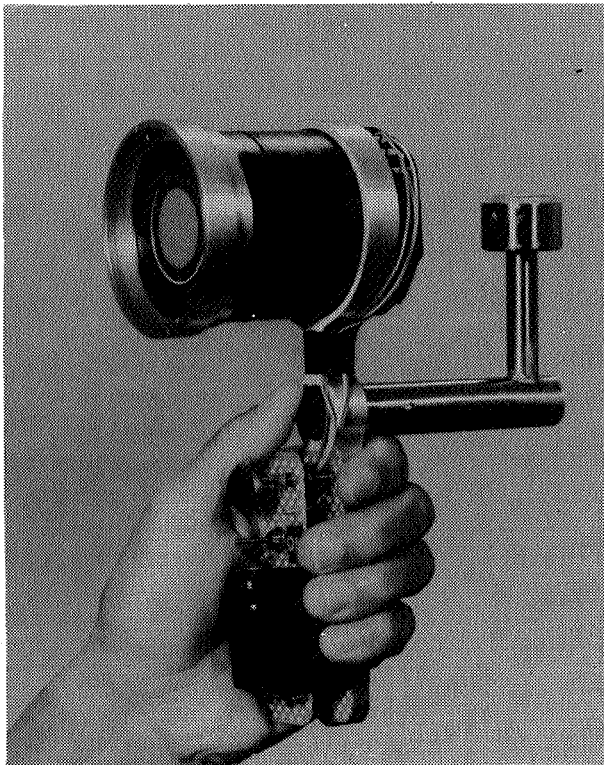
Figure 2. The Lixiscope Prototype

industrial applications. During the past year, experts in some areas of medicine and medical physics have, on a rather limited scale, tested the prototype Lixiscope. The preliminary impressions and evaluations of the potential applicability, advantages, limitations, as well as shortcomings of the Lixiscope in the respective fields are described in this report. There have not been any formal large-scale clinical evaluations of the Lixiscope. This conference can be considered only as an initial effort in this direction.

To put the Lixiscope in its proper perspective, the following characteristics should be considered.

1. The Lixiscope is a small-sized, fully portable fluoroscope.[1-4] As such, its most promising applications are likely to be in those situations where large size is not important but portability is, such as where electricity is not available or where easy maneuverability is necessary. Therefore, it will not replace or duplicate the functions of existing X-ray imaging devices, which are large-sized and non-portable. There are areas of overlap where the Lixiscope can serve as a complement to the larger instrument.

2. When performance characteristics such as image quality and dose rates associated with the Lixiscope are considered, one should take into account the specific manner in which it is to be used. In this regard, publications may have been misconstrued by implying that the Lixiscope is the only low-dose imaging device, or that it can achieve dosage reductions of 10^3 times in all applications. This is not the case. There are other existing devices and methods which have equal performance characteristics at low-dose levels comparable to the Lixiscope. However, in fluoroscopy, the Lixiscope not only achieves these performance characteristics simply and efficiently, but also in an extremely compact, rugged, and *fully portable* manner. Small, portable fluoroscopy is the most important characteristic of the Lixiscope.

3. Because the Lixiscope is essentially a fluoroscopic device for real-time X-ray imaging, the best way to present the real-time images would be in the form of a movie or a video tape. However, in the accompanying photos, the fluoroscopic images were recorded on instant-processing film. As such, they are not direct X-ray radiographs, and should not be compared with the resolution and quality of X-ray radiographs.

4. The prototype Lixiscopes used for these evaluations were constructed entirely from off-the-shelf items. No effort was made to optimize their performance for a given application.

References

1. L. I Yin and S. M. Seltzer, Phys. Med. Biol. *23*, 993, (1978).
2. L. Yin, J. Trombka, S. Seltzer, R. Webber, M. Farr, and J. Rennie, SPIE *143*, 106, (1978).
3. L. Yin, J. Trombka, and S. Seltzer, Nuc. Instr. Methods *158*, 175, (1979).
4. L. Yin, J. Trombka and S. Seltzer, Space Sci. Instr. (1979), in press.

B. FUTURE PROGRESS IN THE DEVELOPMENT OF THE LIXISCOPE

Jacob I. Trombka
Solar Activity Branch
Goddard Space Flight Center

It was GSFC's interest in the imaging of hard X-rays and soft gamma rays that led to the development of the Lixiscope. High spatial resolution imaging devices capable of single-photon counting in this energy domain of the electromagnetic spectrum will find important applications in the fields of astrophysics, solar physics, planetary physics and in studies of weightless effects in the space environment. The directions that the research in the GSFC laboratory will take in the future development of the Lixiscope with respect to these objectives are summarized below.

The end-point in the research related to the investigations in astro-, solar-, and planetary physics is the development of a hard X-ray/soft γ-ray telescope. It is hoped to use the Lixiscope as a position-sensitive detector placed at the focal plane of such a focussing or collimating X-ray/γ-ray telescope. The Lixiscope properties which are important and need to be developed for such a focal-plane device are single-photon counting with the capability of energy sensitivity as far into the γ-ray region as possible. GSFC has demonstrated the pulse-counting capability as well as simultaneous pulse counting and position sensitivity. These methods are described in the Reference, where the limited pulse-height, or energy resolution of a proto-type high-gain microchannel plate (MCP) tube, is also described. A number of different scintillators are now being tested in order to extend the Lixiscope energy sensitivity. The scintillator of specific interest is CsI. GSFC is also looking at cellurized scintillator screens which may improve spatial resolution at higher γ-ray energies.

GSFC is not presently involved in developing X-ray and γ-ray optical systems, but hopes to use the results of recent research in this field. Both collimator and pin-hole systems show great promise for application in the development of a gamma ray telescope. Fan-shaped collimators might be used to study spatially extended sources. However, collimators are rather limited in terms of mapping large regions of the sky. Pin-hole camera approaches permit mapping of larger regions with good spatial resolution. Single pin-hole systems reduce the flux at the focus of the imaging detecting device (possibly the Lixiscope) to such an extent that extremely long counting times would be required to obtain statistically significant results. On the other hand, multiple pin-hole systems (the Dickey Camera) are capable of focusing images with about 30 percent transmission of the incident flux. Rather complex mathematical methods are required to reduce image confusion due to the multiple pin-hole optical system. Both digital and analog methods are being used to perform the required mathematical transformations.

Finally, many of the phenomena to be studied are time dependent. The excellent time resolution of the Lixiscope detector should be ideally suited for such studies. The time resolution should only be limited by counting statistics.

In studies of biological effects due to weightlessness (Zero-g), the Lixiscope would be used as a fluoroscope. An example of such a study is the observation of the increased inter-costal spacing during weightlessness. This effect is most dramatically demonstrated by the fact that the astronauts become about 3 inches taller during space flight. This growth may be attributed to the increase in inter-costal (space between bones) spaces during space flight. This effect in small animals may be studied with the Lixiscope during some of the Space Shuttle flights. The general effect on skeletal structure due to calcium demobilization can also be studied. Growth phenomena in zero-g and away from wall effect can also be studied.

Based on the foregoing discussion, it is indicated that the Lixiscope has various applications to the basic problems in space research. The Laboratory for Astronomy and Solar Physics is planning a research and development program in which those properties of the Lixiscope most applicable to space flight research will be studied and explored.

Reference

Yin, Lo I, J. I. Trombka, and S. M. Seltzer: "A Low Energy γ-Ray Imaging Detector", Space Science Instrumentation (In press), 1979.

Page intentionally left blank

C. THEORETICAL CALCULATIONS & INSTRUMENT DEVELOPMENT & TEST

CHARACTERIZATION OF LOW INTENSITY X-RAY IMAGING DEVICES

Dr. George Ferguson, Marshall Lewis, Rajinderbir Harnal
Howard University

Dr. Javan Anderson, Ms. Sandra Brown
Howard University Hospital

The search for a high resolution imaging device to detect electromagnetic radiation in the 20 Kev to 300 Kev energy range lead researchers at the National Aeronautics and Space Administration (NASA) to the development of the Lixiscope (acronym for Low Intensity X-ray Imaging Scope). A detailed description of the component parts and the principle of operation of this unique instrument is given elsewhere.[1] The device is essentially the combination of a scintillator to convert impinging X-rays to visible light; a photo-cathode to produce an electron image; a multi-channel plate (MCP) to intensify the electron image; and a phosphor screen to reconvert the intensified image to visible light. Fiber optic plates, which are employed to transmit images between component parts, prevent degradation in resolution of the image.

Radioisotopic sources have been used[2] to excite the Lixiscope in preliminary experimental attempts to evaluate the usefulness of this instrument for industrial and medical applications. The purpose of this study is to explore the characteristics of the Lixiscope when excited by X-rays produced by conventional electrically powered X-ray generators. The broad goal is to determine the optimum X-ray spectrum, and mode of operation of the generator, which yields satisfactory Lixiscope images of medical and industrial specimen.

EXPERIMENTAL PROCEDURE

The experimental arrangement employed with the Lixiscope is shown in Figures 1 and 2.

X-Ray Source

The source of radiation used to excite the Lixiscope is a radiographic inspection system (Faxitron Model 8050–310, manufactured by Field Emission Corporation, McMinnville, Oregon). This self-rectified X-ray system produces a continuously variable output voltage whose range is 10–130 kv, with a maximum current of 3 ma. The X-ray spot size is 0.5 mm.
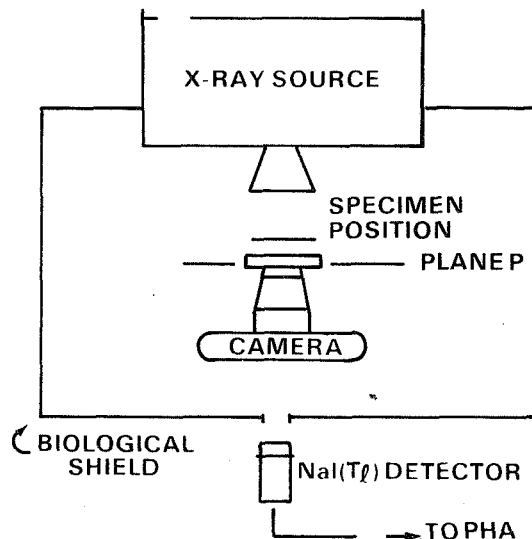
Figure 1. Diagram of Experimental Arrangement used for Lixiscope Investigation

The photon energy distribution of this source, shown in Figure 3, was experimentally measured using a two-inch Na I (Tl) scintillation detector arranged as depicted in Figure 1. The energy scale for Figure 3 was obtained using radioisotopic sources whose radiations are well known.[3]

Image Standards

Exposures of selected specimen were obtained using a standard medical radiographic unit*. The specimen were placed above, and in direct contact with, an 8″ × 10″ film cassette, then irradiated using standard techniques employed by radiologists. The specimen selected were (a) a skeletal hand, (b) a portion of a finger of an Alderson phanthom patient and (c) a composite wire. The composite wire consisted of a small diameter (0.062″ o.d.) inconel tube in

*Medical Radiographic and Fluoroscopic Unit (manufactured by Picker Instrument Corp.), focal point spot 1.4 mm.

7
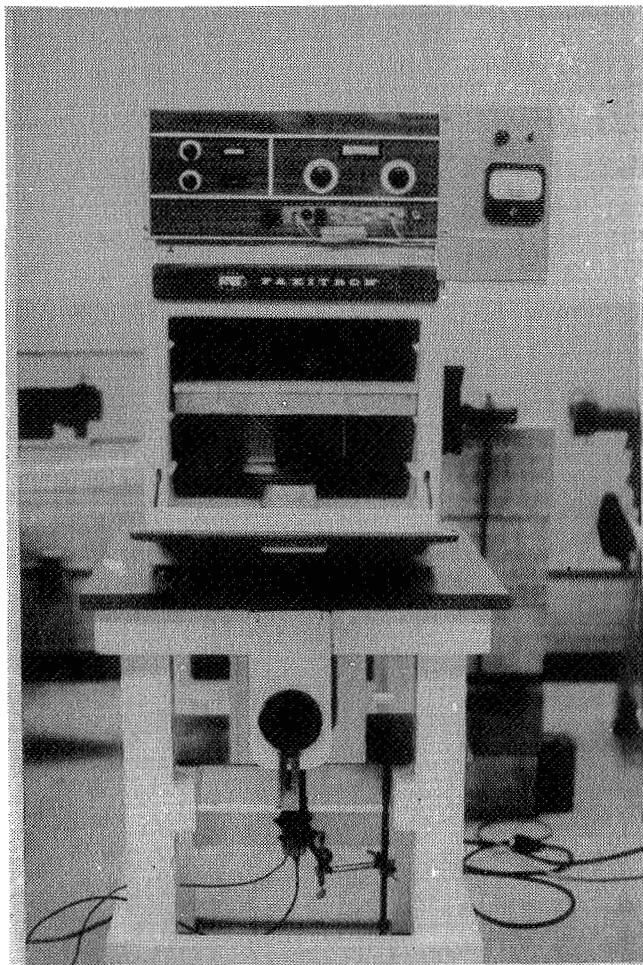
Figure 2. Photograph of Experimental Arrangement

VOLTAGE, KV
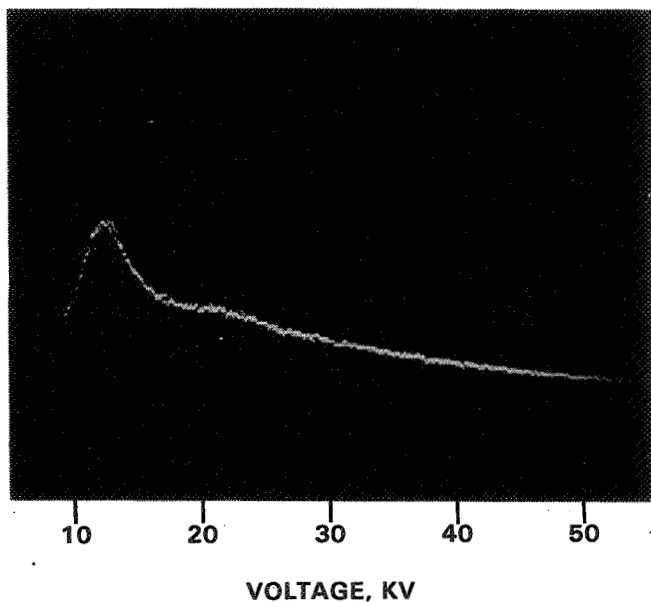
Figure 3. Photon Energy Distribution of X-Ray Source-30 KVP (Faxitron Radiographic Inspection System)
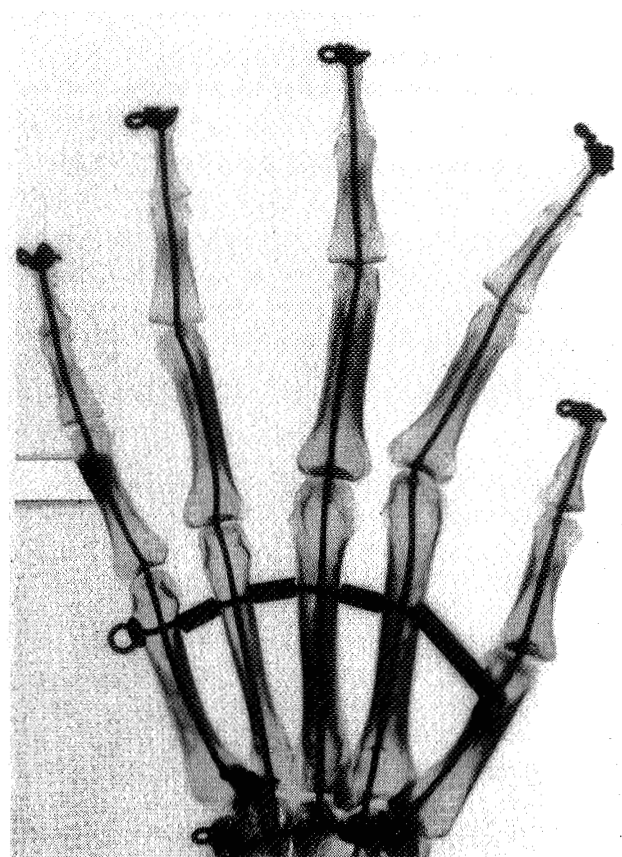
Figure 4. Image of a Skeletal Hand using a Medical Radiographic Unit

Figure 5. Image of an Alderson Phanthom Finger using a Medical Radiographic Unit

which had been inserted rhodium and zirconium wires of two diameters (0.062" o.d. and 0.013" o.d., respectively) and an Al_2O_3 spacer to fill voids. Images of these specimen, as given in Figures 4, 5 and 6 were used as "resolution standards" against which images obtained by other means were compared. Figures 7, 8

8
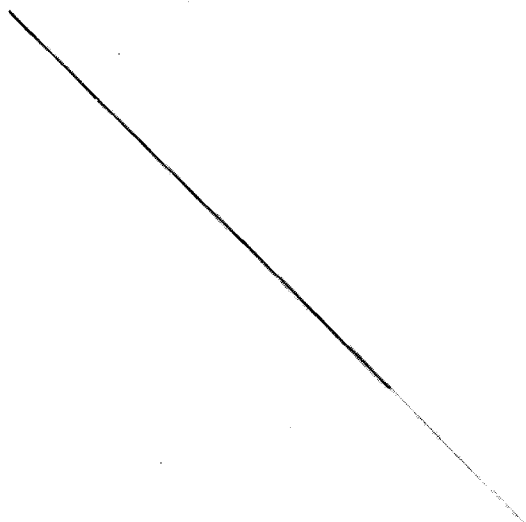
Figure 6. Image of a Composite Wire using a Medical Radiographic Unit

Figure 8. Image of an Alderson Phanthom Finger using the Radiographic Inspection System (Faxitron)
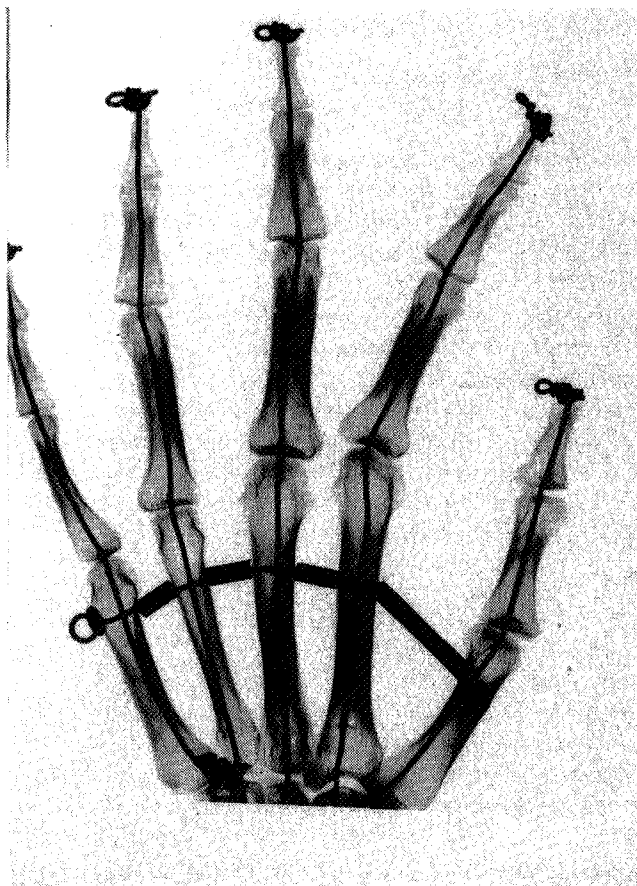
Figure 7. Image of a Skeletal Hand using the Radiographic Inspection System (Faxitron)

and 9 are images of the specimen obtained in the same manner as above, except that the radiation source used was the Faxitron X-ray generator to be employed in the Lixiscope study. A moderate increase in resolution is seen due to the smaller (0.5 mm) spot size for this generator.

Camera Recording System

Photographic images were obtained using a CU-5 Polaroid Close-Up camera (75 mm focal lens at f/4.5, 2× magnification). Measurements indicated negligible darkening of film due to direct exposure to X-rays in the experimental arrangement shown.

Lixiscope Images

Having ascertained that high quality radiographic images are achievable using the Faxitron X-ray system and that sharply focussed photographs (free of background fogging) can be obtained with the camera employed, the Lixiscope images were obtained of specimens (a), (b) and (c) as given in Figures 10, 11 and 12. The resolution of these images is deemed to be acceptable and the Lixiscope could become a useful diagnostic instrument.

Further Studies

The preliminary measurements given above have encouraged us to plan further studies of the characteristics and utility of the Lixiscope. Our plan is to study the response of the Lixiscope as the incident spectral distribution is varied, that is, as the character

Figure 9. Image of a Composite Wire using the Radiographic Inspection System (Faxitron)
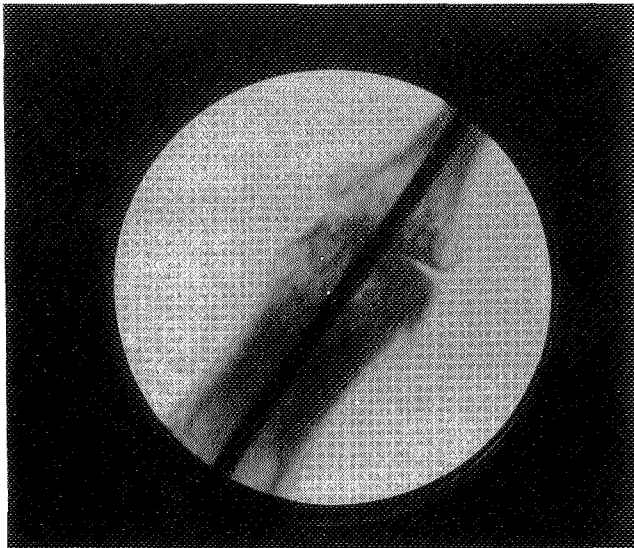
Figure 10. Photograph of Lixiscope Image of a Skeletal Hand (Portion of Index Finger Only)
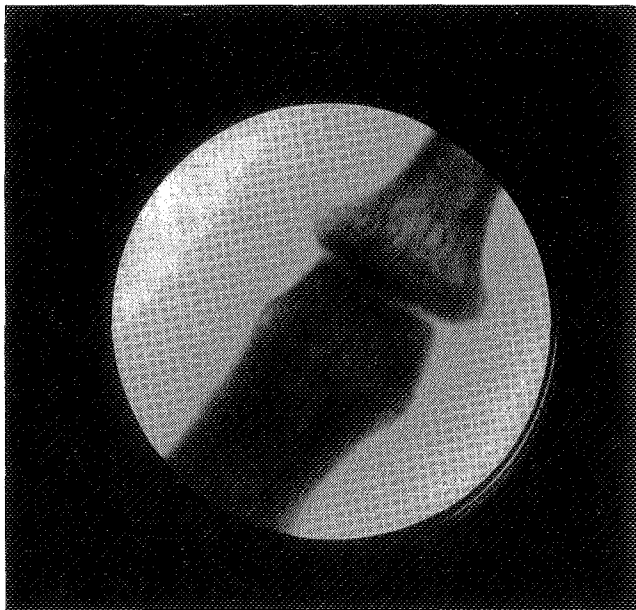
Figure 11. Photograph of Lixiscope Image of an Alderson Phanthom Finger (Portion of Index Finger Only)
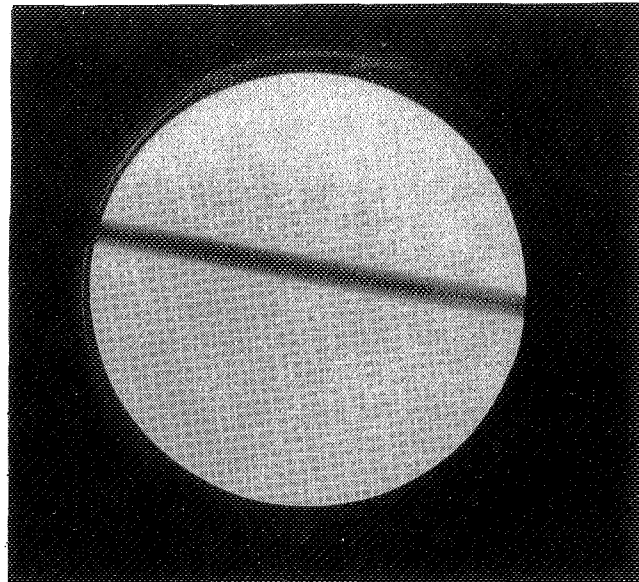
Figure 12. Photograph of Lixiscope Image of a Composite Wire

and magnitude of the incident radiation is changed. We shall further attempt to investigate the response of the Lixiscope when excited by monochromatic radiation (energy range 20–100 Kv) using an X-ray diffractometer available to us. From these studied we will determine the optimum X-ray spectrum recommended for several categories of specimen being analyzed (i.e. medical specimen, industrial specimen, etc.). In addition, we will investigate the preferred mode of operation of the X-ray generator (i.e. continuous vs. pulsed) which minimizes radiation dose to the specimen and the energy consumed in the operation of the X-ray generator.

REFERENCES

1. NASA Technical Memoranda 78064 (January, 1978) and 79634 (September, 1978)
2. Private Communication: R. L. Webber, Lo I Yin
3. See for example: Heath, *Table of Isotopes*

X-RAY SOURCE CHARACTERISTICS AND DETECTION EFFICIENCIES OF PROTOTYPE LIXISCOPES

Stephen M. Seltzer
Center for Radiation Research
National Bureau of Standards

The most compact, portable arrangement of the Lixiscope consists of: (a) an X-ray-emitting radioactive source; (b) at some distance away, a scintillator screen, used to convert the X-ray image into a visible light image, which is coupled to (c) a microchannel-plate, visible-light, image-intensifier tube.

The devices used in the early feasibility study reported here are prototypes, whose performance characteristics have neither been comprehensively evaluated nor optimized. This paper will concentrate on the radioactive X-ray sources and scintillator screens used in our prototype units. This discussion will highlight some of those considerations necessary for the optimization of future Lixiscope designs, as well as provide some semi-quantitative information on the present prototype devices.

Radioactive Source

Success has been achieved with two commercially available radioactive sources, ^{125}I and ^{153}Gd, which decay by electron capture and which have emission spectra that appear to be particularly suitable for medical and dental diagnostic use. The ^{125}I sources were supplied by the Amersham-Searle Corp.* in their standard point-source configuration; the ^{153}Gd source was obtained from the Oak Ridge National Laboratory. In order to estimate the radiation emission characteristics of these finite, encapsulated sources, we must know the energies and intensities of radiation emitted by a single atom, and then correct for the effects of self-absorption in the finite source volume as well as attenuation in the source capsule window foils.

Radiation energies E and intensities n (probability per decay) are given in the first two columns of Table 1 for the decay of single atoms, for both ^{125}I (60.1 day half-life) and ^{153}Gd (242 day half-life). The data for ^{125}I were obtained from Reference 1, with some auxiliary information on energies[2] and relative intensities[3] of the X-rays emitted by the daughter ^{125}Te. For ^{153}Gd, the data were extracted from the Evaluated Nuclear Structure Data File (maintained by the Nuclear Data Group at the Oak Ridge National Laboratory), using auxiliary X-ray data[2,3] and a K-

shell fluorscence efficiency of 0.9184 for the ^{153}Eu daughter atom.

For estimating the reduction factor due to self-absorption in the source and attenuation in capsule windows, the following simplified model was used: (a) the active source volume was assumed to be a homogeneous, right-circular cylinder; (b) all photons were assumed to travel in a direction parallel to the cylinder axis and to cross perpendicularly through the window material; (c) scattering of photons was neglected. Although assumption (b) appears quite drastic, keep in mind that we are ultimately interested only in that portion of the emitted beam, tightly collimated about the source axis, in which the photons are nearly parallel to the axis. Concentrating all of the photons in that direction results in "effective" point-source emission data, and allows the usual factor $1/4\pi$ to account for the isotropic nature of the intrinsic emission.

With these assumptions, it can easily be shown that the reduction factor is given by

$$f = \frac{1-e^{-\mu_s t_s}}{\mu_s t_s} e^{-\mu_w t_w} ,$$

where μ_s and μ_w are the photon total attenuation coefficients (for the photon energy of interest) for the source material and window materials, respectively, and where t_s and t_w are the thicknesses of the source and windows, respectively. Using data on μ from standard references[5-7], estimated emission intensities, $n' = fn$, for the finite, encapsulated sources considered are given in the last column of Table 1. From the data in Table 1, the average photon energy emitted by ^{125}I is ~28 keV; and for ^{153}Gd, the average energies are ~43 keV for the X-rays; and ~100 keV for the gamma rays.

Under the assumption that the source is a point source, we can then easily estimate the photon flux ϕ and exposure X at a distance r from the source:

$$\phi = 2.94 \times 10^6 \, NA/r^2$$
$$X = 0.0543 \, DA/r^2 ,$$

where ϕ is in cm^{-2}sec^{-1}, X is in mR sec^{-1}, r is in cm, and A is the source activity in mCi. In the above equations, the parameter N is the mean number of photons per disintegration that penetrate to distance r and is given** by $N \cong \sum_i n'_i \exp(-\mu_i r)$, where the summation is over the photon energies of interest,

**We have neglected scattering in the air.

Table 1. Estimated Radioactive Source Emission Characteristics*

^{125}I (60.1 d)	Energy (keV)	Mean number of photons per disintegration	
		Single atom	Effective point-source values for finite, encapsulated source
K X-rays:	27.20	0.398	0.378
	27.47	0.742	0.704
	30.94	0.073	0.070
	31.00	0.140	0.134
	31.70	0.045	0.043
Gamma ray:	35.46	0.067	0.064
^{153}Gd (242 d)			
K X-rays:	40.90	0.345	0.071
	41.54	0.623	0.133
	46.90	0.060	0.017
	47.04	0.116	0.033
	48.26	0.055	0.017
Gamma rays:	69.67	0.024	0.004
	97.43	0.295	0.111
	103.18	0.211	0.088

*For ^{125}I, based on an approximate estimate of self-absorption in 1-mm diam. × 1-mm thick C (density≅1.5 g/cm³), and attenuation in a 0.5-mm Be capsule end-face (density = 1.85 g/cm³) and a 5-μm Ti window (density = 4.5 g/cm³).

For ^{153}Gd, based on an approximate estimate of self-absorption in

1-mm diam. × 1.6-mm thick Gd₂O₃ (density ≅ 5.2 g/cm³), and attenuation in a 10-mil Aℓ window (density = 2.7 g/cm³).

L X-rays, heavily absorbed in finite encapsulated source, are assumed absent.

and μ is the photon total attenuation coefficient in air. D is effectively the air kerma per disintegration due to photons that penetrate to distance r, and is given by $D = \sum_i n'_i E_i \mu^i_{en} \exp(-\mu_i r)$, where μ_{en} is the photon mass energy-transfer coefficient in air.

For the energies and distances of interest, we can neglect the attenuation in air and find

		N	D
^{125}I	X + γ	1.4	4.8
^{153}Gd	X	0.27	0.67
	γ	0.20	0.48

Using these results, estimates of the photon flux and exposure produced by sources of 50 mCi ^{125}I and 200 mCi ^{153}Gd are given in Table 2. The approximations made in obtaining these results make their reliability somewhat uncertain. We note, however, that exposure measurements made on these sources with field survey instruments agree with the predictions to within about 30%.*

The lower limit of the detected X-ray flux for which an imaged object can be recognized (the so-called quantum limit) is somewhat subjective, and dependent on a number of factors which can vary greatly according to the task. As a guideline we can borrow an illustrative example used elsewhere[8]: a high-contrast, 0.1-mm object (5 ℓp/mm) whose quantum limit for real-time viewing is ~10^5 cm^{-2}sec^{-1}. Then consider this object behind ~5 cm of tissue, at a source-to-skin-distance of r= 2 cm.** For an attenuation factor of ~0.2 due to the tissue and a detection efficiency of ~0.5, we need an incident flux of 10^5 (7 cm/2 cm)²/(0.2×0.5) = ~10^7 cm^{-2}sec^{-1} for the high-contrast object. A more difficult task might require a flux of, say, ~10^8 cm^{-2}sec^{-1}. We see from Table 2 that we are just in this range with the present sources; that is, we are operating close to quantum limits.

Scintillator Screen

The detection efficiencies (the fraction of incident photons which suffer an interaction) for two scintillator screens are shown in Figure 1 as a function of photon energy. The rare-earth curve is representative of the Kodak Lanex Regular single screen used in the prototype device. The CsI curve corresponds to an ~180-μm CsI screen which has not yet been successfully tried. The curve for a bare X-ray film is included for reference. Indicated by arrows in

* These discrepancies may indicate a faulty characterization of the source matrix. Keep in mind also that the activity specified for the commercial sources were nominal values.

**A plastic spacer might be attached to the source holder to insure r ≥ 2 cm, in order to keep the skin exposure at tolerable levels.
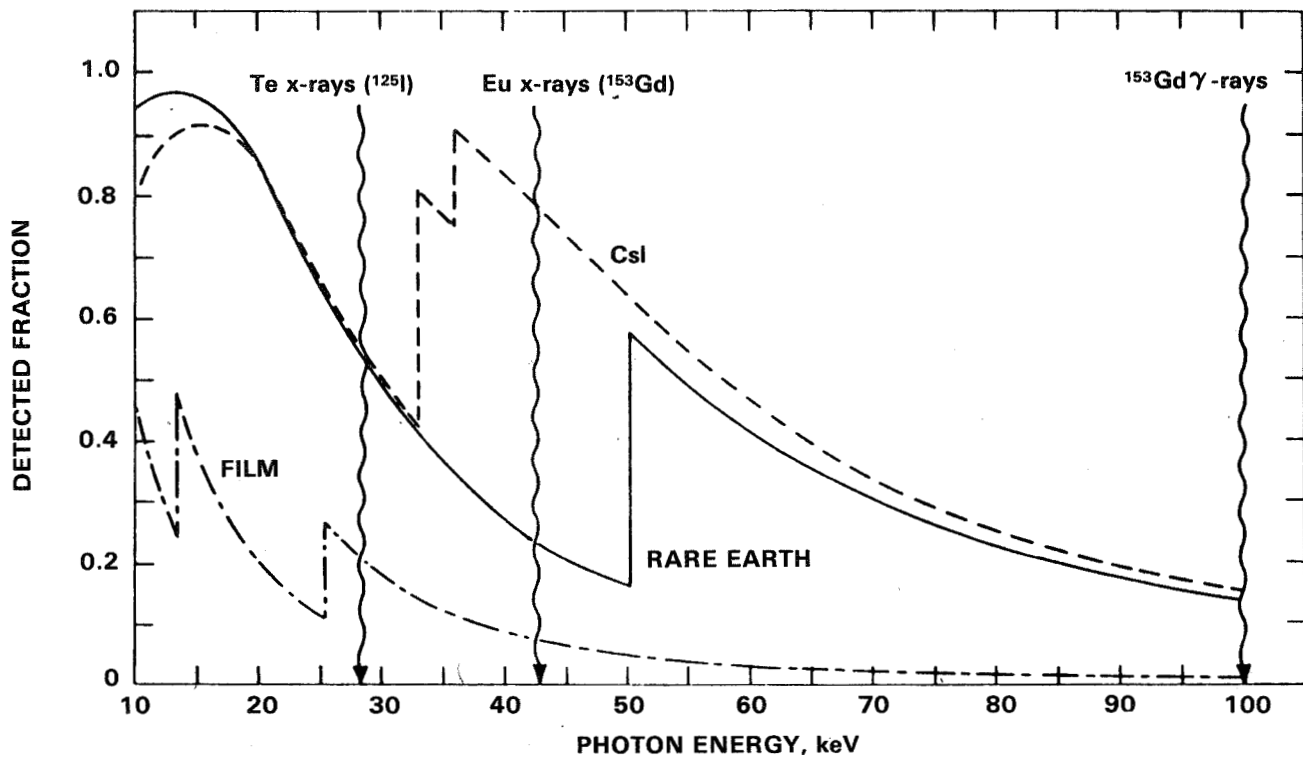
Figure 1. Detection Efficiency for Scintillator Screens, as a Function of Photon Energy. Energies of the photon components emitted by ^{125}I and by ^{153}Gd sources are indicated. The "rare earth" curve pertains to 55 mg/cm² of Gd_2O_2S behind 30 mg/cm² of C. The CsI curve corresponds to 80 mg/cm² of CsI behind 10 mg/cm² of Aℓ. The curve for film, 7 mg/cm² of AgBr, is shown for reference.

Table 2.   Estimated Photon Fluxes and Exposures from the Radioactive Sources*

	50 mCi ^{125}I		200 mCi ^{153}Gd	
r(cm)	ϕ (cm² sec⁻¹)	X(mR/sec)	ϕ_x (cm² sec⁻¹)	$X_{x+\gamma}$ (mR/sec)
2	5.1×10^7	3.3	9.8×10^7	3.1
5	8.2×10^6	0.52	1.6×10^7	0.50
10	2.1×10^6	0.13	3.9×10^6	0.12
20	5.1×10^5	0.033	9.8×10^5	0.031

*For ^{153}Gd, the exposure includes contributions from both the X- and gamma rays; the flux values include only the diagnostically useful X-rays.

Figure 1 are the energies of the ~28 keV X-rays from the ^{125}I source and the ~43 keV X-rays and ~100 keV gamma-rays from the [153]Gd source.

For the ^{125}I source, the detection efficiencies of the rare-earth screen and the proposed CsI screen are both ~55%. For the [153]Gd-source X-rays, the detection efficiency of the CsI screen (~80%) is roughly three times greater than that of the rare-earth screen (~25%). Also, for the case of the [153]Gd source, the CsI screen has the advantage that it detects the diagnostically useful 43-keV X-rays about 5 times more efficiently than the 100-keV gamma-rays which carry little information, and thereby constitute a background.

Because of the very high spatial resolution of the microchannel-plate intensifier tube, the resolution of the Lixiscope is largely governed by the resolution of the scintillator screen. Rough figures of merit can be estimated from available literature on modulation transfer functions (MTF's). The limiting resolution is sometimes defined as the frequency (ℓp/mm) at a modulation transfer of 0.04–0.05. Then, for the rare-earth screen, the resolution can be estimated[9] to be ~4 ℓp/mm, which is consistent with our observations. For a 180-μm mosaic CsI screen, the resolution may be expected[10] to be in the region of 2–3 ℓp/mm.

Other factors will affect the overall resolution of the system. For example, a finite-source spot size, a short source-to-object distance, and a non-negligible object-to-detector distance can combine to produce a significant penumbra and, consequently, a blurring of the image. In addition, eye blur in viewing the output image can reduce the apparent resolution. For this reason, magnifying the output image should improve its sharpness.

REFERENCES

1. M. J. Martin, Oak Ridge National Laboratory Publ. ORNL-5114 (1976).
2. J. A. Beardon, Rev. Mod. Phys. 31, 1 (1967).
3. S. I. Salem, S. L. Panossian and R. A. Krause, Atomic Data and Nuclear Data Tables 14, 91 (1974).
4. M. J. Martin, Nucl. Data Tables 8, 1 (1970).
5. J. H. Hubbell, National Bureau of Standards Publ. NSRDS-NBS 29 (1969).
6. E. Storm and H. I. Israel, Nucl. Data Tables 7, 565 (1970).
7. J. H. Hubbell, Rad. Res. 70, 58 (1977).
8. H. Roehrig, M. Frost, R. Baker, S. Nudleman and P. Capp, Soc. Photo-Optical Instr. Engr. 78, 102 (1976).
9. L. I. Yin, J. I. Trombka, S. M. Seltzer, R. L. Webber, M. R. Farr and J. Rennie, Soc. Photo-Optical Instr. Engr., 143, 106 (1978).
10. S. P. Wang, C. D. Robbins and C. W. Bates, Jr., Soc. Photo-Optical Instr. Engr. 127, 188 (1977).

SOME CONTEMPLATED IMPROVEMENTS TO THE PROTOTYPE LIXISCOPE

Dr. Lo I Yin
Solar Activity Branch, Laboratory
for Astronomy and Solar Physics
Goddard Space Flight Center

The evaluation of the prototype Lixiscope, constructed entirely from easily available components, shows that many improvements can and should be made. The purpose of this paper is to describe some contemplated improvements. These can be divided roughly into two categories: those which are well within existing technology, and thus can be implemented immediately; and those which are more at the state-of-the-art level, and which are directly related to applications in X-ray and gamma ray imaging in astronomy.

OBVIOUS IMPROVEMENTS WITHIN EXISTING TECHNOLOGY

Size

As many people have pointed out, it is highly desirable to have a larger format microchannel plate (MCP) intensifier without sacrificing the portability or the maneuverability of the Lixiscope. A larger size will help significantly in terms of orientation and the ease of examination. The present prototype uses a 25-mm diameter MCP. The next available size of the MCP is 40 mm in diameter. Unfortunately we have not been able to obtain one, although they do exist. An alternative way to achieve a larger format is to use tapered fiber optics. For example, if 2:1 tapered fiber optics are used with the 25-mm MCP intensifier, 2:1 in the front and 1:2 in the back, this effectively gives a 50-mm diameter Lixiscope. Given the present X-ray phosphor and MCP intensifier, there will be little or no degradation in resolution as a consequence of the additional tapered fiber optics. This is because the limiting resolution of 4 line pairs per mm (lp/mm) of the prototype is governed by the rare-earth phosphor converter. The inherent resolution of the MCP image intensifier for visible light is about 30 lp/mm. Therefore, as long as the fiber size in the large-diameter end of the tapered fiber optics remains much smaller than the resolution limit of the phosphor converter and the resolution in the minified end is still well within the capability of the MCP intensifier, there will be little or no loss in resolution. These conditions can be easily met by the available tapered fiber optics. The slight loss in intensity due to additional transmission through the fiber optics can be compensated for by the intensifier gain. Note that there will be no loss in detection efficiency because this is still governed by the same phosphor converter. The resultant object-to-image ratio in this case is again 1:1. In those instances where magnified images may be advantageous, they can also be achieved through tapered fiber optics instead of lenses.

Non-Inverted Image

The image from the inverter MCP intensifier tube used in the prototype is a source of inconvenience and mild annoyance. This can be eliminated by the use of a "wafer" MCP intensifier which is currently available and does not have an electrostatic inverter lens. Furthermore, the wafer tube decreases the thickness of the entire device to about 1.5 cm, making it more compact. However, wafer tubes in general have lower gain than inverter tubes, so that the resultant image is much dimmer at the same input flux. This can be remedied by the method described in the next paragraph. A 180° twisted fiber optics plate can also be attached to an inverter tube to provide a non-inverted image.

Brightness

At present, an automatic brightness control (ABC) circuit is included in the standard power supply of night-vision MCP intensifiers. This protective feedback circuit senses the output phosphor current such that when it reaches a predetermined value the gain of the MCP is decreased by reducing its operating voltage, thereby preventing possible tube damage due to accidental overexposure. When a radioactive source of a given activity is used as the X-ray source there is no danger of overexposure to the intensifier. Readjusting the ABC, or disabling it, will allow the intensifier to operate at maximum gain and possibly brighter output. However, the maximum gain of standard night-vision MCP intensifiers is limited by the length-to-diameter ratio (L/D) of the microchannels (about 40:1), and the onset of ion-feedback noise and oscillations. In this regard, the electrostatic inverter lens serves as an ion trap, and thus enables the inverter tube to achieve higher gain than that of wafer tubes with the same L/D MCP. This maximum gain still may be insufficient to provide enough brightness for operation near the quantum limit of a low X-ray flux. To remedy this situation, but keeping also within the confines of readily available technology, one could use two wafer tubes in cascade, or one MCP wafer tube followed by a diode intensifier, to achieve higher gain and brighter

images. This is especially attractive in the case of two wafer tubes in cascade because the overall thickness of about 3 cm still provides for a very compact device.

Film and Camera

The prototype uses an off-the-shelf Polaroid CU-5 close-up camera and ASA 3000 instant processing film. Clearly there are other alternatives, especially if one increases the output brightness. Improvements are possible in such areas as the proper matching of phosphor output wave length and film sensitivity, optimal choice of film characteristics, and photometer equipped miniature camera. In this regard, it is worthwhile to point out that MCP image intensifiers can also be switched on and off electronically. The intensifier can be switched "off" by applying a negative bias to the MCP input relative to the photocathode, thereby preventing the photoelectrons from entering the MCP. Such electronically-gated operation is available, and can be used to eliminate the mechanical shutter of the camera.

Safety

As demonstrated with a Geiger-counter survey of the prototype Lixiscope, with proper design the radiation exposure to the radiologist can be made insignificantly small, i.e. not above background level. However, because the Lixiscope is compact, portable, and easy to use, it can also be easily overused on a subject. Therefore, it is extremely important to establish safe operating guidelines. It may also be helpful to install digital timers, both interval and integral (accumulative), which are triggered by the switch that unshields the radioactive source or turns on the X-ray tube. In this manner, not only are exposure records kept, but the timers may also serve as a psychological deterrent against overuse.

Another aspect unique to the geometry of the Lixiscope is the short distance between the "point" source and the detector. Because of this short distance, the dose rate to the object increases quickly (i.e. $1/r^2$) as it is moved from the detector toward the source. For example, for a 50-mCi ^{125}I source, while the dose rate at 5 cm from the source is about 0.3 mR/sec, it can reach almost 20 mR/sec a few mm from the source. Therefore, it is desirable to place a mechanical stop in front of the source to establish a minimum distance beyond which the object cannot travel. At a minimum distance of 2 cm, for the same 50-mCi ^{125}I source, the maximum dose rate is now about 2 mR/sec.

Photocathode

In the prototype, the Lanex Regular X-ray phosphor is coupled to an S-25 photocathode simply because these two components were readily available. S-25 is desirable for night vision because of its broad sensitivity extending into the infrared region. It is not especially efficient in the 550 nm and ultra-violet emission region of the Lanex screen, nor for most of the X-ray and gamma-ray scintillators. A proper choice of photocathode, such as S-20, would improve both the detection efficiency and the signal-to-noise ratio.

Decay Time of Output Phosphor

Because the Lixiscope is primarily a fluoroscopic device and the integration time of the eye is about 0.2 sec, it is advantageous to have an output phosphor with long decay time to improve the visual image quality. Of course the decay time should not be increased at the expense of output-phosphor efficiency, nor should it be so long that it interferes with the observation of the dynamic motion of interest.

STATE-OF-THE-ART IMPROVEMENTS
Gain and Gain Distribution

The most important difference between the Lixiscope and conventional X-ray fluoroscopy using diode intensifiers is that of electron gain. In conventional diode intensifiers, the photoelectron image, resulting from the conversion of the original X-ray image into a visible-light image which then impinges on the photocathode, is converted back to an intensified visible-light image by the acceleration of the photoelectrons onto an output phosphor—either with or without minification. In this approach, the number of photoelectrons remains constant; only their kinetic energy is greatly increased by the accelerating potential. In placing a MCP between the photocathode and the output phosphor, the number of photoelectrons is first multiplied, and then their kinetic energy is increased by an accelerating potential to the output phosphor. In the prototype Lixiscope, using an inverter night-vision intensifier tube loaned by the Night Vision Laboratories, the electron gain of the MCP (L/D=40) is about 10^4. As mentioned earlier, wafer tubes with the same L/D MCP usually have lower gain because of ion-feedback problems. Perhaps a little explanation about ion-feedback is in order.

In an MCP with straight microchannels, as the electron gain is increased by increasing the applied potential between input and output, a certain point is reached where the electron cloud near the output end of the microchannels can cause ionization of the residual gas in the tube. The gas ions, travelling in the opposite direction (ion-feedback), may strike the photocathode or the channel wall near the input end. In either case, if an ion liberates an electron, another electron-multiplication cascade can be initiated following the original event. Such ion-feedback pulses increase noise, decrease tube lifetime, and cause runaway oscillations. However, ion-feedback can be eliminated to a large extent by using two or

more MCP's having slanted microchannels in series in a "chevron" or "Z" configuration, or, more recently, by using a MCP with curved microchannels. Either way, the ions are prevented from reaching the input end of the microchannels near the photocathode. Now the feedback pulses can no longer achieve the same gain as the true events. In addition, with the elimination of ion-feedback, it becomes possible to greatly increase the achievable gain of MCP's.

However, when the gain of a curved MCP or chevron MCP's is pushed to 10^6 or 10^7 range, another phenomenon, charge saturation, occurs. That is, for microchannels of a given diameter and resistivity with single-electron inputs, a stage is reached where the 10^6 or 10^7 electrons near the output end, within the pulse duration of about a nsec, significantly decrease the electric field at the output end such that no more multiplication is possible. At this stage, all input electrons will achieve essentially the same gain, and gain saturation results.

Prior to gain saturation, such as in the normal operation of the nightvision MCP intensifier of our prototype, there is a large range or distribution of gains for single-electron inputs. Although one speaks of an average gain of, say 10^4, the distribution in gain is actually very wide and exponential in shape. Such large fluctuations in gain for pulses within a single microchannel, compounded with the fluctuations among microchannels, can give rise to contrast degradation and poor signal-to-noise ratios. Using a curved MCP or chevron MCP's in the gain-saturated mode, not only is the average gain increased by several orders of magnitude thus resulting in brighter images, but the gain distribution becomes narrow and peaked in shape. Such peaked gain distributions significantly reduce the gain variance in a single microchannel as well as among microchannels, and consequently improve the image quality. Furthermore, the high gain of 10^6 to 10^7, together with the saturated gain distribution, make it easy to operate the MCP in the pulse-counting mode. This is the mode of operation which GSFC intends to use for X-ray and gamma-ray astronomy.

It should be pointed out that MCP characteristics such as ion feedback, gain distribution, gain saturation, and pulse counting of single-electron inputs are well known and have been studied by many investigators.

For the investigation of possible use of the Lixiscope idea in X-ray and gamma-ray astronomy, GSFC has obtained, once again through the courtesy of the U.S. Army Night Vision Laboratories, an intensifier tube fabricated by Varo Electron Devices which contains an experimental curved MCP provided by Galileo Electron Optics Corp. Figure 1 shows the pulse-height, or gain, distribution of this experimental tube for single-electron inputs. The average gain
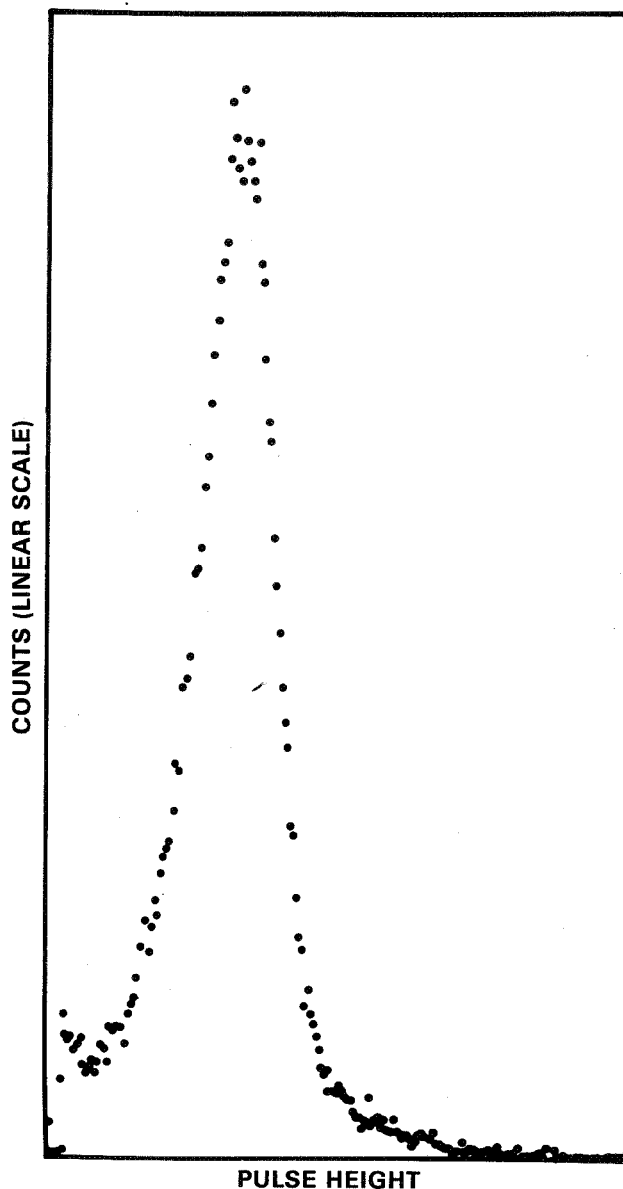
Figure 1. Pulse height (gain) distribution of the experimental curved-MCP intensifier tube with single-electron inputs.

for single electrons is 1×10^6 in this case, with a full-width at half-maximum spread of less than 50%.

With this experimental tube, and using a thin (about 60 μm) evaporated CsI scintillator, we have found that it is possible to achieve simultaneous imaging and single-photon counting of ^{125}I and [241]Am X-rays. Using a thick (0.6 cm) CsI(Tl) crystal scintillator and a variety of gamma-ray sources having energies from 30 keV to about 1 MeV, our results indicate coarse energy resolution as well. These are indeed the characteristics looked for in X-ray and gamma-ray astronomy. On the other hand, it is important to note that once simultaneous imaging and single-photon counting is achieved, we have also reached far below the quantum limit of fluoroscopy, whatever that limit may be.

17

X-Ray Gamma-Ray Scintillators

If one can pulse count each absorbed X-ray or gamma-ray photon in the scintillator, it is clear that the limit of information retrieval has been reached. Further increase in information content can only be achieved by improving the detection efficiency of the scintillator. In this regard, one is faced with the conflicting requirements of high quantum detection efficiency which demands a thick scintillator, and high spatial resolution with low lateral light spread which demands a thin scintillator. Activated CsI is an attractive choice for several reasons. First, it is more efficient than rare-earth phosphors at higher X-ray energies. Secondly, it has a fast decay time of about a μsec which is ideally suited for pulse-counting circuitry. Thirdly, there are commercial capabilities in depositing, or growing, activated CsI such that it has light-guiding properties in the longitudinal direction, with minimum spread in the lateral direction.

Collimators

The prototype Lixiscope uses a "point" radioactive source. For the purpose of imaging extended or spatially distributed sources, such as those encountered in radioisotope-intake studies, focusing or parallel collimators can be used in front of the scintillator. Alternatively, a pin hole, or multiple pin holes in conjunction with deconvolution instrumentation, can also be used to image extended sources. As is well known, collimators can also be used to reject scattered radiation.

Portable X-Ray Tubes

Nature provides only a limited choice of radioactive sources with the desired energy spectra, lifetimes, and specific activities. To be truly versatile, it is desirable to have an X-ray tube with continuously variable energy and intensity. The high gain of the MCP intensifiers makes it possible to use very low power. Furthermore, the X-ray tube can be operated in the pulsed mode with pulse rates of say, 20 to 30 per sec. Using these criteria, it is within the realm of present technology to design and fabricate a miniaturized, fully portable, battery-operated, rechargeable X-ray tube. Such an X-ray tube would extend the usefulness of the Lixiscope to much wider ranges of industrial and medical applications.

D. A COMPARISON OF THE LIXISCOPE WITH OTHER X-RAY IMAGING SYSTEMS

Fearghus O'Foghludha, Ph.D
Department of Radiology
Duke University

The purpose of this paper is to review some basic imaging matters that are vitally important in determining the clinical potential of the Lixiscope.

1. Nature of Objects Examined

The objects so far examined with the Lixiscope share one or all of the following characteristics:

(a) high contrast,

(b) small thickness, and

(c) small area.

It is the possession of these attributes that has made it possible (and so convenient) to examine them with the Lixiscope in its present form, that is to say, with a screen of small area coupled to a low-energy nuclide source of modest activity.

Though objects simultaneously having all three properties do occasionally turn up in normal radiological practice, it is very much more common to meet subjects having only two or one or even none of these characteristics. Therefore, each of the above properties should be looked at to see how the Lixiscope and its radiation source must be modified to deal with more typical subjects. It is easiest to handle (a) and (b) together, since the contrast and thickness taken in combination largely determine the kind of radiation source that must be used.

2. Contrast and Thickness

In the human body substances such as bone, muscle, fat and air must be dealt with. Some of them (muscle and fat) have about the same density in g/cm^3, some of them (air, muscle and fat) have about the same atomic number and all of them have about the same number of electrons per gram (see Table 1).

Unfortunately, only if the tissues differ appreciably in at least one property—as bone and muscle do in atomic number or as air and bone do in g/cm^3—is separation of their images on the receptor possible. Even then, differences do not show up well, that is to say the contrast is poor, unless the photon energy is low. To get optimum radiation contrast, then, one needs to use the *lowest* practicable photon energy.

The use of low photon energies to accentuate contrast unfortunately carries a heavy and often unacceptable dose penalty. This is because the penetration of low-energy X-rays, though satisfactorily different in different tissues, is small in all of them, and a great deal of radiation must therefore impinge on the entrance surface of the patient if one is to get enough at the exit surface to actuate the radiation receptor (film, fluorescent screen, intensifier, etc.). From the point of view of reducing dose, the *highest* possible photon energy should be used, whereas contrast calls for the reverse. So in practice, some sort of compromise must be struck.

Table 1

	ρ	$\bar{Z}$	e/gram
air	1.29×10^{-3}	7.64	3.01×10^{23}
bone	1.85	13.8	3.00×10^{23}
muscle	1.00	7.42	3.36×10^{23}
fat	0.91	5.92	3.48×10^{23}

In view of the many sites at which radiographs are required and the tremendous variability among individual patients, it is difficult to make anything but the crudest generalization about the optimum operating point. For the sole purpose of discussing the Lixiscope, we may assume that a suitable energy is somewhere in the region of 35 to 60 keV; this corresponds with tube voltages of roughly 70 to 120 kV when X-rays are used.*

3. Source Energy

If the Lixiscope is to be operated with a radionuclide source it is first necessary to find a nuclide whose principal emission is somewhere in the above energy region. A quick search reveals some ten or twelve potential sources, but closer examination shows that several of the candidates selected on an energy basis are unsuitable on other grounds. Some of them, for example, emit gamma rays and/or characteristic X-rays that lie at undesirable energies, in addition to the principal radiation that would make them useful for Lixiscope work. In some, such as Tm 170, there is an intense Bremsstrahlung component generated by accompanying beta emission; some have inadequate half-life; some, such as gaseous Xe 133, are in an unsuitable physical form, and so forth. Considerations such as these further limit the practical possibilities.

The photon spectrum emitted by a tube working at e.g. 100 kV, contains very few photons with an energy of 100 keV. These are accompanied by a vast number with considerably lower energies, so that the average energy is only $\frac{1}{2}$, or less, of the maximum possible value.

4. Geometry

To the difficulties of finding sources with suitable energy and half-life must be added even more severe restraints arising from the geometrical requirements of image formation. The most notable of these is that the source of radiation, for reasons to be explained in a moment, should be as far from the radiation receptor as possible, while the object to be radiographed should be as close as possible to it; that is to say, the source-receptor distance should be much larger than the object-receptor distance. In the case of thin objects such as human jaws and small animals, the requirement of relatively large source-receptor distance can be met easily enough; but in the more usual case of the human torso, it may be necessary to station the source at a meter or so from the receptor. This requires that very large source strengths be available if an image is to be formed in a reasonable time.

The reasons why the source-receptor/patient-receptor distance ratio should be large are to reduce image unsharpness, to reduce magnification and distortion, and to increase the effective penetration of the radiation through the patient:

(a) *Unsharpness:* To produce a perfectly sharp image by shadow-casting (and radiography must rely on such a process because X-rays are not usefully refracted or reflected, and so cannot use image-forming elements of the optical type) it is necessary to use a point source of radiation.

A practical source, whether it is the anode of an X-ray machine or a radionuclide, unfortunately has a finite size. Now each point on the surface of a finite source may be considered to cast its own image of the object, and the final image seen on the receptor is a composite of all the images cast by the multitude of points making up the finite source. In Figure 1 (a), for example, the left margin of the source images one edge of an object at A, whereas the right side of the source images the same edge at a point B slightly displaced from the first (Figure 1 (b)). The existence of this partially-illuminated or penumbral region between A and B means that the edge of the object is undesirably blurred (Figure 1 (c)).

Figure 2 shows that the penumbral region (and the blurring) gets smaller as the source moves away from the receptor, assuming that the object-receptor distance is unaltered. For a given source size, then, it is always advantageous to back the source off from the surface of the patient until, when the source is far enough away, its dimensions as far as penumbra formation is concerned are effectively zero and the ideal point-source condition is realized.

(b) *Magnification and Distortion:* Because, as just seen, the radiographic image is really a shadow, the image is always bigger than the object, and the receptor must therefore be larger than the anatomical area that one wants to observe. This severely limits the usefulness of a small-area detector such as the present Lixiscope. The only way to overcome this limitation (unless sequential scanning is used, as described in Section 5) is to make the Lixiscope screen at least as large as the anatomy.*

*but see Section 6
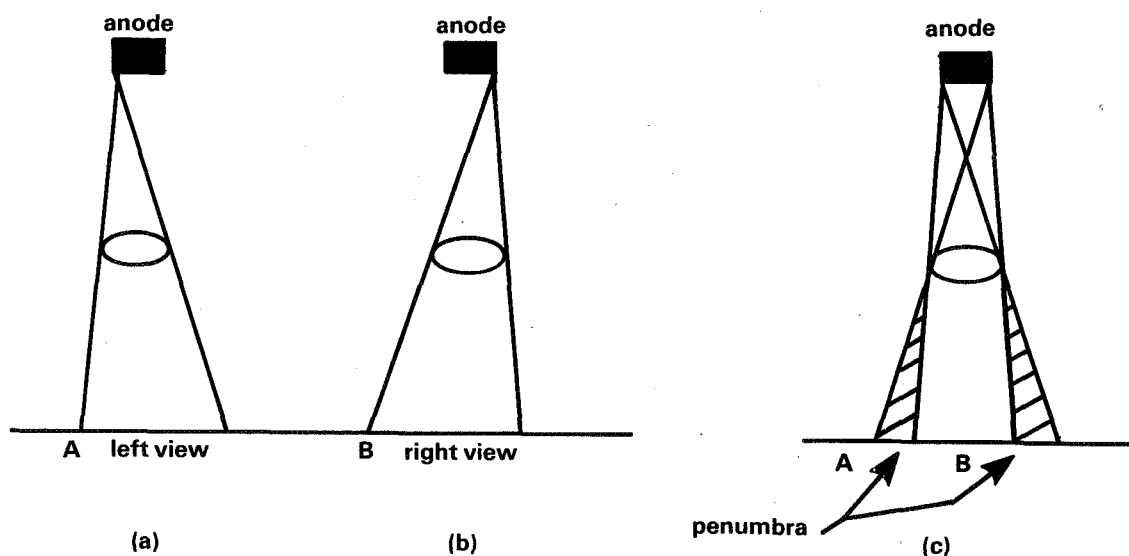
Figure 1.
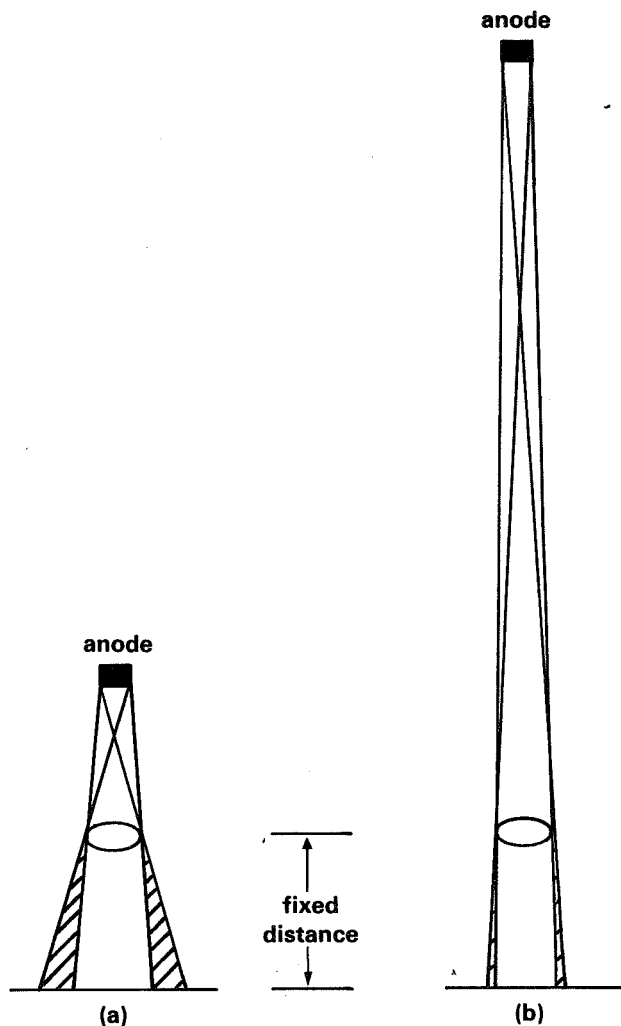
Figure 2

This requirement is least crippling when the source-receptor/patient-receptor distance ratio is maximized—a step we also wish to take for reasons given in the discussion of unsharpness—because the magnification diminishes as the distance ratio increases, falling to unity when the ratio is infinite (Figure 3).

The presence of magnification introduces another distressing complication; the patient is never as thin as the object shown in Figures 1(a) and (b), so the parts of him closest to the source are magnified more than the parts closest to the receptor (Figure 4(a)). This differential magnification leads to a potentially confusing distortion of the image. Again, however, this effect will be reduced by backing the source away from the patient's skin (Figure 4(b)).

(c) *Effective Penetration:* A third reason for using relatively big source-receptor distances, even though they demand large source activities, is

that the effective penetration of the photons is thereby increased. This comes about because the relative importance of one of the two photon attenuation processes is diminished at large distances.

The attenuation mechanisms at work in any radiographic procedure are (a) photon removal through photoelectric absorption or through scattering encounters that deflect photons out of the useful beam and (b) inverse-square fall-off or geometrical attenuation. The latter arises because the source is a point that emits its photons in straight lines equally in all directions; a given batch of photons therefore has to spread itself over an ever-increasing area as the point of observation recedes from the source. The net result is that the photon flux, expressed in photons/cm^2, depends inversely on the square of the distance from the source; this (b)-type inverse-square dilution occurs simultaneously with any (a)-type absorption or scattering processes and its effect is always to reduce the effective photon penetration below the value that would be observed if only (a)-type processes occurred.

It turns out that the undesirable effects of geometrical dilution are reduced (as were unsharpness, magnification and distortion) by using the largest possible value of the source/object distance ratio. In Figure 5(a), for example, the inverse-square law dictates that not more than 25 units of radiation can emerge from the underside of the patient for every hundred units put in at the top *even if there were no absorption at all*. In Figure 5(b) on the other hand, where the source-receptor distance has been increased, keeping the patient-receptor distance constant, the inverse-square reduction is less severe and the maximum possible emergent amount (assuming (b)-type attenuation only) is 83 units for every 100 units entering at the top.

The accompanying (a)-type processes will of course reduce the emergent intensities in both Figure 5(a) and Figure 5(b) by an additional large factor that is however roughly the same in both cases. This means that the emerging intensities will still be in the approximate *ratio* calculated using the inverse-square law alone, even though the absolute value of each intensity is greatly reduced by (a)-type processes (in Figure 5, the (a)-type reduction is taken as 0.1). If matters are adjusted so that the *exit* (rather than the entrance) intensity is the same in both cases and is just adequate for Lixiscope viewing, the examination can be made with far less entrance dose to the patient using the set-up of Figure 5(b) than using the arrangement of Figure 5(a).
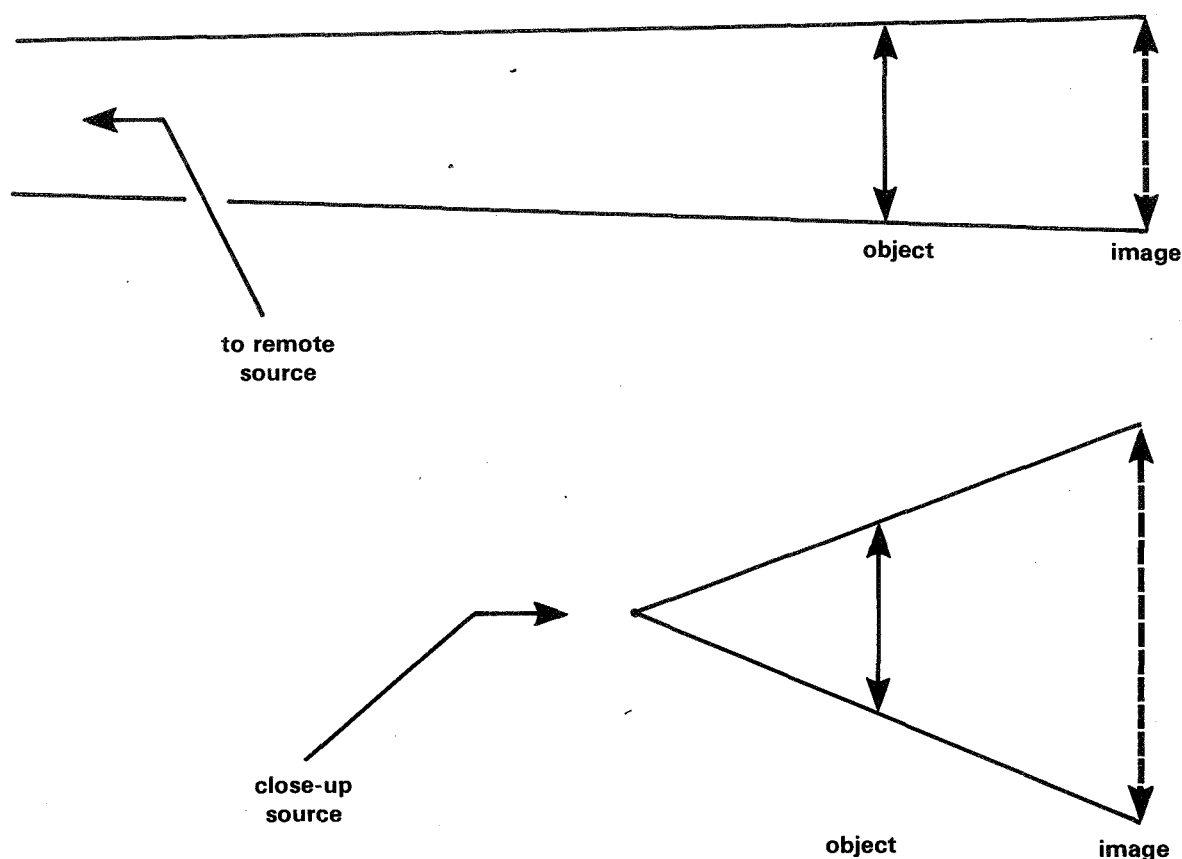
Figure 3. Magnification is Less at Large Source-Receptor Distances (Top Figure) Than at Small Distances (Lower Figure). At Infinite Distance There is No Magnification

5. Source Strengths

For all these reasons, it is highly desirable to examine typical subjects at very much greater source-receptor distances than it is possible or necessary to use in certain kinds of dental or small-animal study. Very rough calculations, based on the figures Drs. Yin and Seltzer have given for the I-125 sources that they have found usable at short distances, indicate that source activities of some 2 or 3 Ci (curies) will be necessary at working distances of 100 cm or so.

Quite apart from the initial and frequent renewal expenses, the considerable hazard, and the difficulty of obtaining possession licenses for activities of this order, another problem is encountered with most available nuclide sources. The volume of a source, other things being equal, depends on the product of the mass number and the half-life, divided by the physical density of the source material. It also depends on the decay scheme (which essentially tells the number of desired photons produced in one disintegration) and on whether or not the source can be made carrier-free, that is, on whether all of it is radioactive or whether it includes inactive material that adds unwanted volume without contributing to the activity. When these additional considerations are brought to bear, it emerges that only one or two commonly-available sources have any real hope of filling the bill; they are I-125 and Am-241. Unfortunately, the energy of I-125 is rather too low for objects of appreciable thickness. Am-241, with its higher energy, at first sight looks quite promising but the theoretical maximum specific activity is about 3.3 curies per gram. This means that the diameter of a carrier-free source with an activity of 2 or 3 curies is a few mm, which is very much greater than the focal-spot size in a typical X-ray tube. No doubt there are other nuclides that could be used* but the point is that the choice is very limited.

For this reason, work on nuclide-Lixiscope combinations should be somewhat de-emphasized, except in applications where portability is the prime requirement and/or the objects happen to be suitable for short-distance low-activity work; the notion should be discarded that nuclide sources must

---

*See "Some Remarks on X-ray Source Characteristics and on Detection Efficiencies of Prototype Lixiscopes," Dr. Stephen M. Seltzer, Center for Radiation Research, National Bureau of Standards (p. 26).
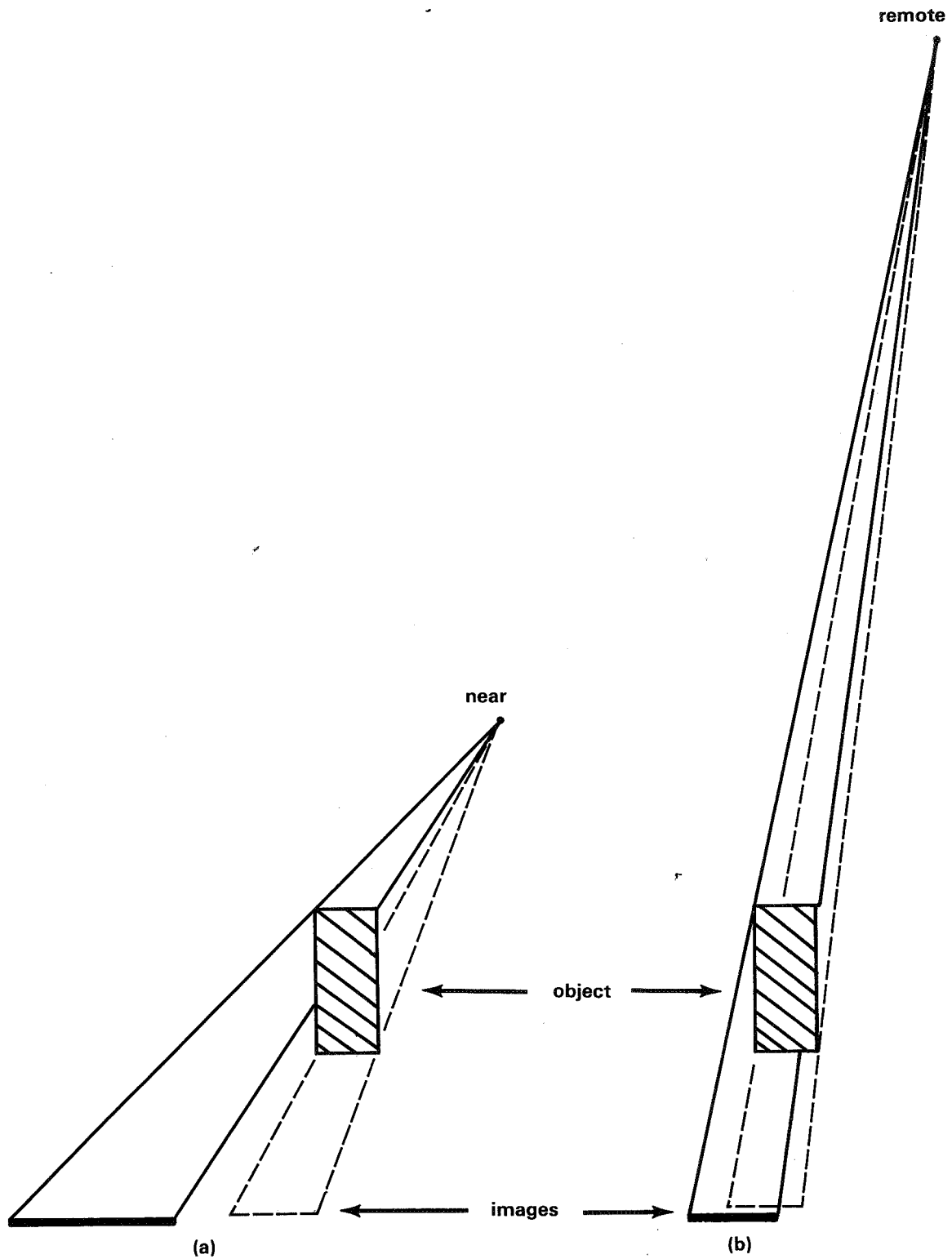
Figure 4. Image Distortion is Less at Large (4(b)) Than at Small Source-Receptor Distances (4(a)).

23

Figure 5

(a)

Source

25×0.1
$= 2.5$

(b)

Source

$100 \leftarrow$ Entry $\rightarrow 100$

$25 \leftarrow$ Exit $\rightarrow 83$

83×0.1
$= 8.3$

forever be an essential part of the Lixiscope just because they played an important part in its original development. Once free of the nuclide emphasis, the Lixiscope may evolve as a new and very advantageous version of just one link (the standard image intensifier) in the imaging chain and not as a replacement for all links simultaneously. If this is done and attention is given to modifying the "back end" of the present instrument so as to give it some of the desirable characteristics mentioned below, a very rapid development should result.

The key is to switch from gamma-ray to X-ray sources. With such sources, the vastly greater photon output is adequate for work at the large distances needed for good image quality and higher effective penetration. The effective photon energy can be readily changed to suit the object under investigation, the source diameter can be made small enough for good detail, and the constant hazard encountered with nuclide sources can be eliminated at will simply by switching the machine off. Last but by no means least, licensing becomes a very much simple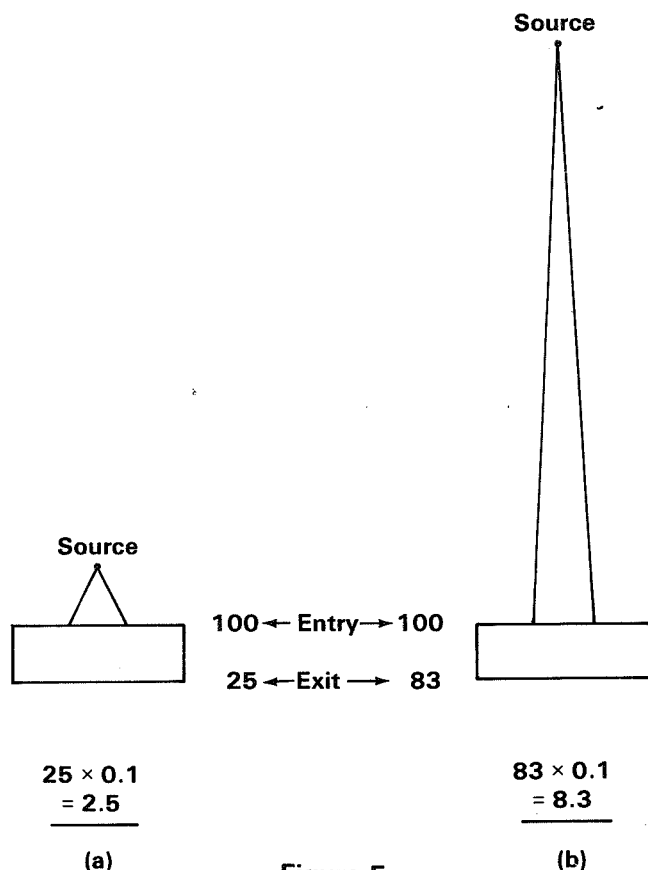r process. Use of an X-ray source reduces portability, but the problem is not insoluble since portable generating equipment of field-emission and other types is commercially available.

If one then ceases to worry about the source and concentrates on receptor development, the first problem that needs to be tackled is that of image area.

A patient's skull, for example, could show an anomaly that may not be detected with a small-screen receptor unless the screen is properly positioned at the first try or unless many exposures are made, thereby building up a large image from a mosaic of smaller ones.

With existing Lixiscopes, a scanner to make the required mosaic could be built, as shown in Figure 6(a). In this figure, a large beam of X-rays covers the total anatomy that is potentially involved. At the exit side of the patient, a lead screen is placed to shield the observer from the instantaneously unused part of the beam; the Lixiscope exit face must also be screened with lead glass, of course.

With this apparatus, an arbitrarily large area could be examined, given enough time, but examinations involving dynamic processes over such a large area are clearly ruled out; besides, the dose is increased over the minimum necessary with a large-screen device in the same ratio as the total observing area bears to the area of the Lixiscope. This dose difficulty can be eliminated by placing the patient between two shields and linking them with the Lixiscope and with the radiation source so that they all move as one unit during the scan (Figure 6(b)). However, the time-penalty still remains.*

6. Gamma Camera Applications

One of the few fields where the small area of the present Lixiscope, though disadvantageous, is not entirely crippling, is in the examination or self-luminous gamma-sources. Examples are implanted radioactive needles (cesium 137, radium, iridium 192, gold 198, tantalum, etc.) and ingested or injected sources such as iodine 131 or technetium 99^m.

In such cases, one can make use of the pinhole camera principle, whereby the source "projects" an image of itself onto the Lixiscope through a very small hole in a plate otherwise opaque to the emitted radiation (Figure 7). This scheme is widely used in certain of the gamma cameras so familiar in nuclear medicine departments, though the receptor in those cases works on a somewhat different principle. By suitably choosing the distances d_1 and d_2, it is possible to produce an image that is diminished (or alternatively magnified) to any extent desired, and can easily be made small enough to fit on the screen of the present Lixiscope.

This approach was tried at Duke, with the help of Dr. J. K. Goodrich** by mounting a tungsten shield containing a biconical hole of 1 mm diameter in front

---

*An interesting point about the dual-shield scanner is that the volume of tissue instantaneously irradiated is quite small and the disturbing effects of scattered radiation at the receptor are greatly reduced, possibly eliminating the need for the anti-scatter grids normally used in radiography.

**Formerly Director, Division of Nuclear Medicine, Duke University Medical Center, now at Radiology Associates of Erie, Erie, Pa.
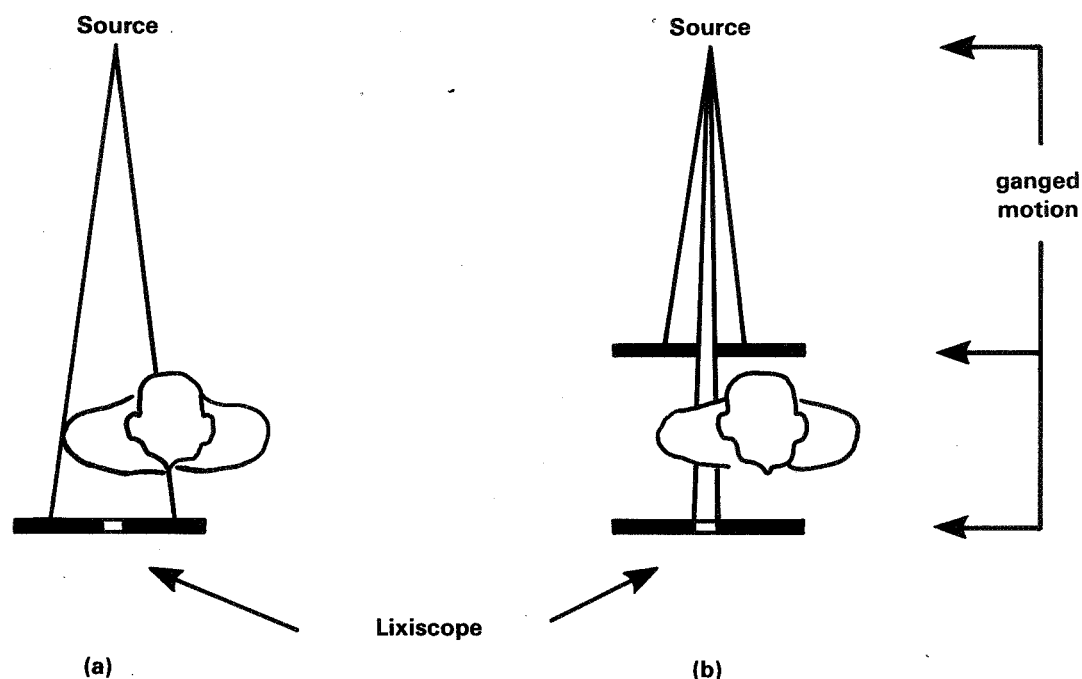
Figure 6

of the Lixiscope and photographing the output screen with an oscilloscope camera. (See Figure 8.) With this apparatus, which had provision for varying the pinhole-Lixiscope distance so as to change the magnification continuously, we were able to produce images of a 100 mCi Am 241 disc source. With approximately the same Te 99^m activity, we could photograph liquid-source containers at reasonable resolution in geometries that would be conveniently usable in thyroid function studies, but the observation times were unacceptably long. With Ir 192 in the form of implantable "seeds", the images were of much poorer quality, most probably because pinhole edge-penetration effects are appreciable at this higher energy (~0.4 MeV). With radium needles (~1 MeV average energy), no more than a reasonable indication was gained of the presence and layout of sources, and the pinhole design will have to be modified—and the screen sensitivity greatly increased—if the Lixiscope approach is to have any great utility in this energy region. This energy-limitation is not a special characteristic of the Lixiscope, however, and the drawback is shared with other gamma cameras; so also is the flaw that the Lixiscope sees only the sources, whether they be concentrated or diffuse, and not the inactive ("cold") anatomy in which they are situated.

These experiments demonstrate the great potential of the Lixiscope as a compact and inexpensive gamma camera, usable in both industrial and medical applications. For routine medical use, however, im-

provements in the present model are necessary. One is to increase the area, since too much minification is at present needed, and another is the substitution of a much more efficient detector for the existing input screen. A thin crystal of sodium iodide, for example, would greatly enhance the sensitivity. This aspect of Lixiscope development should be pursued with vigor, as the possibility of a hand-held gamma camera is a very attractive one.

It is even conceivable that two such cameras, viewing a nuclide-filled organ or region, would provide a degree of on-line stereoscopic vision that might be extremely useful in areas such as nuclear cardiology. In this connection, it is worth remarking that the inverting stage which seems to be responsible for the lower gain of some existing Lixiscopes, should be retained in gamma-camera applications where it would rectify the automatic image inversion produced by operation of the pinhole-camera principle (see Figure 7); visual observation without the additional inverting stage would be quite confusing.

7. Future Developments

A pressing problem that will remain when large-area Lixiscopes become available is that there is no contrast amplification, because of the nature of the fluorescence mechanism; this serious drawback is shared with existing image intensifiers. Unless some contrast gain can be introduced (possibly by photographic or electronic means), the utility of the

25

image

receptor

opaque plate , (with shaped pinhole)

gamma source
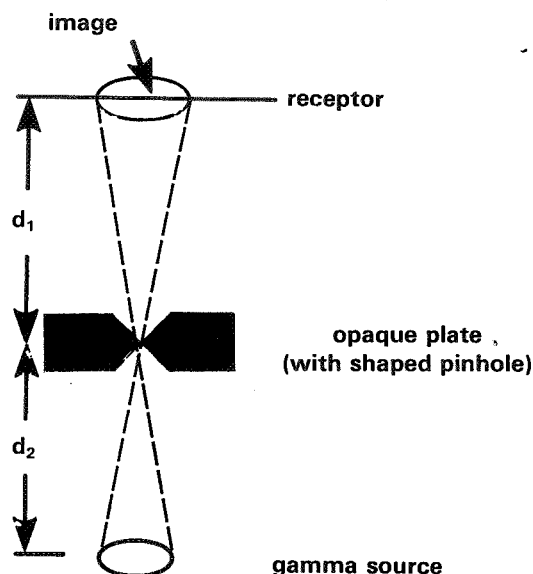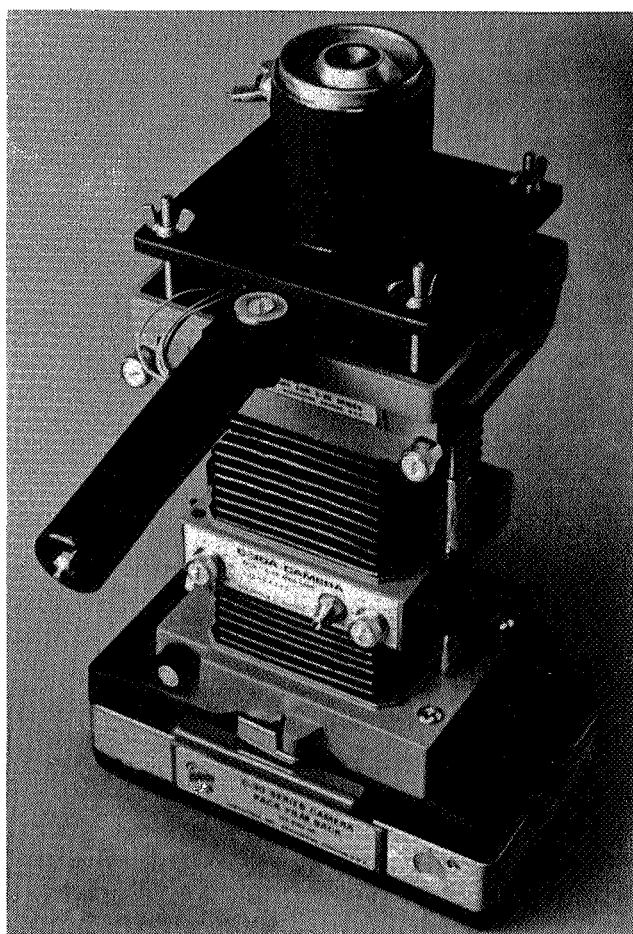
Figure 7

Figure 8

device will suffer in examination of low-contrast objects. However, it appears that the multipliers in the microchannel plate can be addressed individually, at least in principle. If this is so, then contrast manipulation (including edge enhancement as in the present Xeroradiography system) becomes possible and would repay study.

A further interesting possibility arises. If, when individual addressing becomes possible, some kind of energy discrimination were also introduced, then one would have a large-area detector with both spatial and energy resolution. This could be applied to the ever-present radiological problem of scatter suppression if a source of monoenergetic radiation were also available, since the scattered radiation that degrades the image could then be discriminated against on the basis of its reduced energy. For reasons already discussed, gamma-ray sources are unsuitable (although they are essentially monoenergetic), but Duke has gone some way in developing a single-energy X-ray source in the form of a rhodium anode tube, and we are now working on other fluorescent anodes from which intense monoenergetic radiations of different energies are emitted. A combination of these tubes with an energy-selective Lixiscope would be a powerful tool in radiography, permitting scatter suppression with essentially no loss of primary image-bearing radiation, thereby decreasing the required patient dose. In the nuclear medicine field, energy discrimination would not only reduce background (as in the standard gamma camera) but would permit simultaneous observation of more than one nuclide, possibly with digital manipulation of several images simultaneously.

8. Conclusions .

The limited opportunity Duke had to work with the Lixiscope has led to the following conclusions:

1. Operation of the device with a nuclide source, while profitable in certain limited applications, is unlikely to be useful in the more standard radiological procedures. Greater effort should therefore be devoted to combining the Lixiscope with an X-ray source to provide a convenient, inexpensive and portable alternative to conventional image intensification systems.

2. High priority should be given to the development of much larger viewing screens.

3. The Lixiscope has great potential in nuclear medicine as a complement to the gamma camera.

"Complement" is indeed the key word. It is quite unlikely that the Lixiscope will ever completely supplant more conventional radiographic and fluoroscopic equipment, but it will undoubtedly

complement these techniques in certain situations, where its use will give greater convenience in bulk and portability and, very probably, will save expense; this is particularly true and almost immediately realizable in the field of nuclear medicine and will become apparent in radiographic and fluoroscopic applications as large-area screens and miniaturized X-ray supplies are developed.

Page intentionally left blank

III. PRELIMINARY EVALUATION OF POTENTIAL APPLICATIONS OF THE LIXISCOPE

A. ORTHOPEDICS
OVERVIEW

Dr. Harry C. Press, Jr.
Head of the Department of Radiology
Howard University

Howard University was given the opportunity to see the Lixiscope about six months ago. It was very exciting from the outset because most of the fluoroscopic images observed to date have been in large machines, while the Lixiscope is small and can be taken around the room for observation. Based on these limited evaluations, there are some limitations, and there are some advantages. Both are presented here.

The Howard University evaluation was basically related to observations of the hand; although one could observe the foot. The source that Howard University had was not penetrating enough to evaluate other extremities. This is one of the major limitations. However, it is understood that there are features being investigated which will allow observation of the extremities. There are some very excellent opportunities that the Lixiscope would offer a physician if he was in the emergency room. It may eliminate the possibility of long waits for many patients, particularly those with hand injuries. The physician could walk by 10 patients and say, "This one can go home, this one to the X-ray," because the patient has a fracture or some other pathology that can be picked up by a quick observation. The Lixiscope will be helpful in this regard.

The other potential application that is interesting is the possibility of its use at sports events. As the team doctor for the Silver Spring Boys Club for about six years, which had five teams, I used to look at anywhere from six to seven games. The Lixiscope would have been helpful on many occasions.

There is a certain amount of expertise that is necessary to evaluate or look at the image that is coming off of the fluoroscopic Lixiscope. Today a radiologist is used for evaluation and it is very easy and simple for the physician. The problem seems to be that if you have to train someone that has this Lixiscope observation expertise, then what is the possibility of using the Lixiscope since the radiologist is already there, seeing the part and examining the part? For instance, if you had 1,000 patients, and the physician could examine the part clinically and make a diagnosis, there would be no additional information added by the Lixiscope. Thus, this would be a major disadvantage to him.

So Howard University is excited about the Lixiscope and was pleased to look at it, but it must be realized that there are some advantages and some disadvantages. In the following discussion, both the limitations and advantages will be presented. Six or eight months more of additional evaluation should produce a far better idea of the things that can be done with the Lixiscope. Its use in areas that have not even been thought about at this time are envisioned. For example, laryngeal fluoroscopy could be performed very quickly and easily.

Detailed results of the Howard University evaluation are given in the following paragraphs.

Page intentionally left blank

ORTHOPEDIC EVALUATION

Dr. Thomas Walden
Department of Orthopedics and Radiology
Howard University

The Howard University Department of Radiology was pleased to participate in the preliminary investigation of the Lixiscope. I have in the past performed athletic team doctor type functions, where you are actually on the field, and a member of the team may be injured, and the coach wants to know, can he play, does he have to go to the hospital, does he need ice, exactly what would you do? In high school sports and college sports, in particular, the majority of the fields are just simple fields, and there are no electronic facilities available. However, the Redskins, the Colts, and all the other pro-football teams have X-ray facilities on the premises, so they have no problem. But for youngsters, and 99 percent of the injuries at that level are going to be benign injuries, either sprains or soft tissue injuries, they are rarely serious enough to send anybody to the hospital. A portable fluoroscope would be ideal to, first of all, help alleviate anxiety and to progress and speed up the treatment of the patient.

The Lixiscope was first brought in for evaluation less than a month ago, and in an effort to prepare as many patients as quickly as possible, arrangements were made to have patients from the emergency room and from the Orthopedic Clinic come to the X-ray Department. Here, a team of observers first clinically, and then with the Lixiscope, examined the patient. These were all trained radiologists who spend all day looking at bones, so perhaps any bias is understandable. In this evaluation, the radiologist examined the patient with the Lixiscope, formed a separate clinical opinion, and then the patient proceeded to have a routine radiograph of the part in question. The initial studies were limited to the hand since the Lixiscope is not developed sufficiently to do knees or even ankles, and the opportunity to examine a foot did not arise.

The other problem that became immediately apparent was the acutal reproduction of the initial impression under the Lixiscope. Figure 1 shows a skeleton. There are no soft tissues, and a dense structure that is actually a wire that holds the bone together can be seen. The picture shows the joint space, a toe, and the contical margin of one of the bones of the toe. The light areas in the picture are a part of the problem of using Polaroid film. The emulsion is much less inferior to X-ray film even, and much less inferior to other recording media.

In the picture the Trabecular pattern can be seen. This pattern is the dark lines, which are actually the densest portion of the bone. The size is magnified on the order of two times magnification, which is another limitation of the camera. This picture is actually twice the size of the image that can be seen in the Lixiscope, and it has about a one-inch diameter orifice. It has one basic limitation in that the part that can be examined is of a small area.

Figure 2 shows the hand and the beginning of the wrist of a patient. The picture shows an abnormality in the base of the phalanx (finger). From the picture, one can follow the contical margin to where there is a break, whereas, by following any of the other contices, which is just the outside edge of the bone, it is very sharp and very distinct. There are no projections or evidences of what this is—a fracture. Figure 3 is a close-up of that same finger.
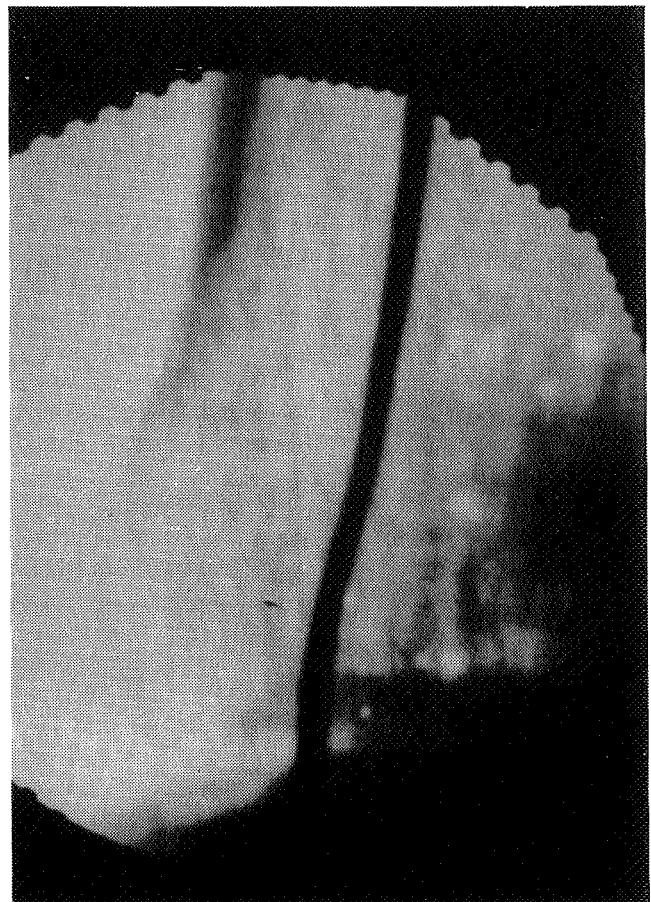
Figure 1. Photograph of a Skeleton

Figure 2. Photograph of Patient's Hand and Wrist
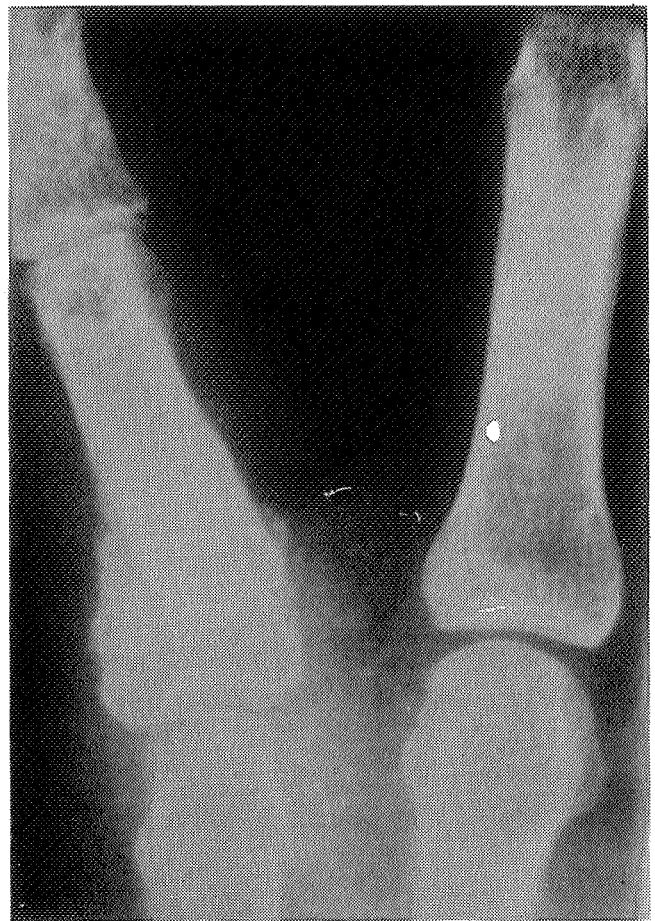
Figure 3. Close-Up of Patient's Finger

Figure 3 is a photograph of much greater detail. In this picture, one can see the thumb to the side, the wrist, the fifth finger, the little finger, and the joint space clearly. The "contical margin" can be followed to a black line, a denser black line, and then another black line. The fracture of the bone can be seen. Some evidences of new bone, or callous, can be seen which indicate healing of the fracture. This fracture is about a month old, or maybe older than that, and the patient has no complaints at this time of pain; but there is still some swelling.

The Polaroid image in Figure 4 accompanied the initial clinical evaluation of this patient's fracture. The base of the bone is off of the picture, but the beginning of contical margin can be seen. In this picture, one must reverse the images so that things that were white before are now black, and the white line which can be seen was the black line on the fracture. The callous, the indication of healing, can be seen and the fracture is evident.

This is very gross, and to an untrained eye, probably doesn't mean a great deal, but it must be realized that the resolution of the Lixiscope is probably on the order of five times better than the Polaroid picture. The radiograph is another magnitude greater than the Lixiscope.
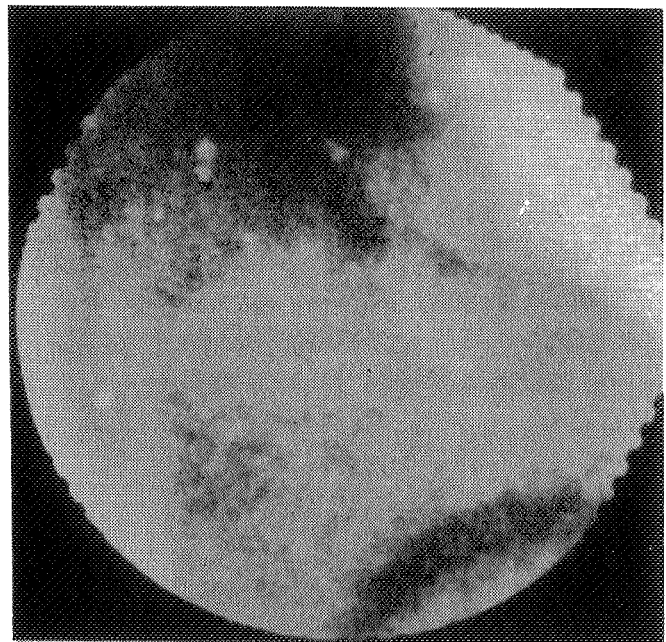
Figure 4. Polaroid Photograph of Patient's Hand with Fracture

Figure 5 shows the hands of another patient. This is an even more subtle finding. In this picture some abnormality can be seen at the base of the tip of the finger. The so-called "ungal tuff" of the finger is abnormal.

A different projection of the same finger is shown in Figure 6. In this picture a projection of some abnormality at the tuff can be seen. This patient was a construction worker who closed his finger in the door of the truck. He has considerable pain and swelling at the fingertip. With the Lixiscope, his particular injury was not readily apparent. Based on clinical examination, it was believed he had a fracture. With this specific index of suspicion and knowing that the fingertip was turning blue, it was obvious that something was wrong. However, with the Lixiscope, all that was apparent was that there was a loss in the normal part of the bone; it was disorganized. If you imagine a pattern of lace of a fine handkerchief, you can imagine the lace being overlapped upon itself, and you don't have a clear image anymore.

Figure 7 is a Polaroid picture of just that area of bone where there is a suggestion of a clear line and a dark line. It looks disorganized and doesn't have the

appearance of a definite fracture. But certainly, this patient deserves the benefit of further follow-up and of a standard radiograph and treatment. What this bears out is that if the Lixiscope is going to be used as

Figure 6. Different Projection of Same Finger

Figure 5. Photograph of Patient's Hand Showing Abnormality
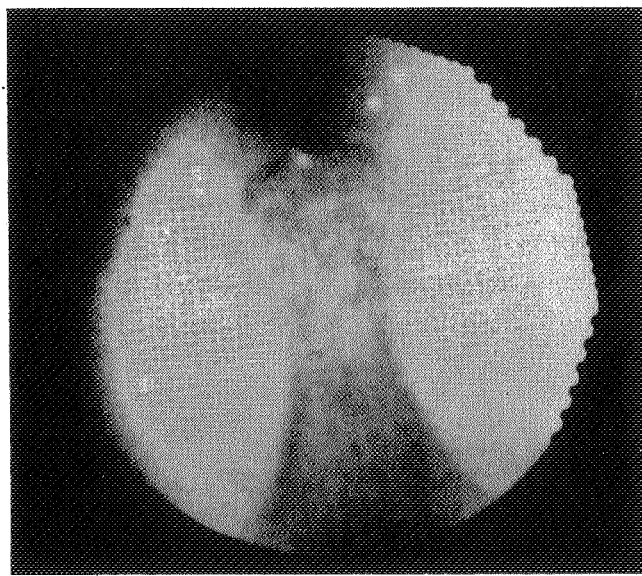
Figure 7. Polaroid Photograph of a Bone with Possible Fracture Line

a screening device, it is effective. At least this patient wasn't sent home from the emergency room without further therapy. From this, it looks like the specificity of the Lixiscope is probably going to be pretty good.

Figure 8 is a photograph of an individual who had a soft tissue injury to his hand. He had a laceration or a cut, which had been stitched. He was sent to the Radiology Department to make sure there was no involvement with the bone or evidence of a fracture. Under the Lixiscope, it was observed that he had an irregularity. In the picture, a very, very subtle evidence of a projection can be seen along with a little white line and then the suggestion of some abnormality in the cortex. Clinically, it was believed that the chances of a fracture in this area were pretty slim, because the injury to the hand was the actual laceration. It didn't show on the X-ray, but it was believed that he may have had an old fracture because of the abnormality.

Figure 9 shows a close-up of the same area, and as suggested, some time in the past he had some sort of an injury. The Lixiscope was actually able to pick up that little area of bone on the examination.

Figure 10 is a picture of that bone, and it corresponds to some injury he had in the past. On questioning the patient, he admitted that he had boxed as a younger individual and probably broke his finger. It was such a small injury that he never had any treatment, and the injury healed up.

This small number of cases and the small amount of experience Howard's Radiology Department had with the Lixiscope certainly justifies further evaluation as well as some clinical trials.
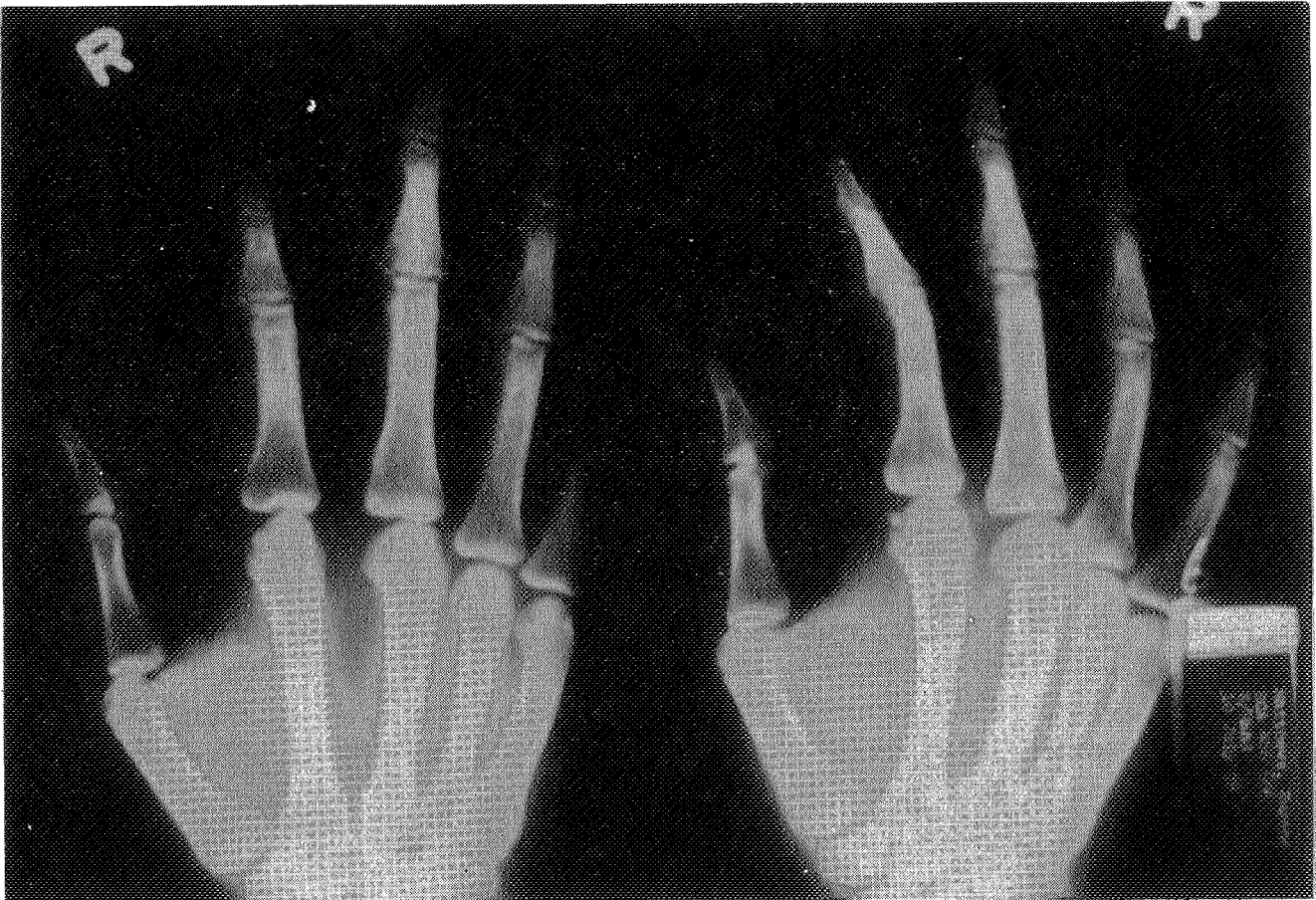
Figure 8. Photograph of Soft Tissue Injury to Hand

Figure 9. Close-Up of Soft Tissue Injury
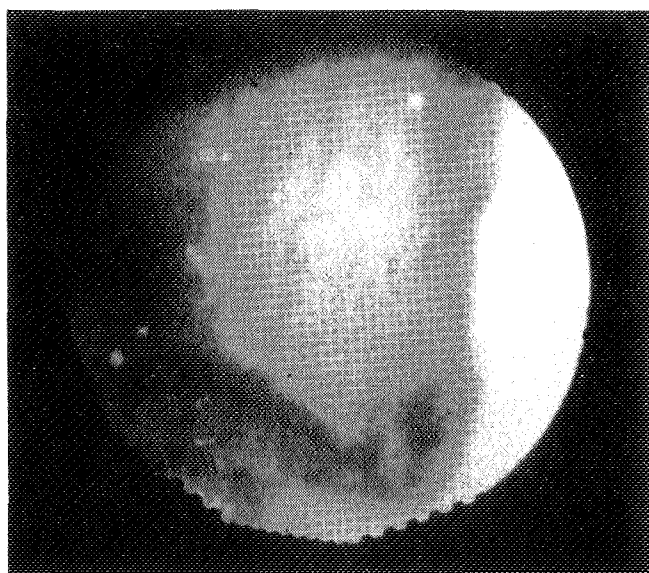
Figure 10. Polaroid Photograph of Old Cortical Injury

The advantages of the Lixiscope are its portability and its size. It can't weigh more than 10 pounds. Furthermore, the fact that it can be used in remote areas and even in easily accessible areas where there is a need of time and movement of patients makes it advantageous. Certainly, it has no more radiation hazards than a standard X-ray.

Its disadvantages at this point in time are its small size and its lack of ability to study large areas. There is currently some work being done to alleviate these problems.

Page intentionally left blank

B. DENTAL RESEARCH
PRELIMINARY OBSERVATIONS AND PROJECTIONS

Dr. Richard L. Webber
National Institute of Dental Research

Although there was a desire to emphasize clinical applications for the Lixiscope, this report is limited to preliminary observations and projections for two reasons:

1) Objective clinical evaluation requires formal testing, which involves a research protocol. Any protocol involving human subjects at potential risk requires appropriate clearances and reviews, which take substantial amounts of lead time. This is particularly true in an organization as large as the National Institutes of Health (NIH). In the case of the Lixiscope, a prototype has not been in existence long enough to get such a project initiated, much less reviewed.

2) A prototype suitable for clinical application in dentistry has specific requirements and environmental restrictions over and above those associated with the orthopedic applications described by the previous speakers.

The design of the Lixiscope at this stage in its development is not precisely determined. About all that can be said is that it involves three distinct considerations:

1) a small self-contained source of ionizing radiation,

2) a high-speed photon detector capable of producing an on-line image derived from a microchannel plate image intensifier, and

3) a suitable geometric relationship which determines the coupling between these two components.

These conceptual ingredients are yet to be integrated into a prototype suitable for clinical application in dentistry and thus no device exists which can be tested for the potential applications currently being considered at the National Institute of Dental Research (NIDR). Given that no Lixiscope currently exists which meets the needs of a clinical research protocol yet to be completed, one might conclude that little is known about the potential applicability of the Lixiscope in dentistry. Fortunately this is not entirely true, because the three conceptual ingredients cited above have been independently under investigation by NIDR scientists for some time. Therefore, it is possible to consider conceptual limitations on basic design requirements common to the Lixiscope in the absence of a clinical experience with a suitable

prototype. Hence, the remainder of this paper concerns pertinent observations applicable to the Lixiscope considered within this rather loosely defined conceptual framework.

Exposure Geometry

By placing the source of radiation in the mouth and the imaging device outside, it is possible to significantly reduce the amount of radiation dose to the patient as compared with the conventional dental radiographic technique as shown in Figure 1. It should be noted that conventional radiographs are produced from film packets situated inside the mouth. The x-ray source must emit a beam sufficiently larger than the film to assure that a portion of the film is not missed in the process of aiming. As a result, a substantial portion of the head is subjected to radiation extending beyond the film plane, which contributes to patient dose and image degradation due to radiation scatter from deeper structures.

Contrast this geometry with that shown in Figure 2 which corresponds to that made possible by the Lixiscope. The intraoral collimated source is rigidly coupled in such a way, that it is impossible for the beam to miss the detector. Hence, the beam can be made small without risk of "cone-cutting" the image. Unnecessary exposure is further reduced by having the x-rays directed from inside the mouth to the outside, because the only tissues irradiated are those of diagnostic interest plus the soft tissues of the lips or cheek. Figure 3 is a plot of the theoretical dose
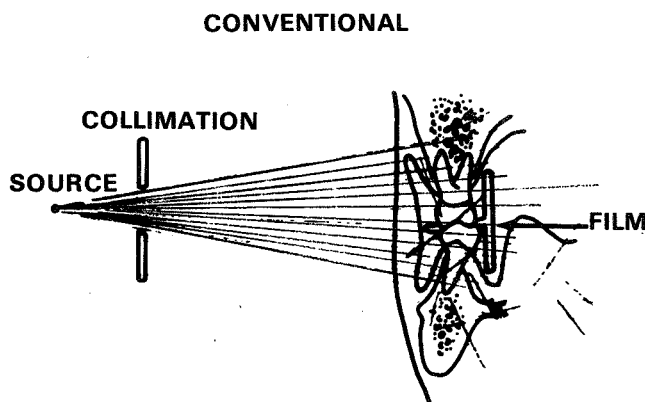
CONVENTIONAL

Figure 1. Schematic Diagram of Conventional Dental Radiographic Geometry

37

PROPOSED ALTERNATIVE
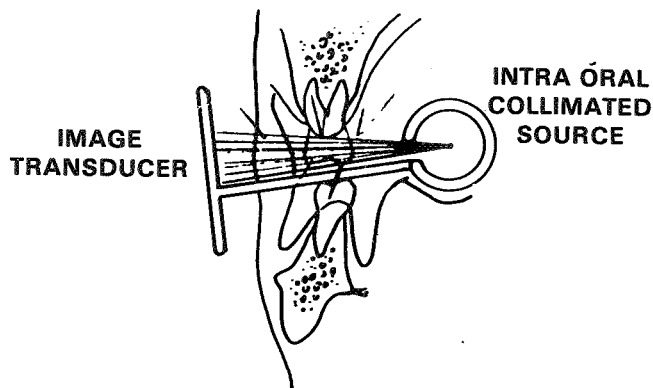
Figure 2. Schematic Diagram of Alternative Geometry Made Possible by an Intraoral Source of Radiation
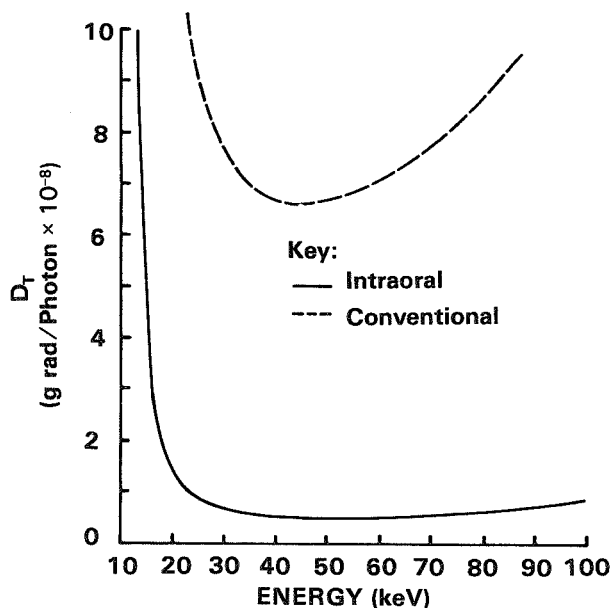
Figure 3. Integral Dose per Photon Reaching the Detector Expressed as a Function of Energy for Conventional and Intraoral Source Models

advantage expressed as a function of x-ray photon energy computed from a water phantom using a simple geometric model designed to compare these two configurations.[1] It can be seen that at no level of energy does the estimated integral dose per photon reaching the film plane for the intraoral source exceed that computed for the conventional source geometry. Even when a liberal allowance is made for the acknowledged limitations of the model, it is intuitively obvious that exposure efficiency is greater when the source is located intraorally, because radiation extending beyond the film plane does not contribute to patient dose.

Another geometrical advantage of the Lixiscope when compared with the *status quo* is the fact that it functions as a true fluoroscopic device. This is to say, that it can be manipulated on-line to permit multiple views to be sequentially observed to yield an integrated three-dimensional conceptualization of the structure being imaged. The dental significance of this multiple-view capability provided by the Lixiscope is illustrated by the effects of a change in source angulations shown in Figures 4 and 5 respectively (reproduced with the permission of Dr. K. Thunthy, Louisiana State University, School of Dentistry). The radiograph shown in Figure 4 indicates interproximal bone between the second bicuspid and first molar extending all the way up to the point where the dental enamel of the crowns joins the cementum

Figure 4. Angled Projection of Periapical Structures Showing Interproximal Bone Between the Bicuspid and Molar

Figure 5. Same Tissues as Shown in Figure 4. Altered Projection Geometry Reveals Large Periodontal Lesion Between the Bicuspid and Molar

38

covering the surface of the respective roots of these teeth. Figure 5 shows the same teeth projected from a slightly different source position. The bone in the interproximal region of interest is now seen to be missing next to the molar all the way up to the apex of the root. Thus, it is easy to see how this huge periodontal lesion could be missed by limiting consideration to a single x-ray projection as conventionally practiced. The potential diagnostic advantage afforded by the exposure geometry of the Lixiscope under these conditions is self-evident.

Radiation Source

In addition to the obvious advantages of simplicity, self-containment, and small size afforded by the use of an isotope as an x-ray source, the monoenergetic nature of the energy spectra produced by suitable isotopes has interesting implications for fluoroscopic applications. For example, ^{125}I used in the prototype Lixiscope described previously has line spectra narrowly clustered around 29 keV (see Figure 6). Also shown is a typical aluminum-filtered spectrum produced by a conventional dental x-ray machine. The relative maximum spectral output is approximately at the same energy as that produced by ^{125}I, but the conventional source produces a much broader spectrum ranging from zero to 60 kVp or more. This basic difference in energy distribution has a significant effect on the potential maximum amount of information available depending on the nature of the diagnostic task to be accomplished.

The exact nature of this relationship was explored by C. O. Henrikson[2], who used a hydroxyapatite-water phantom to model the caries detection task in teeth having a variety of equivalent thicknesses. By taking into account the linear attenuation characteristics of the tissues he was able to determine the minimum radiation dose as a function of x-ray energy required to reliably detect a one mm^3 lesion assuming an ideal radiation detector.

The results of this exercise are shown in Figure 7. It can be seen that the optimum energy, i.e. the energy requiring the lowest dose for reliable caries detection, depends on the thickness of hydroxyapatite to be penetrated. Of particular interest is the fact that energies around 30 keV appear optimum for the detection of small lesions in the 2 mm hydroxyapatite model. This suggests that for relatively thin calcified tissues ^{125}I has a nearly ideal spectrum. On the other hand, thicker tissues require significantly higher energies to efficiently yield diagnostic information at the same level of reliability. Translated in terms of the Lixiscope, this means that ^{125}I will require significant doses to produce satisfactory images of calcified structure with equivalent hydroxyapatite thickness greater than 3 mm. Of even more importance is the fact that this limitation is of a fundamental nature that cannot be changed by manipulation of other elements

in the system. Clearly, efficient use of an isotope such as ^{125}I requires that the Lixiscope be limited to a relatively narrow range of diagnostic applications.

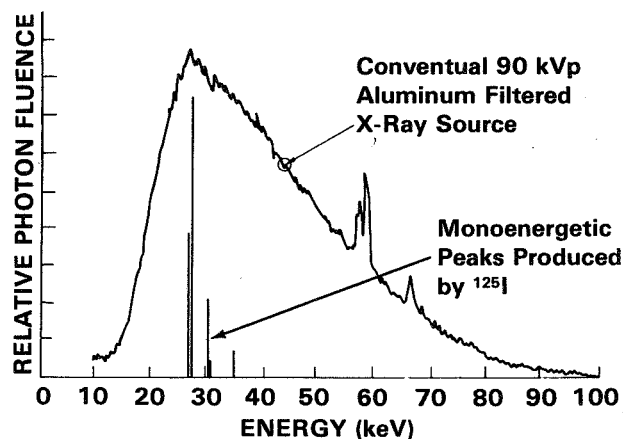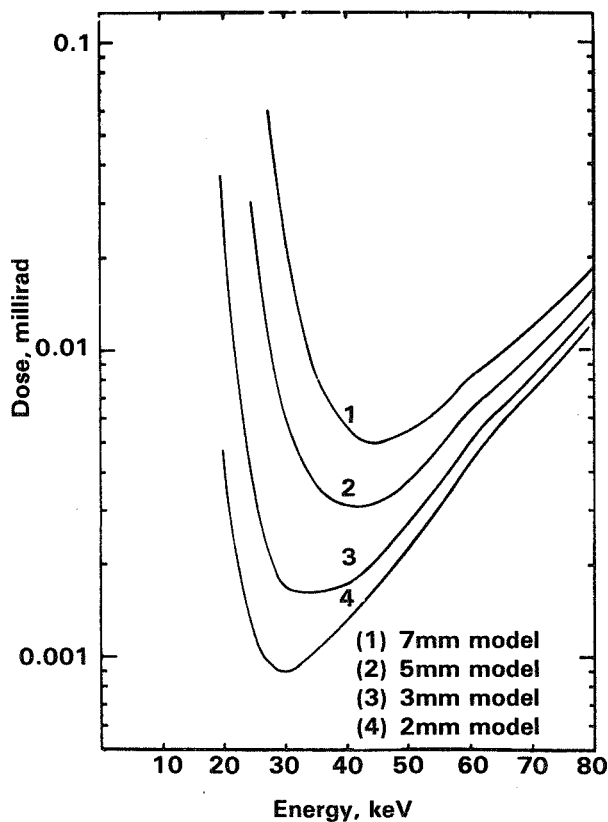Figure 6. Relative X-ray Energy Spectra of a Conventional Source and ^{125}I

Figure 7. Dose as a Function of Energy for Various Hydroxyapatite Models (Courtesy of C. O. Henrikson)

39

X-Ray Detector

Perhaps the most novel aspect of the prototype Lixiscope involves the use of a high-gain micro-channel plate image intensifier as an x-ray detector. Figure 8 shows schematically the basic elements of this device. x-ray photons containing information of diagnostic interest cause a fluorescent screen to emit luminous energy which in turn activates a proximity-coupled photocathode. The resulting electrons are accelerated at high potential through a coherent array of hollow glass tubes fused into a disc-shaped structure called a microchannel plate (MCP). Each tube acts like a miniature photomultiplier, so that each electron entering the plate creates an avalanche of electrons, which are detected at the output by a proximity-coupled phosphor screen to create a visible image.

Rational selection of MCP specifications demands an assessment of clinical requirements. Quantum-limited photomultiplying devices are intrinsically noisy, so that there is a definite need to determine how much information is necessary to perform tasks of diagnostic interest. The research in this area is only beginning to yield answers which confirm the task-dependent nature of image quality. The over-all efficiency of information transfer is also influenced by the choice of detector. This effect is illustrated by comparing the information capacity per dose produced by two typical x-ray imaging-systems as shown in Table 1. It can be seen that there is slightly more than a three-to-one ratio in information capacity between screen and no-screen systems, whereas the ratio between respective doses is more than an order of magnitude. This means that the higher speed system is more than five times as efficient in transfering information. The use of high-speed screens with the Lixiscope makes possible a substantial increase in efficiency for a variety of potential applications in dentistry. The anticipated compromise in image quality is illustrated in Figure 9 (courtesy of Dr. J. Gibbs, Department of Radiology, Vanderbilt University). The only difference between the dental radiographs shown is that the one at the top was

Table 1. Relationship Between Information Capacity and Dose

	PA	PA c̄ Screens
Information Capacity (Bits)	168,000	52,000
Dose (mR)	50	3
Capacity/Dose (Bits/mR)	3,360	17,200

produced conventionally, whereas the bottom radiograph was produced with an intensifying screen inside the intraoral film packet.

For many routine diagnostic tasks in dentistry, it appears obvious that the image quality of the bottom radiograph would be adequate. This conclusion is substantiated by the observation that a reduction in computed signal-to-noise power ratio of approximately 30 percent failed to significantly influence the detectability of incipient interproximal lesions from bite-wing radiographs when tested parametrically with 140 degrees of freedom.[3] In this case, image degradation was produced by prefogging
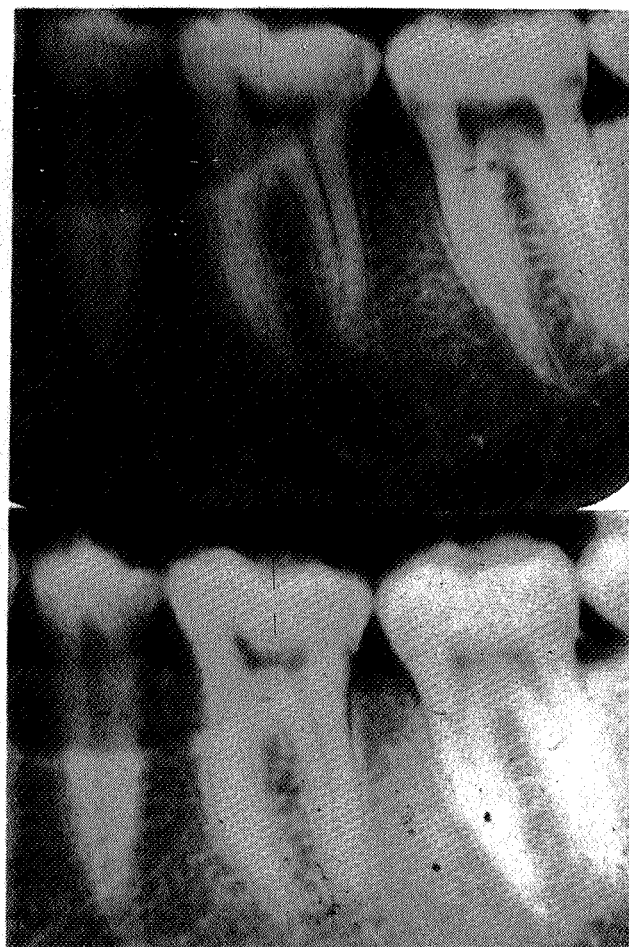
Figure 9. Comparison of Conventional (Top) and Screen-Film System (Bottom)

Figure 8. Schematic Diagram of MCP Image Intensifier Used in the Lixiscope

no-screen film with unmodulated x-ray exposure as exemplified in Figure 10. Of course factors other than source geometry, spectral characteristics, and detector speed influence image quality obtainable from Lixiscope, and these too must be considered in order to characterize unequivocally its diagnostic potential in dentistry. At least some of these have been addressed by Dr. Yin in a recent paper presented under the auspices of the Society of Photo Optical Instrumentation Engineers.[4]

Figure 11 is an actual example of a dental image produced from a skull phantom with a prototype Lixiscope. It clearly shows the root canals in maxillary teeth including the relative position of an endodontic file. It should be noted that the image was photographed with a Polaroid camera optically coupled to the output screen of this Lixiscope. The result is a photographic "positive" rather than the conventional radiographic "negative." Hence, radiopaque structures are imaged dark rather than light.
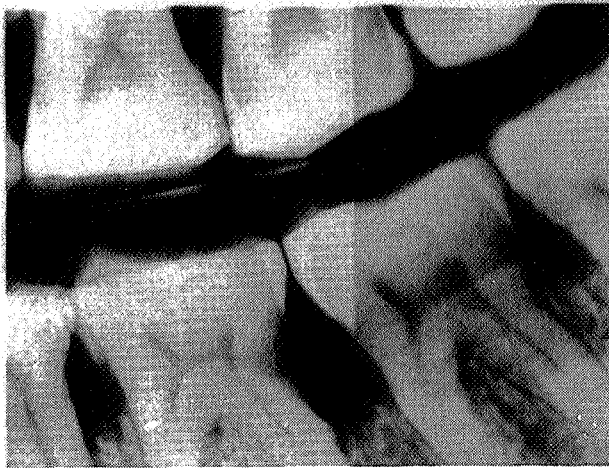
Figure 10. Effect of Unmodulated Radiation on Posterior Bitewing Radiograph. Darker Region on Right has 30% Reduction in Estimated Signal-to-Noise Power Ratio

While the image appears to be an encourgaging example of what has already been accomplished with the Lixiscope, its future in dentistry will undoubtedly depend on how well it performs in actual clinical situations, particularly when used as a fluoroscope. Hopefully the interest generated by its development and expressed in this conference will be sufficiently sustained to adequately test its potential in the clinical practice of dentistry.
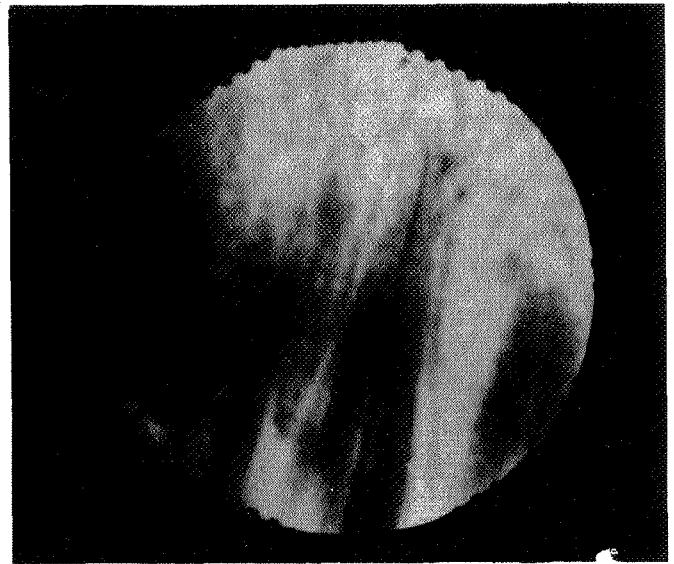
Figure 11. Photograph from Lixiscope Image of Maxillary Teeth Showing Root-Canal File

References

1. Webber, R. L and R. Nagel, Workshop Proceedings Rod Anode X-ray Source in Dentistry, DHEW Publication (NIH) 78-248.
2. Henrikson, C. O., Acta Radiologica Suppl. *269*, 1, (1967).
3. Webber, R. L and L Stark, Investigative Radiol. *7*, 6, (1972).
4. Yin, L, J. Trombka, S. Seltzer, R. L Webber, M. Farr, and J. Rennie, NASA Technical Memorandum 79634.

Page intentionally left blank

DOSIMETRIC CONSIDERATIONS IN DENTAL APPLICATIONS

John C. Goble, Sc.M.
National Institute of Health
Department of Health, Education, and Welfare

The use of intraoral sealed sources in conjunction with the micro-channel plate technology may provide increased diagnostic information with decreased radiation dose compared to conventional dental radiographic techniques. These reductions in radiation dose are a result of several factors, some specific to the prototype NIH device, and others more generally applicable. These advantages include:

1) Reduced depth dose
2) Reduced volume of irradiated tissue
3) Real-time operator feedback

In addition to these specific advantages, the integration of the Lixiscope into dental procedures may reduce the total number of normal radiographic exposures required.

Reduced Depth Dose

Due to the spectral distribution of energies produced by bremsstrahlung in the target of an X-ray machine, some of the photons emitted from the tube head approach the applied accelerating potential. In general, dental radiographic exposures are made at 80-90 kVp. Since these high energy photons penetrate both bone and soft tissue quite readily, they provide little radiographic contrast yet penetrate deeply into the irradiated tissue.

In using isotopic sources of photons, the problem of high energy contamination of the beam is eliminated. Since the photons are emitted at discrete energies, beam energy may be optimized for a particular application by selection of the appropriate radionuclide.

Reduced Volume of Irradiated Tissue

A collimated intraoral source provides many advantages with respect to volume of irradiated tissue (whether the image receptor is a microchannel plate device or not). In the normal dental techniques, at least two factors contribute to the large volume of tissue irradiated.

Since there is considerable uncertainty in the positioning of the film within the patient's mouth, the beam must be wide enough to ensure that the structures of interest will be imaged. In a more narrowly defined beam, the incidence of retakes will be much higher. This geometry produces irradiation of tissues that are not of interest to the dentist, and which are outside of the image receptor. By rigidly coupling the image receptor to the source, and collimating the beam size to the diameter of the input phosphor, needless irradiation of tissue is reduced. The effects of depth dose and of limited beam geometry are compared for the NIH prototype device and an 80 kVp unit commonly used for endodontic procedures. Doses are normalized to 1.0 rad at 1 cm on the beam centerline (Figures 1 and 2).

A second major advantage stems from the fact that radiation dose to the tissue beyond the film is eliminated. The volume of tissue irradiated during the normal radiographic exposure includes not only those structures between the source and the film, but those tissues in the "shadow" of the film as well. In the intraoral geometry, only the tissues of interest are irradiated.

Real-time Operator Feedback

The real-time imaging technique permits the dentist to examine the structures of interest at an angle that optimizes their visibility. In the normal radiograph, patient movement, poor film placement, improper techniques, and many other factors may contribute to the necessity of a retake. By receiving real-time feedback, the dentist optimizes the information available from the minimum number of exposures.

Specific Design Considerations in the NIH Prototype Device

With the practical nature of this conference in mind, a few comments on design considerations in
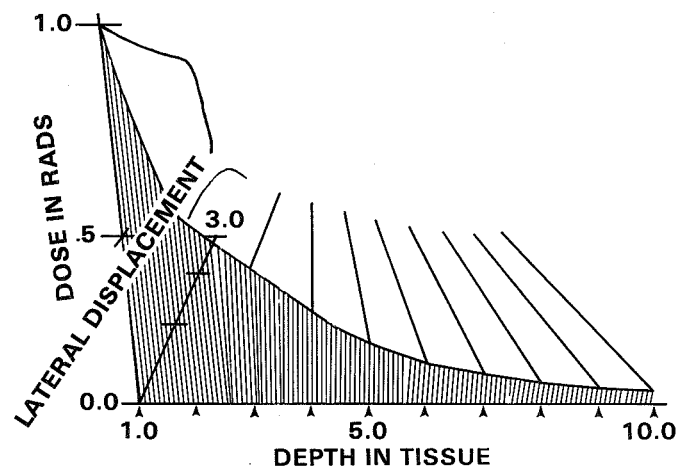
Figure 1. Effects of Depth Dose using 80 kVp X-rays

43
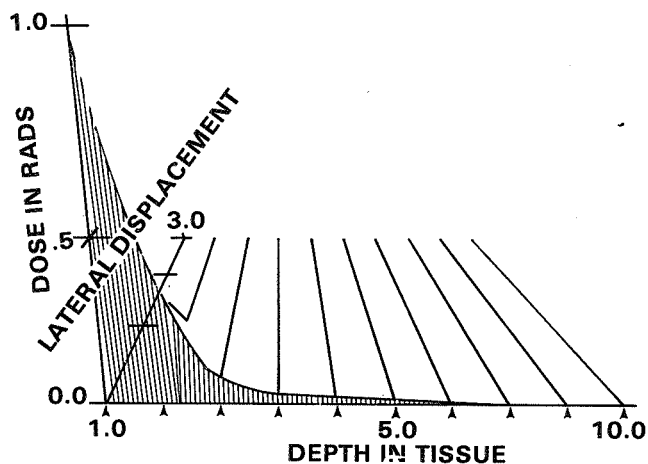
Figure 2. Effects of Depth Dose using I-125 Lixiscope Source

the NIH device are probably appropriate. Although no specific standards for the device exist, the NIH Prototype was designed to meet or exceed requirements for diagnostic type units. Some specific design goals of the device include:

1) Maximum Exposure Rate: 1.0 R/min
2) Maximum Leakage Radiation: .1 mR/hr at 1 meter
3) Beam Collimation: Rate at edge of input phosphor to be less than 10% of center-line rate
4) Shielding of Operator: Less than .1 mR/hr to eyes

Although these considerations are quite conservative and are specific to the NIH device, they are at least a starting point in making the Lixiscope a practical clinical tool. Many of the advantages seen in this design follow from the intraoral geometry and from the rigid coupling of source and image receptor. Similar improvements in radiation dosimetry might well be made in devices not using the microchannel plate technology. Because of the unique advantages of this particular configuration, however, it seems likely that the Lixiscope can provide adequate diagnostic information for a great many tasks with decreased radiation dose to the patient.

C. MAXILLO—FACIAL DIAGNOSIS

Dr. Allan B. Reiskin
University of Connecticut Health Center
School of Medicine

The use of fluoroscopy in dental practice is uncommon for many reasons. Dynamic studies, for which fluoroscopy is best suited, are not often required. The cost of currently available devices is extremely high, the units are large, and image detail is poor compared to film. While the Lixiscope in its present form has made substantial progress toward resolving the problems of the cost and size, image quality is still a problem.

As illustrated in Figure 1, the structures which are dealt with in dentistry are extremely small. The periodontal ligament which forms the attachment of tooth to bone is only a fraction of a millimeter wide. A change in the size of this space is often one of the most significant indications of incipient but treatable disease of the tooth, its supporting bone, or its attachment. A doubling of the size of the ligament space may represent less than one quarter of a millimeter, and therefore, images must be capable of resolving these extremely small changes to be of primary diagnostic value. The periodontal ligament space was selected as an example of the dimensional requirements of X-ray diagnosis in dentistry because it is similar in size to a variety of normal and pathological structures which are of importance.

The image in Figure 1 was produced with Kodak ultraspeed film. Its resolving power is illustrated by

Figure 1(b). This tooth has been treated endodontically, that is vital tissue has been removed and replaced with a sterile dressing. The attachment at the apex of the root is thickened (arrow) indicating residual disease.

Figure 1(a). This radiograph represents a view of the roots of molar and premolar teeth. The attachment of tooth to bone (the periodontal ligament) is indicated by the arrows.

use of a test pattern shown in Figure 2. The films are quite small (Figure 3) because most dental structures are paired and would superimpose upon each other if both the radiation source and the image receptor were outside of the oral cavity. In current practice, it is the image receptor which is inserted into the oral cavity, although this projection geometry can be reversed by using either rod anode X-ray tubes or isotopic sources such as those described by Dr. Webber and others (see reference).

In addition to the high resolution radiographs already seen, other types of diagnostic images are used in dentistry. A thick section tomogram (panoramic) is shown in Figure 4. This image reveals a disadvantage of static images, namely artifact associated with movement. The illustration reveals the image of a bony fracture with all of the
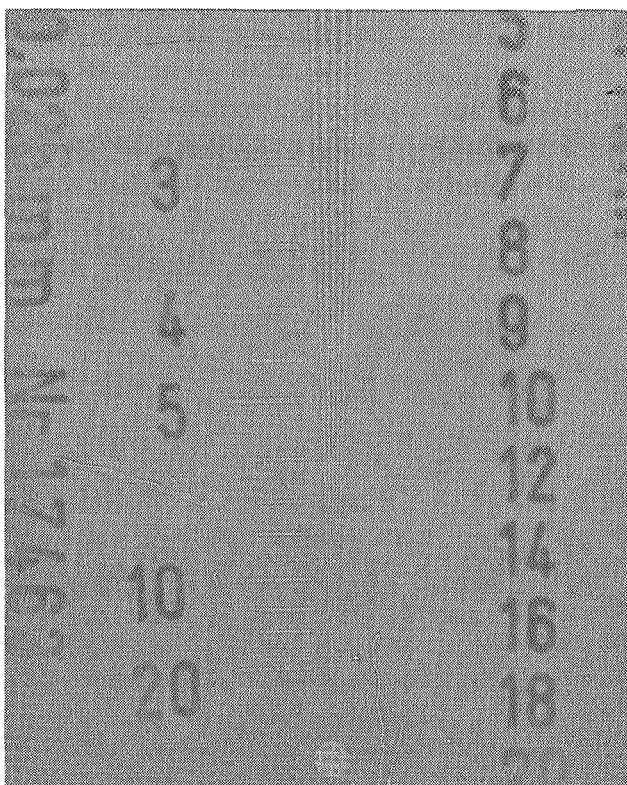
Figure 2(a). This image of a lead test target was made on Kodak ultraspeed film using 90 kVp X-rays and standard processing conditions. With magnification, one can resolve 20 line pairs per millimeter.
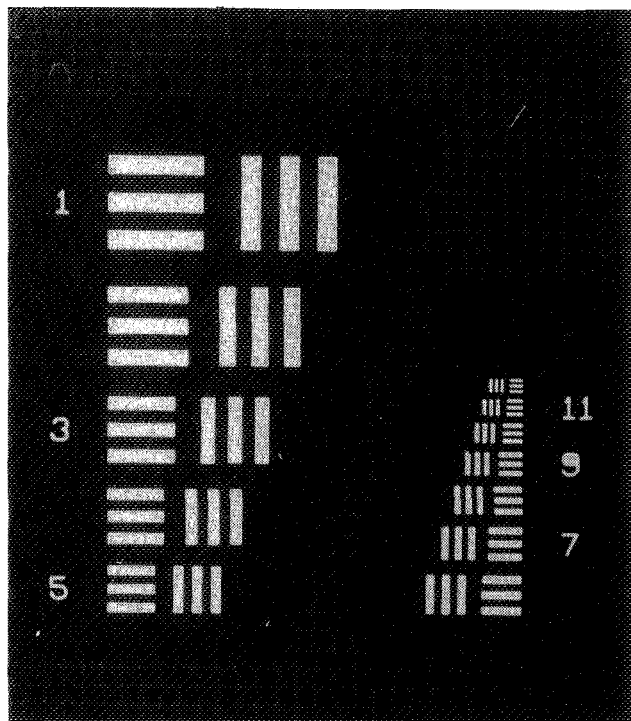
Figure 2(b). A bar pattern used for assessing focal spot size was also imaged on Kodak ultraspeed film and confirms the high resolution observed with the diverging lines.
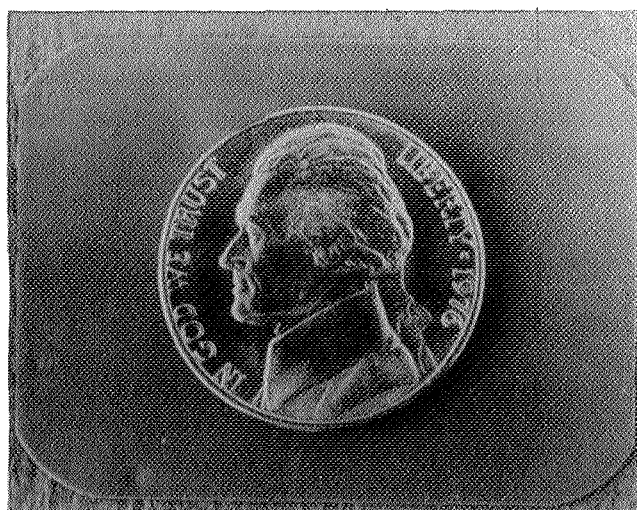
Figure 3. A coin was placed on top of a dental film to illustrate its relative size. Courtesy of the Eastman Kodak Co.
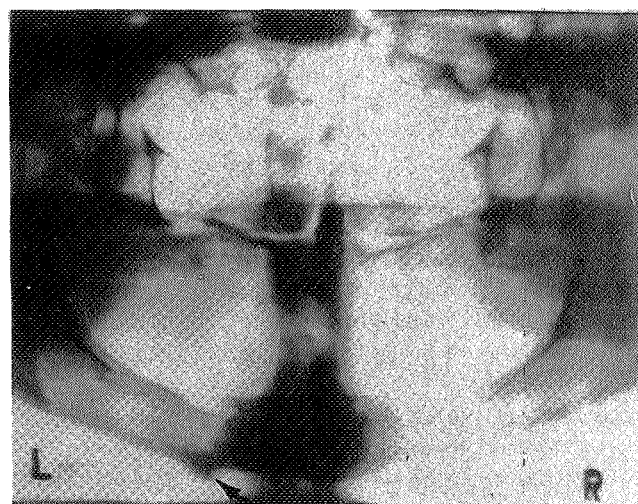
Figure 4. The defect indicated by the arrow represents motion artifact.

radiographic characteristics that one expects to see in a classical case of trauma. In reality, however, the fracture is an artifact which resulted from the sudden movement of a patient during the exposure (16 sec.). The dynamic nature of Lixiscope images would certainly reduce the probability of confusing this type of artifact with genuine trauma.

Figure 5 shows a thin section tomogram through the articulation between the mandible and the cranial base. In this, as in other instances, it is found that thin section tomography, which is a comparatively high dose procedure, is necessary because anatomical constraints do not permit one to view this area adequately with conventional imaging systems. However, the reversed geometry which could be used with the Lixiscope might eliminate the need for tomographic examinations in many patients. The
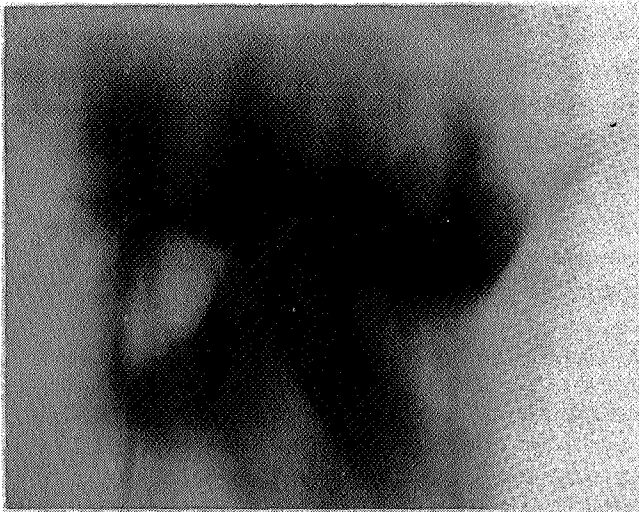
Figure 5. This tomogram represents a thin section (approximately 1 mm) using a linear tomographic system and a 40° angle.

Lixiscope would also provide a less expensive substitute for the tomographic equipment which is now required.

The evaluation of any imaging device must ultimately include a consideration of the radiation economy of the image detector. There can be a considerable dose-sparing affect by reversing the geometry of image production in some dental procedures. This reversal, compared to more commonly used geometries, reduces the total amount of tissue which is exposed in the radiation field. However, as shown in Figure 6, one can use
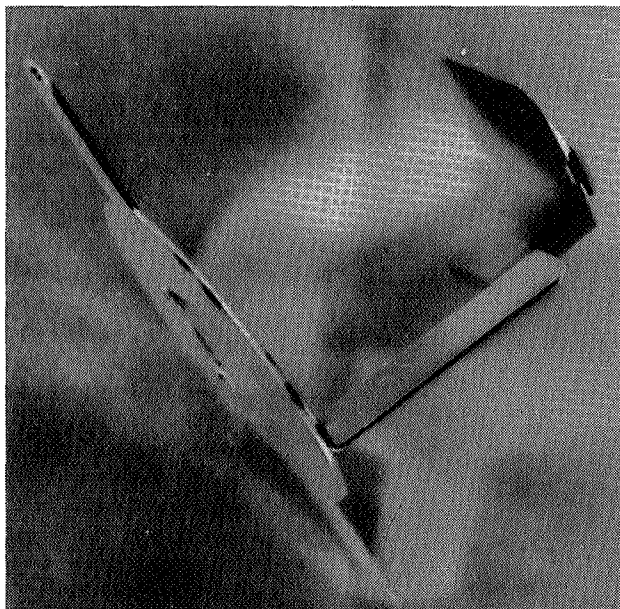
Figure 6. A large number of collimating devices are available for use with dental films. This particular instrument is made of stainless steel and restricts the X-ray field to the size of the film. A metallic backing behind the film prevents penetration of the X-ray beam beyond the image plane.

collimating devices which ultimately provide the same dose-sparing affect achieved by reversing the geometry. As long as the radiation field is no larger than the size of the image receptor and shielding is provided to prevent penetration beyond the plane of the film, then substantial savings can be attained. Under these conditions the dose-sparing advantages of reversed geometry may be less dramatic.

It is important to remember that there are problems other than the small size of the objects which are dealt with and the exposure requirements of any particular system. For example, the reduction of a three-dimensional object to a two-dimensional image can result in significant information loss. Small changes in angulation can have dramatic effects on the information content of a resulting radiograph and in many instances it is impossible to predetermine the optimal projection geometry without some type of system for previewing the final image. In spite of its relatively poor resolution, the Lixiscope might provide a simple and inexpensive device for previewing projection geometry prior to the production of an image on film. Such a procedure may be practical because of the Lixiscope's high gain. Obviously, the Lixiscope could be used either with isotopic sources (see reference), or with an extended rod anode X-ray source shown in Figure 7. Rod anode x-ray sources are commercially available and have been used for a variety of diagnostic procedures in the maxillofacial region. The configuration and size of the x-ray source make it possible to insert the device into the oral cavity so that any imaging device can be placed in an extra-oral position. Combined use of the Lixiscope as a previewing device with high resolution hard copy films should reduce the total number of films and improve their quality.
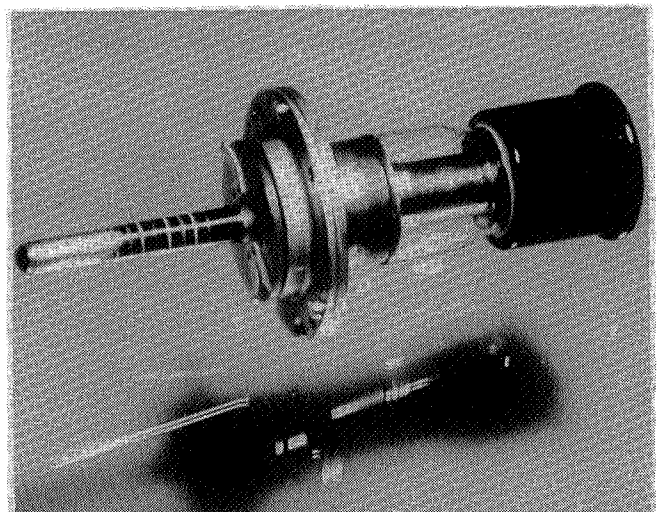
Figure 7. This illustrates the tube of a Siemens Status-X device. X-rays are emitted from the end of the tube which is small enough to be inserted into the oral cavity. Courtesy of the Siemens Corp.

A further advantage of extended rod anode x-ray sources and reversed geometry is the possibility of using extremely small focal spots and magnification as a means for improving image quality. In order to assess the impact of source size and other factors on image quality with the Lixiscope, we conducted several preliminary studies. Resolution was measured with a variety of test targets using bar and star type patterns. The data is summarized in Figure 8. Studies were conducted with x-ray sources having different spectra, including narrow energy bonds produced with rare earth filters and conventional sources. Isotope sources of iodine and gadolinium were also used. The sources varied in size from approximately six tenths of a millimeter to more than one millimeter and source to object distance was varied from a few inches to several feet. Under these conditions, images were produced on two Lixiscopes with different gain characteristics. Both instruments had variable gain controls and each was used in extreme high gain and low gain settings. The basic conclusion of our studies was that the resolution of these Lixiscopes was limited by several factors to approximately four line pairs per millimeter. First, the phosphor which converts radiation to light in these prototypes was relatively coarse. Second, since both instruments produced higher quality images in their low gain modes and the low gain instrument produced an image with greater resolution than its high gain counterpart, we presume that internal problems such as ion feedback near the surface of the microchannel plate or poor contact between screen and fiber optic might limit the resolution of the Lixiscope to levels which are below the requirements of many diagnostic procedures. It is also important to note that resolution measurements were made by recording images on Polaroid films which required relatively long exposure times. The resolution data which we obtained included the integration which is achieved by the film over a period of time. This integration is considerably greater than that which can be achieved by human eye and our measurements may be deceptively high. Our conclusions should also be qualified by the observation that there were consistent differences between measurements made with each test target and it was not possible to determine which of the test targets provided the most appropriate type of measurement.

Thus far, the Lixiscope evaluation has been in the context of a primary diagnostic device. It is important to recognize, however, that there are many situations in which an imaging system is used in conjunction with, or as support for, other procedures. A procedure has been described in which the Lixiscope was used to obtain working information during endodontic procedures. Similar uses of the Lixiscope might be made at other anatomical sites during other types of clinical procedures. Prime examples include arthrography and sialography. In these procedures, contrast agents are used to fill joint cavities or the ductal structures of salivary glands. These are usually dynamic studies in which it is important to establish that the contrast agent is deposited at the correct anatomical site and flows according to some predictable pattern based on our knowledge of normal anatomy and physiological function. Figure 9 shows a Lixiscope image of a needle placed in the knee joint of a rabbit. The size of the needle and the size of the joint are similar to what we would encounter in a human temporomandibular joint. The ability to manipulate the Lixiscope around the joint proved to be an enormous advantage in correctly placing the needle. On the other hand, the Lixiscope had the disadvantage of making the production of a hard copy record extremely difficult. Because exposure times were relatively

LIXISCOPE RESOLUTION

MCP	SOURCE	RESOLUTION (L.P./mm)	
		Max. G.	Min. G.
H.G.	70 kVp x-ray	4.0-5.0	5.0
H.G.	36 kVp x-ray	2.2-4.0	
H.G.	^{153}Gd	3.5	3.0-4.0
L.G.	36 kVp x-ray	5.5	
L.G.	70 kVp x-ray	4-5.5	
L.G.	^{125}I	4-7	

Figure 8. Resolution measurements made under different conditions with different Lixiscopes are summarized. Resolution of four or five line pairs per millimeter may not be achievable by direct viewing and may represent a gain resulting from integration accomplished by the film.

Figure 9. Shows a needle inserted into the knee joint of a rabbit. All of the structures are sharply defined including the bevel on the needle.

long, it was not uncommon to produce images such as that seen in Figure 10 with a large blur fringe that obscured detail. By comparison, Figures 11 and 12 show temporomandibular joint arthrograms photographed on Polaroid film from a video screen after recording on a magnetic disc and a similar image obtained on film by a tomographic procedure. Figure 13 shows a plain film of the same site which was necessarily taken at an oblique angle. Although the image quality is relatively high, the projection geometry required to view this site compromises the utility of the examination. Direct lateral viewing which could be achieved with an intraoral source and a Lixiscope would have distinct advantages.

In conclusion, the very brief experience with the Lixiscope established several points. First, in its present configuration, the Lixiscope appears to have value primarily as a previewing device for conventional radiography or as a working instrument to be used in association with or in support of other procedures. Second, the Lixiscope, in its existing configuration does not have sufficient resolution to function as a primary diagnostic tool for most dental needs. Finally, it is necessary to emphasize that we have examined primitive models of the Lixiscope and the technology for substantially improved devices already exists. Sufficient information has been developed to support the desirability of constructing second and third generation Lixiscopes with larger and more uniform fields, with advanced design, microchannel plates, and with improved phosphors.

Reference

Henrikson, C. O.: "Iodine 125 as a Radiation Source for Odontological Roetgenology," Acta Radiologica Suppl., 269, 1967.

Figure 11. The quality of images recorded on magnetic discs may be significantly poorer than those visualized directly on a Lixiscope screen.
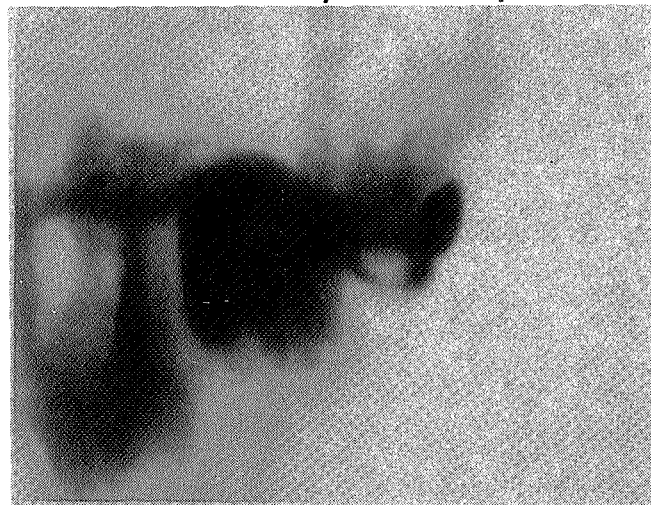
Figure 12. The Lixiscope and the video disc do not compare in image quality with thin section tomograms such as that illustrated here.

Figure 10. This image shows the result of motion introduced as a result of long exposure times. A blur fringe can be seen along the edge of the needle and less clearly, at the edge of bone.

Figure 13. Greater sharpness and detail is obtained in plain films such as this arthrogram in which the lower compartment of the temporomandibular joint has been filled with opaque material.

Page intentionally left blank

D. PEDIATRICS

Dr. Thomas J. Spackman
Chairman of the Department of Radiology
University of Connecticut Health Center

There are a couple of things about pediatric radiology that indicate a particularly apt application for a low-dose portable X-ray device such as the Lixiscope.

The actual experience that any of us has had with the Lixiscope in approaching clinical problems and applying it to phantoms has been relatively limited. There is a certain risk in discussing clinical applications in a simplistic or facile fashion because it is not certain what the Lixiscope can or should be in its final configuration. There is another problem when one leaves small dental structure application for larger structures of medical radiographic application, in that the configuration of the Lixiscope as it is now is fairly constraining. Part of the problem is that the device has been given a name and a patent number and one tends to think of it in its current configuration; that is, an isotope source rigidly coupled to a high-gain image intensifier that measures one inch in diameter.

As various medical applications are analyzed, it becomes apparent that a more flexible design approach is needed. The device is a series of components which includes a source of radiation and an input phosphor with some characteristic that will complement the radiation incident upon it. The image intensifier, a competent high-gain intensifier, is really the device that makes this instrument different from existing systems. The use of a radioisotope source for diagnostic imaging is not unique. It has been used for field pack radiographic units in the past with high energy isotope sources.

From the medical standpoint, bigger patients require more flexibility in thinking about the design approach to the whole imaging system.

However, given the present constraints on the instrument, it was convenient to think about using the Lixiscope for a tiny patient. The youngest of the pediatric patients are quite tiny. The application that was most tempting to think about was in the neonatal intensive care unit for premature infants, usually with respiratory distress. Sometimes these tiny little babies are only 800 or 1,000 grams or 1,500 grams. In the Lixiscope evaluation, an experimental rabbit was used which was much larger than a very tiny premature infant.

The other important consideration in pediatrics relates to radiation exposure. This brings up a whole new problem area regarding radiation effects, and that is not the intent of this paper. It is known, at least as a generalization, that radiation is not good for us, and it should be avoided if possible. There is some indication that the risk of late tumor development may be enhanced in infants that are born to mothers who have had abdominal radiation, pelvimetry, while the baby was in the uterus. That is still controversial, and the data vary, but there is strong concern about what is being done to these babies. Even once they are beyond the *in utero* stage, there is a general acceptance that during the sensitive phases of development, whether *in utero* or in the first months or even years of life, the theoretical risk to the patient is greater than in an adult organism. Thus, the low dose aspects of this device are appealing.

The potential use of the Lixiscope for the infant intensive care unit is very interesting. The neonatal intensive care unit at the University of Connecticut Health Center has some 15 or 18 bassinets. There are 250 or 300 transfers each year of distressed infants from surrounding community hospitals which do not have sophisticated maintenance facilities into the University of Connecticut Health Center. The actual transport mechanism, or vehicle, is affectionately called the "whale." It is a large bus, or superlarge van, that measures about 40 feet in length and is manned by a driver, a physician-nurse team and additional supporting personnel when necessary. It provides numerous support devices for monitoring and maintaining blood pressure and respiration. Some laboratory facilities, including blood gas determinations, are available, and it is really a fairly sophisticated transport vehicle.

The object of this obviously is to get the baby from the referring hospital into the neonatal intensive care unit in as safe and as rapid a way as possible. These are critically ill infants who are very sensitive to temperature changes and changes in ambient oxygen concentration, and the transfer has to be made relatively quickly. Actually, what happens is that the pediatric intern goes with a nursing team to the referring hospital, examines the infant to be transferred, and decides what immediate stabilization must be done in the referring hospital. This often includes obtaining radiographs and placing various tubes. The infant is then put in the transport vehicle and brought to the Medical Center.

There would be some advantage if part of that sta-bilization time could be avoided. Thus it was tempt-ing to think about the possible use of the Lixiscope in the transport vehicle so that tubes and catheters could be placed and some radiographic evaluations could be made of the infant during transport. Again, the Lixiscope seemed to satisfy some pediatric needs.

It will be necessary to be careful in using this instrument to conform to each institution's human investigation guidelines. One of the concerns the developers of the instrument have had is what it will do to the radiation burden for the entire population. It is nice to think that the dosage or radiation will be cut down by fluoroscoping the tip of a finger to see if the broken needle is still impacted, but it makes one a little bit anxious to think of legions of physicians running around with Lixiscopes in their pockets, screening patients and doing various other evaluations. This could result in a substantial in-crease in the total population radiation dose and is reminiscent of the old fluoroscope in the shoe store before it went out of vogue.

The following paragraphs describe some of the ideas and the direction of thinking regarding potential applications for the Lixiscope. The figures which are presented fall into three groups. First are some con-ventional radiographs to illustrate the type of thing that is presently being dealt with in the infant or neonatal population: different things that happen to the babies, where their tubes are, what the tubes are for. Also presented is a series of pictures that il-lustrate the images that were made with the Lix-iscope using an experimental rabbit. Finally, in a very theoretical and speculative frame, some of the other uses appropriate for the Lixiscope or a modification of it are presented.

Figure 1 is a normal chest X-ray in an infant. The heart is in the center and partly surrounded by a mass of tissue which is the thymus gland. The picture shows some faint markings running out to the periphery of the lungs which represent pulmonary blood vessels, and some of the airways can be seen.

Figure 2 shows one of the problems that might be encountered. The heart is no longer in the center; it has shifted to the patient's right side, and the left lung is very radiolucent. What has happened is that the lung blew out. It was stiff because of underlying pulmonary disease; it required greater airway pressure to maintain oxygenation. It simply popped like a balloon and collapsed when air leaked out. The collection of free air within the chest markedly decreases the ability to oxygenate the baby. If one could recognize this sort of a problem, when an acute change in the clinical status occurs during transport, therapy could be given by tapping the air collection with a needle or tube.

Figure 3 shows the chest tube that was placed in the same patient. The heart has moved back to the midline because the abnormal air collection was successfully drained.

Figure 4 shows some other types of tubes. One is used in an infant who had a gastrointestinal problem, and it is called a hyperalimentation line. It is placed in a vein over the shoulder at the base of the neck, and inserted into the vena cava that runs into the right side of the heart. It is a mechanism for getting high caloric concentrations into an infant, but that can't be done well in the tiny veins of the arms and legs because they will clot. It is not uncommon to see one of these tubes, when placed blindly, directed into the

Figure 1. Normal Chest X-Ray of an Infant
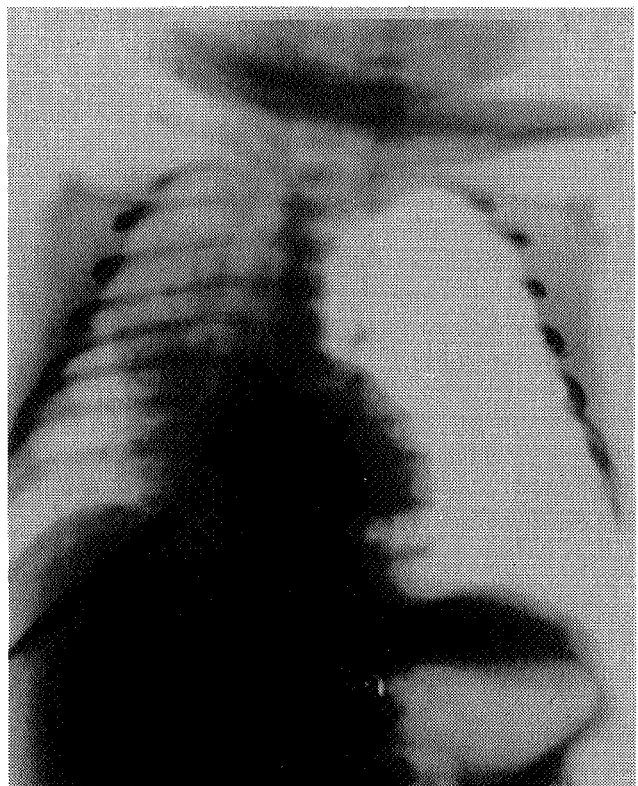
Figure 2. Abnormal Chest X-Ray of an Infant
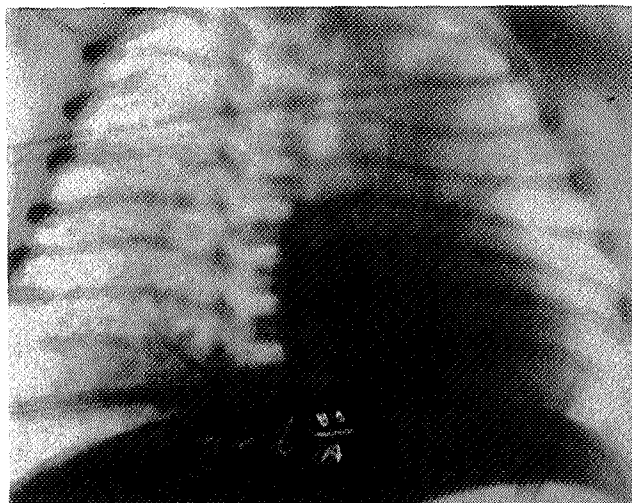
Figure 3. Chest X-Ray of Chest Tube in an Infant
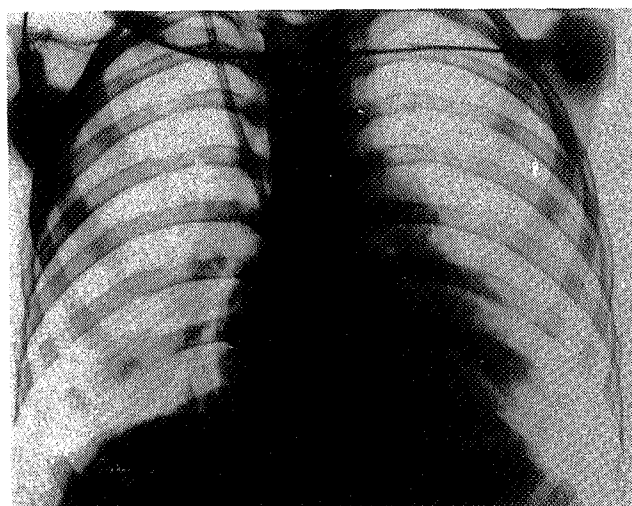
Figure 4. Chest X-Ray of Other Types of Tubes in an Infant

head rather than the heart, and that is not a good place to put a very high concentration solution.

Figure 5 shows an endotracheal tube which is used to maintain respiration. It is placed in the upper trachea, and one has to know where the tip of the endotracheal tube is so that it is not wedged in one of the two major airways, one supplying the right and one supplying the left lung. Obviously, if it is wedged in the right one, then the left lung is not going to get aerated very well, so one would like to know fairly accurately what the position of this tube is.

Also on the radiograph is an umbilical vessel catheter. It is fed in through the stump of the umbilical cord into the umbilical artery, and it is advanced into the major artery of the body, the aorta, where it is used for taking blood samples. Again, the position of the tip is fairly critical. It should be kept away from the orifice of the vessels to the kidneys and some other major abdominal organs, and that requires knowing where the tip is.
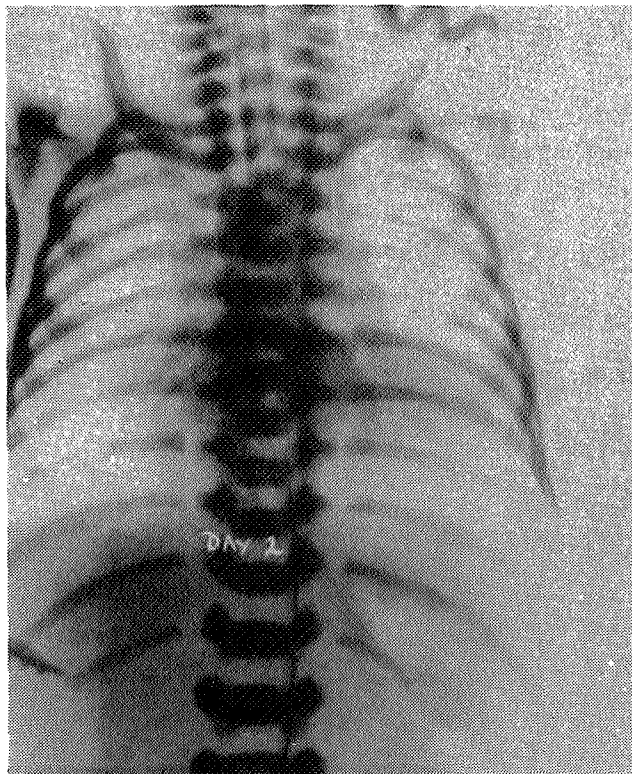
Figure 5. Endotrachael Tube Placed in the Upper Trachea of an Infant. Along with the endotracheal tube is an umbilical vessel monitor

Figure 6 shows a nasogastric tube. This has a radiopaque strip, either lead or barium, impregnated within the wall of the tube. In general, these are some of the things that one is concerned with in the neonate.

Figure 7 is the first in a series of pictures made of the rabbit used in our evaluation. Some of the Lixiscope screen defects mentioned earlier appear. Some of the anatomic studies made on the rabbit are presented. There was interest in seeing whether an
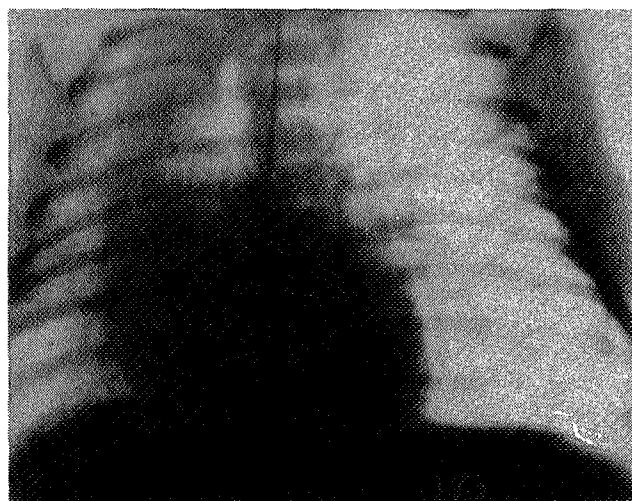
Figure 6. Nasogastric Tube with a Radiopaque Strip Impregnated within the Wall of the Tube
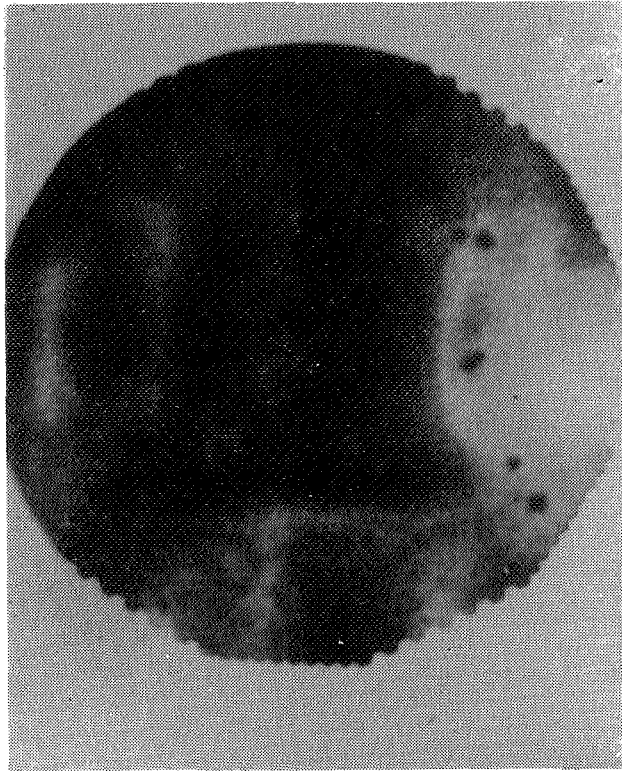
Figure 7. Image of Interspace between Two Bony
Vertebrae of the Spine of a Rabbit

Figure 8. Diaphragm of a Rabbit

image could be made of the spine itself or the space between the bodies of the spine for space application. It's fairly crude, but one can distinguish an interspace between two bony vertebrae and can see some of the structures of the vertebral body.

It was also decided to test the Lixiscope to see the diaphragm, the junction between the chest above containing air, and the water density abdomen below. One could see it, but it wasn't easy in the rabbit, as illustrated in Figure 8. Interestingly, even though with the hard-copy image one gets a chance to integrate more information because it's exposed over a period of time, there's a certain advantage in being able to move the fluoroscope over the part that you are looking at or having the part move under it. The diaphragm was clearly recognizable because it could be seen moving up and down and one sometimes gets a three-dimensional concept by being able to observe a structure from a variety of directions.

Figure 9 is a chest tube placed within the esophagus. It is reasonably well-defined, and the ribs are again well-seen against the aerated lungs.

After sacrificing the animal, some iodinated water soluble contrast material, sodium diatrozoate, was placed into the trachea. As shown in Figure 10 it produced very nice imaging. That it has to do with the combination of using an iodinated compound for contrast material and radioiodine as a radiation source. The filled esophagus shows up as a very black

Figure 9. Chest Tube Placed within the Esophagus
of a Rabbit

54

Figure 10. Sodium Diatrogonate Placed into Trachea of a Rabbit
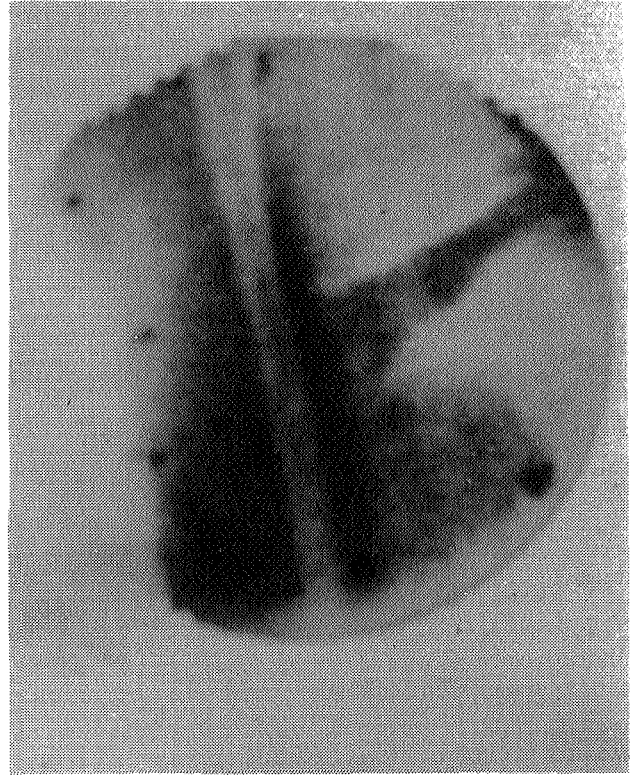
Figure 11. Feeding Tube in the Esophagus Exposed through the Neck of a Rabbit

band. This was in the neck, and some of the bodies of the vertebral column in the neck can be seen.

Figure 11 shows a feeding tube that was placed in the esophagus and is also through the neck. Once again the vertebral bodies can be seen and the space between the bony structures, the joint space, is detectable in the picture.

A post-mortem angiogram was made using a needle to place the iodinated contrast material directly in the heart by a blind puncture. In Figure 12, the dark shadow of contrast in the left ventricle and a tubular structure—the major artery or the aorta—coming off the heart can be seen. It is therefore possible to image these deep structures, in a 3,000 gram rabbit, particularly if aided by the use of contrast material.

In the following discussion some very speculative applications are presented. These are speculative in the sense that it's questionable as to how much will be added to patient care by being able to do these studies, and, secondly, because the equipment in its present configuration is not capable of performing the studies.

Figure 13 is a fracture of the skull in an infant that was born by a forceps delivery; it's pushed in. It is usually not terribly important to know about skull fractures unless they happen to be pressing on the adjacent brain tissue, and this is fairly gross. Normally, it is hard to see the depressed fracture unless you get the patient into exactly the degree of obliquity that
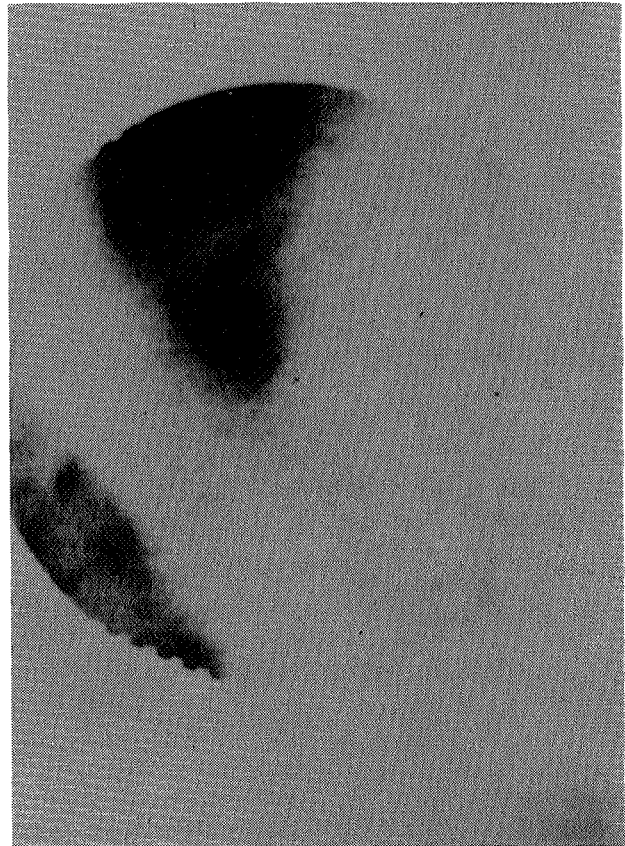
Figure 12. Left Ventricle and Aorta of the Heart of a Rabbit
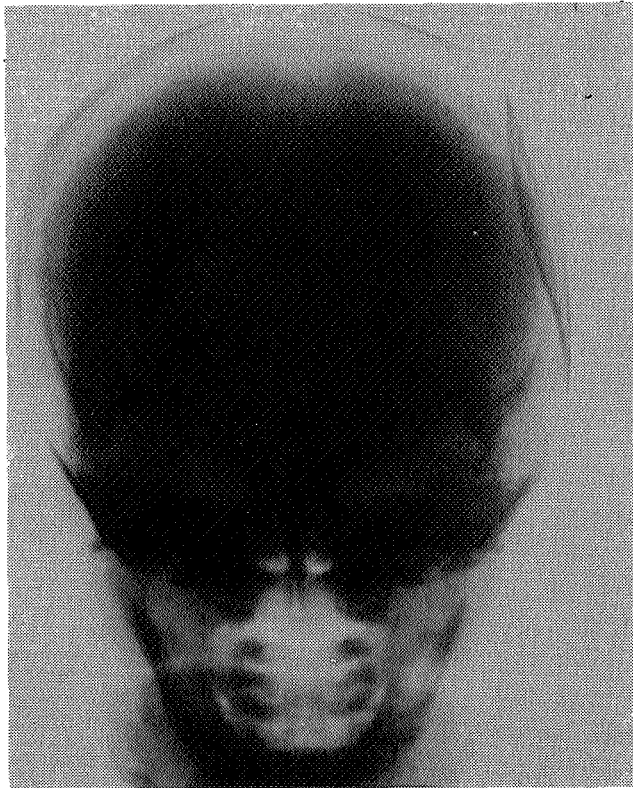
Figure 13. Fracture of the Skull of an Infant

Figure 14. Tube Placed within the Ventricular System of the Brain of an Infant with Hydrocephalus

Figure 15. Patient with Slipped Capital Femoral Epiphysis
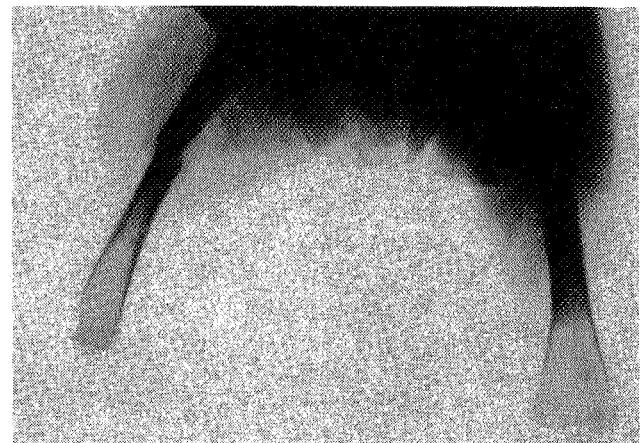
Figure 16. Front Picture of Simple Fracture

will show it in profile, and that's difficult to do with standard views. What is really needed is an infinite number of images or fluoroscopy while rotating the head. It might be possible to use the Lixiscope for preliminary evaluation the same way the dental lab patient might be screened for caries, to at least scout the skull if there is sufficient penetrating power with the instrument.

A child with hydrocephalus, or water on the brain, is shown in Figure 14. Tubing has been placed within the ventricular system of the brain, to drain the excess fluid, and it is of some interest to the neurosurgeons, as they do this procedure, to determine the location of the tube.

Figure 15 shows a patient with slipped capital femoral epiphysis. The head of the femur has slipped off of its neck and it had to be stabilized by use of these pins. In this situation one would like to be able to see an infinite number of projections to be sure that one of the pins isn't sticking into the joint space. This would be difficult for the Lixiscope because the pelvis and hip are very thick structures requiring high energy for penetration.

The simple fracture in Figure 16 looks like it is well-aligned when seen from the front. One might be inclined to say, "Well, this is a pretty good reduction of the fracture, and all we have to do is put it in a cast." However, as seen in Figure 17, which was taken from the side, there is marked angulation at the fracture site. Again, the actual geometry is important

Figure 18. Kidney Stone in Right Kidney

Figure 17. Side Picture of Simple Fracture

and may be difficult to work out using conventional studies.

In Figure 18, a kidney stone is seen in the right kidney as an oval density. At the time of surgical removal of multiple renal stones, it is useful to radiograph the kidney during the operation to be certain all stones have been removed. There are ways of using a sterile film holder behind the kidney or adjacent to the kidney in the surgical wound, and exposing the film with a portable X-ray machine, but there is no theoretical reason why the entire Lixiscope could not be introduced into the surgical site, into the peritoneum. In other words, one could gas sterilize the Lixiscope screen and heat sterilize the radiation source and then just wrap the Lixiscope up after it is sterile and put it into the patient during the surgery to image what is going on—where the stones are.

Figure 19 is an operative cholangiogram. The gall bladder has been removed because of stones, a tube has been placed in the duct that carries bile from the gall bladder and the liver into the bowel. One would like to know at the time of surgery whether all the stones are out or if they are impacted in the duct. If the Lixiscope were introduced into the abdominal cavity,

Figure 19. Operative Cholangiogram with Tube

57

it would be interesting to see if better detail imaging or better geometrics of imaging in this type of intra-operative procedure could be obtained.

Figure 20 shows a patient who had a long period of fever and had some ill-defined bone lesions. The figure shows the pelvis, and there is an abnormal lucency in the right iliac bone.

As seen in Figure 21, there was a similar abnormality in one of the ribs, and it was decided to get some tissue by biopsy for diagnosis. The possibilities included a primary or mestastic tumor, an osteo-myelitis or infection that had seeded to the ribs, or some other kind of unusual abnormality. It is of obvious importance to have a diagnosis, and this requires getting a biopsy of a piece of the involved tissue.

The surgeons initially went in and did a biopsy of a rib which came back negative. A follow-up radiograph was done on the patient and found that the wrong rib had been removed, an understandable error resulting from difficult orientation at the time of surgery. This raises another theoretical possibility: could the fluoroscopic screen of the Lixiscope be used to image radioisotopes that have been injected in the patient, such as for conventional nuclear medicine studies? Can a bone-scanning agent be injected in the patient at the time of surgery, to expose the bone through the incision and look at it with the Lixiscope to decide whether the abnormality has been identified as indicated by increased radioactivity? If this can be done, and there is no inherent reason why it cannot, this sort of an error might be avoided by accurately localizing the site for bone biopsies.

Figure 21. Picture of Ribs with Abnormalities

Figure 22 is a lymphangiogram, a very tedious study where one makes a skin incision in the foot, finds a tiny little lymphatic channel, half a millimeter in diameter and almost transparent, and sticks a tiny needle into it to instill contrast material that will fill up the lymphatic vessels and then fill the lymph glands. Using this examination, one can see whether there is leukemia or lymphoma or other tumor invading the glands, or at least if there is destruction of the normal glandular architecture by a disease process.

After the needle has been inserted, one is not always sure that contrast material is going where it ought to be going, that is, into the vessel, or whether it is just leaking into the adjacent tissues. It might be possible to use the Lixiscope to identify whether contrast material is beginning to go up the lymphatic channels.

Secondly, there are some radioisotopes presently in use that are useful in identifying tumor tissue or infected or necrotic tissue, and one can occasionally discover hidden foci of tumor or infection by external scanning. It would be interesting, at the time of operation for lymph node biopsy, to have injected some of this material sufficiently ahead of time so that the Lixiscope screen could be used to identify the most abnormal lymph nodes by determining the site of the greatest radioactivity.

In summary, one can get far afield without restraint on imagination. The first group of pictures showed

Figure 20. Picture of Pelvis

Figure 22. Lymphangiogram

what the problem is; the second group showed what type of images can be obtained now using a rabbit for evaluation purposes. In the third set of photographs, some very speculative applications for the Lixiscope were presented. There are potential benefits in the Lixiscope, but to a medical radiologist the concept of the Lixiscope should be relaxed. It does not have to have the specific form of the present instrument but might be a series of component parts that could be designed in different ways and exchanged in different ways: an isotope source for some applications, a conventional X-ray source for other applications, an input phosphor designed to meet the task at hand, and hard-copy image or simply fluoroscopic real-time viewing depending on the specific information desired.

More clinical experience will be needed with the Lixiscope and it will be necessary to be mindful of the population burden of radiation that may be introduced with the Lixiscope. Certainly the engineering possibilities for the Lixiscope can be very exciting, and seem almost limitless.

Page intentionally left blank

E. PODIATRY

Dr. Stephen Weissman
Department of Radiology
Pennsylvania College of Podiatric Medicine

It should be noted from the outset that this is a "pre-preliminary" report since Dr. Anthony Kidawa and Dr. Gerald Gorecki and I had the Lixiscope for approximately an hour in the foot clinic at a not very busy time.

However, based on this limited evaluation time, the use of the Lixiscope stirs the imagination and the possibilities for its clinical use seem endless.

Podiatry is a very surgically-oriented speciality and a great deal of this surgery is done in an office. Along these lines, a technique of minimal incision surgery has developed in the last few years. It is used primarily for permanent removal of excressences, commonly called corns, on people's toes or between people's toes. Usually they are caused by small, bony prominences, an exostosis or a hypertrophy of a phalanx. It is quite simple to remove them, and cure the patient's problem, by making approximately a quarter of an inch incision, which is why it is called minimal incision surgery, and remove the offending, bony prominence.

Figure 1 is a drawing of the toe. It has a little red nail on it and three phalanges in it. On the head of the proximal phalanx is a very common place for an increase in bony density, just enough to cause the patient to develop a localized pressure reaction or hyperkeratosis.

However, it often does not show up well on an X-ray and there are limitations in the views that are taken.

Of course, additional views can be taken, but then the patient is exposed more and more to radiation.

In the surgical procedure a quarter of an inch incision is made, a bone rasp is inserted, and the bony prominence is removed. Thus, the Podiatrist is almost doing the surgery blind or by feel.

However, if the Podiatrist had a small fluoroscopic unit that he could quickly put over the area and take a look to make sure he was in the right place or that he had removed enough bone or had not removed too much bone, the procedure would be much improved. Every Podiatrist would have one of these units in his office.

On a slightly larger scale, the use of such a device on the operating room table would be an advantage. Figure 2 shows the metatarsal bones in a foot. Frequently, the Podiatrist does surgery on the bases of the metatarsals as shown in the Figure.

Obviously, if work is done on the first or the fifth metatarsal, there is very little trouble in properly

Figure 1. Drawing of a Toe with an Increase in Bony Density
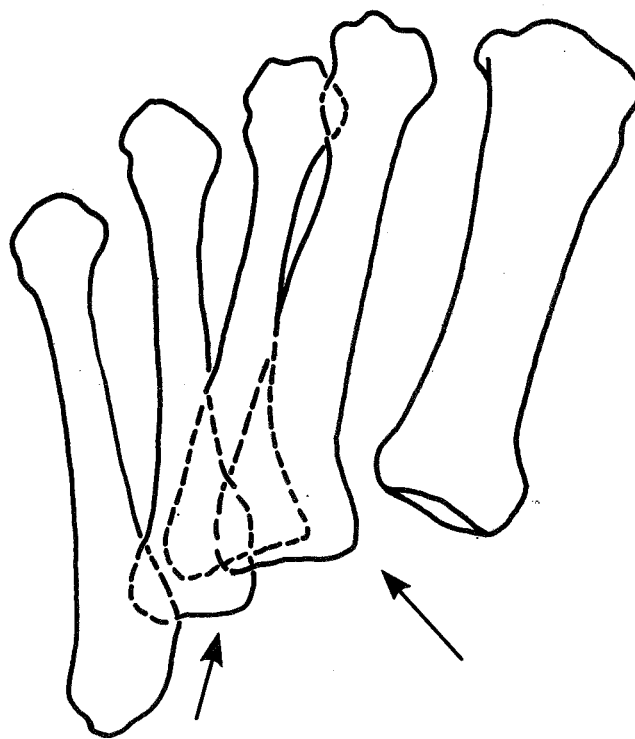
Figure 2. Drawing of the Metatarsal Bones in a Foot

locating these. However, on the base of the second, third and fourth, where the area is primarily bone, it is very difficult to determine whether the Podiatrist is operating on the correct one or not. This is especially true on the third or fourth, which is between all the others.

Again it would be advantageous to have a quick fluoroscopy unit that would be sterile and could be used in the operating room to make sure that the Podiatrist is working on the right one.

Figure 3 is a side view of the heel bones: the ankle bone, or the talus, and the bone in the heel, the calcaneus. There is a little hole in the middle called the sinus tarsi.

In children who have very flat feet, a surgical procedure is done in which either a piece of bone or a piece of medical grade silastic is inserted into the sinus tarsi. It only takes about an inch or an inch-and-a-half incision. It is right underneath the skin and is easy to get to. But grossly it never looks the same as on X-ray with these abnormally shaped bones. This necessitates bringing in an X-ray unit, and taking a picture on the table to make sure it is in the right place. This wastes a half hour and the longer the child is on the table and under the anesthesia, the more morbidity, post-operatively.

Again, a Lixiscope could show this right in the operating room. It would tell the Podiatrist that he is in exactly the right place and has accomplished what he wanted to.

The Lixiscope would have the same applications in treatment of trauma, fracture reductions, and so forth. If the dose is as low as claimed, then it beats a regular fluoroscopy unit, and it is better than doing a closed reduction of a fracture, X-raying it, doing another closed reduction because the site was missed the first time, and then X-raying it again and maybe doing it a third time. The X-ray exposure would be reduced considerably.

Another application that is very desirable is the
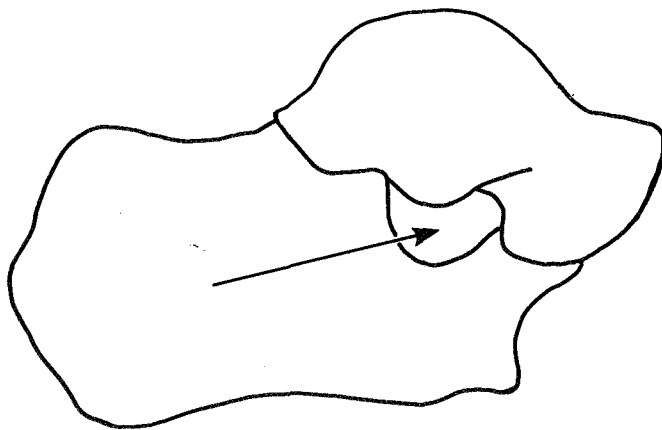
unlimited number of views one can get with a quick sweep with a Lixiscope. The Lixiscope can pass almost 360 degrees around a small joint in a matter of a few seconds, something that would take a considerable number of X-ray views and still not catch exactly what was wanted.

This was demonstrated very neatly in the clinic on a patient with an ulceration on the toe. Osteomyelitis or a bone infection was suspected. The bone infection was not detected with standard X-ray. However, the Lixiscope showed that right around the corner, where the two-plane radiograph could not show, the beginning periosteal reactions to the infection could be seen. Therefore, using the Lixiscope, a case of osteomyelitis was detected two weeks before it showed up on standard radiographs. Again, another great use for the Lixiscope.

The Lixiscope also magnifies. It was found that one of the screens magnified everything by about twice the size. This can also be accomplished on a regular X-ray. It was also found that the resolution was not as great as desired at times.

For foreign body location, the value of the Lixiscope is obvious. Today, a number of implants in the foot are made of metal or silastic. To examine an implant after it is in, the regular or standard X-ray views are taken and a static or nonfunctioning view of the implant is made. To look at it under fluoroscopy, a rather long exposure is needed.

If it could be done quickly with a low-dose Lixiscope, it could be determined if the prosthesis is functioning properly as planned or if it is in the right place during gait.

In the lower part of Figure 3, where the talus and calcaneus can be seen, two of the three joints between these two bones, the posterior and middle facets, are indicated. Occasionally, a tarsal coalition is found in young adults. That means that the two bones that should be separate are fused together. This causes muscle spasticity in the leg because the muscles are not able to function properly, leaving quite a painful foot. It is difficult to diagnose.

If an X-ray view is made of the posterior aspect of the ankle with the right angulation, the middle and the posterior facets can be seen. However, it is very difficult to get that view properly and have it be meaningful.

If the X-ray is off by two or three degrees, the joint space will be missed. That is a problem because in every individual the angulation of those facets is different. To get the proper view, it is necessary to expose them at least three or four times.

If the Lixiscope could penetrate a thick part such as described, it would be a natural; and it would cut down the radiographic exposure considerably.

Sometimes X-rays are taken with a patient's shoe on, since shoes can cause a great deal of pathology.

Figure 3. Drawing of the Side View of the Heel Bones

So a device with good penetrating power is needed. It should be stronger than the Lixiscope is now. But, again, it would be a natural for that use.

Another useful application would be in arthrography, or taking X-rays of joints with dye in the joint. The hardest part is placing the needle in the joint. If the joint is missed, the dye is spilled into the soft tissues, and nothing can be seen. An X-ray or the fluoroscopy unit can be used, but a device that gives a much lower dose and can be used rather quickly is a natural for this application.

The Lixiscope, therefore, seems to have a few features that make it appear quite promising. It is really easy to use and it is fast. It is easy to over-expose a patient because once you start looking, you just keep going from joint to joint and around and around. It also takes a fair amount of experience to be able to pick up what you want to see. It is not the same as looking at an X-ray. Without experience the patient can be over-exposed. However, it does give a low dosage. It is excessively movable, sometimes too movable, and it is a bit difficult to photograph some of the pathology. For example, a foot was placed under the Lixiscope or in the Lixiscope, and the camera was connected. It was difficult to find what had originally been found because everything had been moved. To get a good picture, the patient's leg had to be twisted because the stand would not move properly. To alleviate this problem, the Lixiscope definitely needs a lot of development.

There are also some other negative factors or disadvantages. For instance the resolution was found to be less than adequate at times, especially when trying to examine joint surfaces. Arthritic joint surfaces don't show well. It did, however, show bony impingements. If the two opposing surfaces of the joint were no longer parallel, it could be seen, and when the joint was moved, the bony prominences could be seen impinging. Of course, this could be done under any fluoroscopy unit.

It was a little difficult to get used to the inverted image at times. The Lixiscope does not penetrate a thick part. It is great for toes, but unfortunately it is not so great for the back of the foot and for ankles.

The Lixiscope needs a system for exposure calculation. In its present configuration, you turn it on and maybe time it; although it would be nice if it had a built-in timer. A little beeper like a Polaroid camera would be advantageous.

Figure 4 shows a distal phalanx, the middle phalanx, and the interphalangeal joint space. The resolution is not too good. It is not as good as looking through the actual Lixiscope. Figure 5 again shows an interphalangeal joint. The break in continuity, a minor trauma, can be seen in this picture.

Figure 6 shows the medial aspect of a metatarsal phalangeal joint. The patient had a very small bunion.
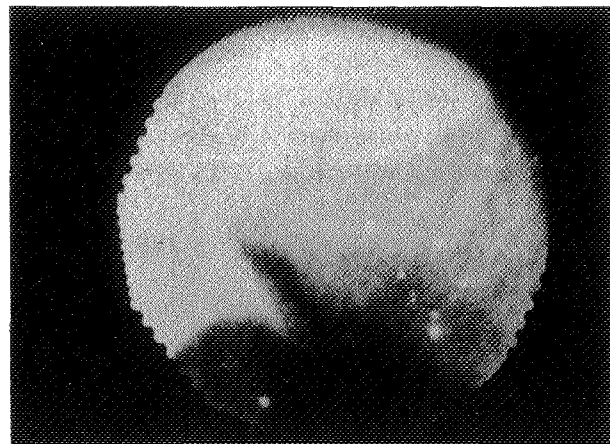
Figure 4. Distal Phalanx, Middle Phalanx, and Interphalangeal Joint Space

Figure 5. Interphalangeal Joint
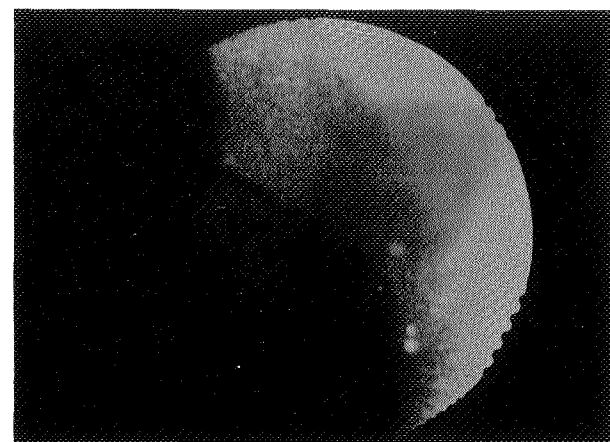
Figure 6. The Medial Aspect of a Metatarsal Phalangeal Joint

The uneven joint space was defined. Unfortunately, the patient moved and the desired picture was not obtained which appears to be another problem with the Lixiscope.

Figure 7 shows a patient's finger with psoriatic arthritis. The little grooves which are characteristic of the disease are on the tip of the phalanx. The picture shows some bony reaction. The patient caught the finger, or injured it, in a lawn mower a week before this was taken.

Figure 8 is a lateral view of the distal end of the toe and the distal phalanx. The curve can be seen. This picture is one that is never seen with an X-ray. It is very difficult to take little pieces of film and put them between people's toes and shoot without having them move. This just illustrates one of the unique applications for this Lixiscope. It has a great future with a little bit more development. Eventually, it may be in every Podiatrist's office and quite a few dental offices.

Figure 7. A Patient's Finger with Psoriatic Arthritis
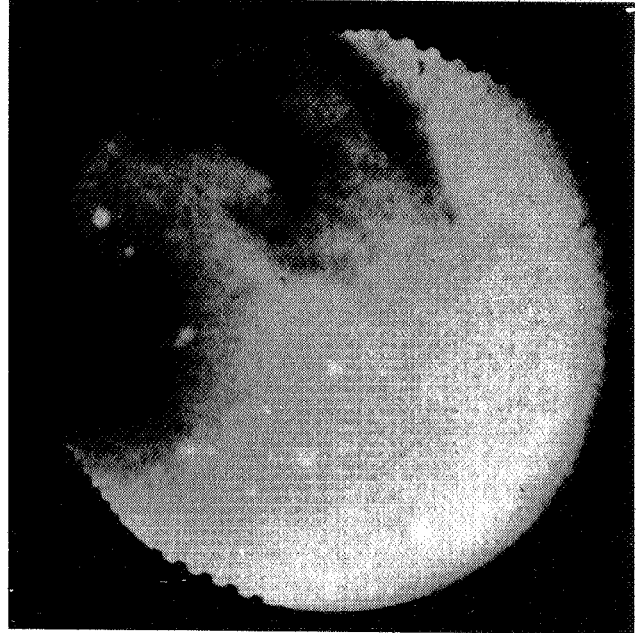
Figure 8. Lateral View of the Distal End of the Toe and the Distal Phalanx

F. VETERINARY MEDICINE

Lt. Col. Richard Simmonds
Uniformed Services University of the Health Sciences
Department of Laboratory Animal Medicine

The Lixiscope was evaluated in relation to veterinary medicine at the Uniformed Services University for about three hours. However, before reporting on the results of this evaluation a few words on fluoroscopy in veterinary medicine are in order. It must be stated that there are very few clinicians in veterinary medicine who use fluoroscopy.

This primarily relates to the fact that most veterinary medicine is done, at least in small animal practice, in what is usually a fairly well-equipped hospital. Most veterinary practitioners have their own radiographic equipment handy.

In large animal medicine, it is probably more a matter of economics than anything else. Most farmers probably wouldn't be willing to pay the fees necessary for on-the-farm fluoroscopy examinations. Veterinary clinicians in regular clinical practice do very few implantations of prosthetic joints and what-have-you which further limits their requirements for fluoroscopy.

For these reasons there probably is not a great need in clinical veterinary medicine for a fluoroscope. Following its development, if the Lixiscope maintained its portability, and if the costs could be reduced, it is possible that there would be a market for it in clinical veterinary medicine. The market would be primarily with the large animal practitioner who would want something to take out on a farm; in animal sporting events such as horse and dog races, pet shows, horse shows; and possibly even in the small animal clinic for rapid real-time examination of an injury.

In academic medicine, it is a different situation. In research, fluoroscopy is used considerably, but it usually relates to cardiovascular work or research work to a certain extent similar to some of the material presented earlier about rabbits. Such use would include looking at catheter implantations or blood flow using radiopaque dyes, and frequently the examination is done on larger animals than the Lixiscope currently can penetrate.

So, in general, fluoroscopy is not used all that much in veterinary medicine.

However, the Lixiscope was evaluated in several ways using a mouse, a rat, a cat, and a dog. Even though the unit is very portable, it gets to be "athletic" with unanesthetized animals. It took six people to operate the Lixiscope and the camera, hold the animal, and get the position.

A good resolution was obtained with the bony structures in the smaller animals (the rat and the mouse) and the extremities of the cat. If there is a need to take a good, quick scan of the bony skeleton of a mouse or rat, it can be done very well with a Lixiscope.

With the Lixiscope, internal organs of the smaller animals could be visualized by the movement of the organs. A Polaroid picture of that view or visual field would not show very well. The same situation applied to the diaphragm in smaller animals.

The resolution of the bones in the extremities of the cat and dog was fairly good, as can be seen from the photographs which follow. The body and torso bones of the larger animals were not visible; the tissue could not be penetrated with the iodine, and too much penetration occurred with the dylinium.

Figure 1 shows photographs of radiographs taken out of a text book, to illustrate the type of detail desired with bony structures. This is a radiograph. With fluoroscopy, you do not get this kind of detail. However, one can see the internal structure of the bones, and when compared to the Lixiograph photographs, it gives some idea of the difference between the two.

One of the things noticed with the Lixiscope was that it had very poor soft tissue definition with the current model. If it could obtain more soft tissue definition as in Figure 2, it would be helpful.
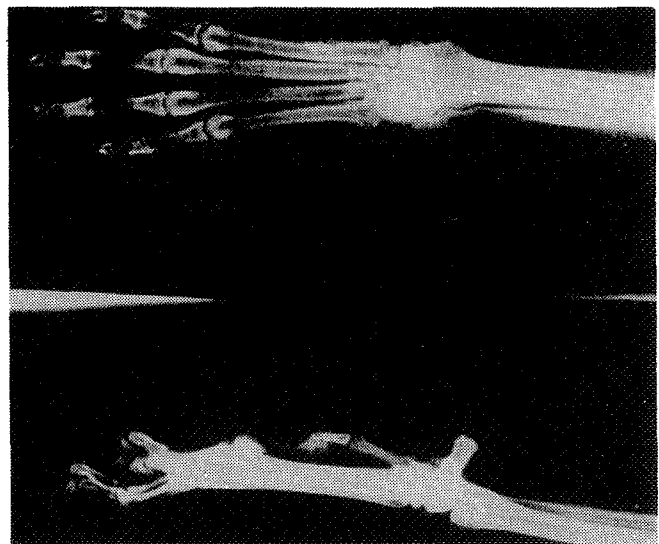
Figure 1. Photographs of Radiographs from Text Book
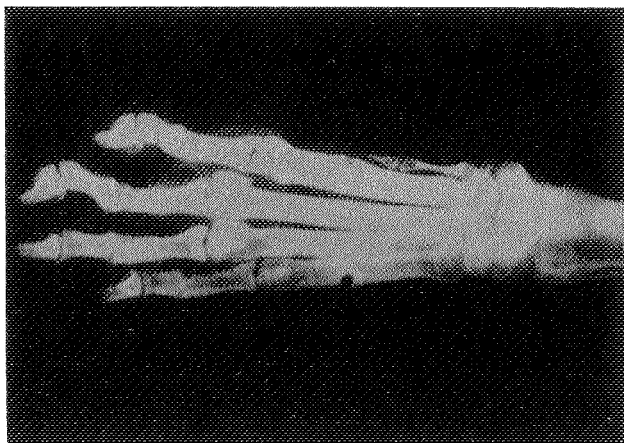
Figure 2. Desired Soft Tissue Definition

Figure 3 is the metatersus of the cat with the I-125 source and a lanex screen. This was a two- or three-second exposure and the movement of the cat resulted in a foggy photograph. However, it is not bad as a clinical picture. As pointed out earlier, the orifices, the joint spaces, and the condyles can be seen fairly well. From a clinical standpoint, this probably would be all a practicing veterinarian would need to scan a cat's paw for a lesion which may have something to do with the bone.

Figure 4 is the heel bone of a rat, using the os calcis process with the I-125 source, lanex screen and a one-second exposure. If you had some interest in the skeleton of a rat, keeping in mind the degradation of the detail on the photograph versus the actual screen of a Lixiscope, it is quite applicable and quite usable.

Figure 5 is approximately the same view using the wafer tube screen. Considerably better detail can be seen. It is a little fuzzier because a longer exposure was taken, there is less visual light output from this screen, and the animal moved. Nevertheless, it is fairly good detail, and if the animal was a bit more immobilized and the camera set up and everything steadier, some pretty good pictures could be obtained.
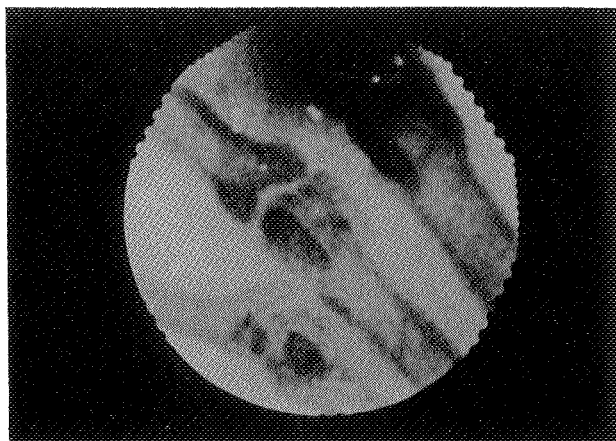
Figure 3. Metatersus of a Cat with I-125 Source
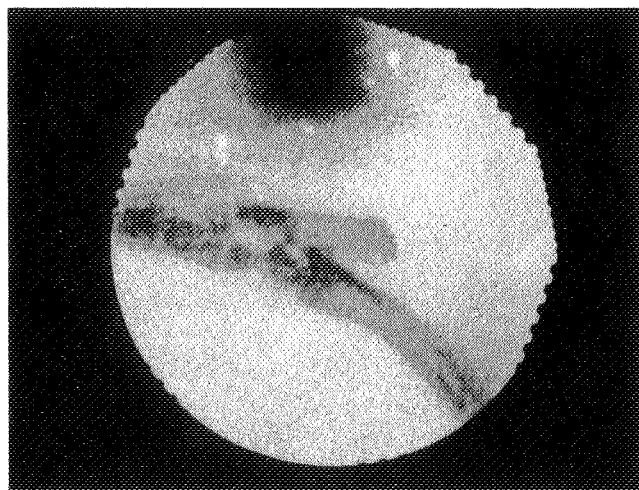
Figure 4. Heel Bone of a Rat using I-125 Source and Lanex Screen
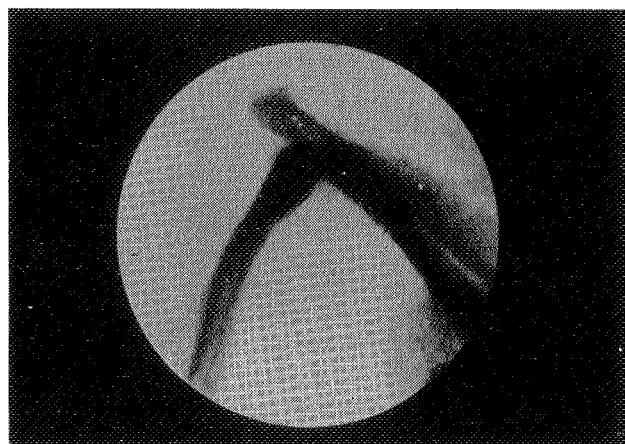
Figure 5. Heel Bone of a Rat using Wafer Tube Screen

In conclusion, based on the evaluation, it is believed the Lixiscope has a great deal of promise. Depending upon the economics of the final product, there may be a place for it in clinical veterinary medicine.

If the cost of the Lixiscope is about $5,000, with anywhere from $800 to $1,000 a year for the isotopes, there are very few practicing veterinarians who are going to pay that much for one. However, if the price came down in development, it has a good future in veterinary medicine. It probably will be limited to a great extent to rapid evaluation of bone fractures or abnormalities and possibly to veterinary dentistry.

There is a small problem with licensure. There are very few veterinarians currently with isotope licenses. However, that would be a minor problem which could be easily resolved.

It is believed that veterinarians probably will be able to use the Lixiscope as described here, but they will not be the drivers. They will ride along with somebody else pushing the system.

IV. TECHNOLOGY UTILIZATION

A. AN OVERVIEW OF THE NASA TECHNOLOGY UTILIZATION PROGRAM

Mr. Louis Mogavero
Technology Utilization Program
National Aeronautics & Space Administration
Washington, D. C.

The speed with which technology is moving is an awesome thing, and to those who are in the business of transferring technology, it is even more so. Technology sets the pace for our entire economy and way of life; and therefore, whatever, benefits and stimulates technology, benefits everyone. One of the world's largest and most effective pacesetters of this advance in technology is the NASA aerospace program. The purpose of this paper is to explain how NASA develops the technology and gets that technology into the warehouse of knowledge and then out of the warehouse and into the economy.

In the following paragraphs some examples of where the technology comes from and its uses or spinoffs of our technology, are presented. Briefly, NASA's mission is to explore the Earth and its surroundings, conduct aeronautical research, and put the results of this Research and Development to work for the benefit of mankind. The Shuttle is a reusable Earth-to-orbit work horse that delivers payloads to orbit, eliminating costly launch vehicles. One important feature is its ability to retrieve unmanned satellites for repair or return to Earth. It is launched like a rocket, and returns like an airplane.

In aeronautics, NASA is doing research to provide safer, quieter and more energy efficient aircraft which has less impact on the environment. Earth orbiting satellites provide information that offers enormous practical benefits to help manage the Earth's resources such as crop growing conditions and changing land uses. And finally, NASA has launched more than 300 spacecraft into Earth orbit and into deep space to gain knowledge about the past, the future, and perhaps man's destiny.

In less than two decades, man has learned more about the Universe than in all the prior years of history. It is from these programs that NASA develops a vast reservoir of knowledge which can in turn be used to solve earthborn problems. The second use of this technology is called "spinoff". While the list of spinoffs is impressive, the process is far from automatic. Technology may move or it may not move, and if it does move, it moves slowly if left alone. What

NASA has done to accelerate this transfer process is to develop a technology utilization program. The purpose of this paper is to discuss NASA's technology utilization program.

The problem is — how does NASA get this technology into the warehouse; how does it extract it from the warehouse of knowledge and get it back into the hands of taxpayers who paid for the technology in the first place?

The first step to be considered is how to get people to know that the technology exists and is available? First of all, when NASA contractors, and also NASA people within the NASA field centers such as the Goddard Space Flight Center, develop new technology, the technology is reported and screened for some potential commercial use. If it has potential commercial use, it is then written in a one-page dissertation called a "tech brief" (Figure 1). This is a one-page description of the technology in lay language with pictures or sketches explaining some of its potential uses. Each tech brief identifies the name of the innovator. For instance, if a person from the Goddard Space Flight Center has developed an innovation, his name is included. Therefore, if you have a question when you read the tech brief you can call that person to get more information.
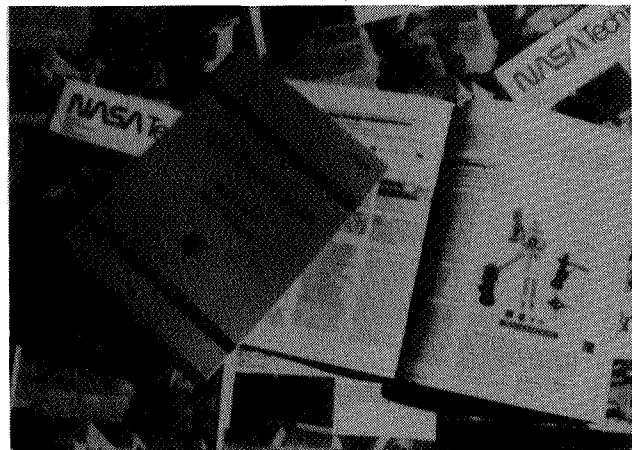
Figure 1. Tech Brief

About two years ago NASA developed the Tech Brief Journal. Previous to the Tech Brief Journal, each piece of NASA technology was written on one page and sent out as a one-page description. People read them and sometimes misplaced them or threw them away. It just wasn't a very effective way of retaining the information.

The new Tech Brief Journal contains about 150 tech briefs per journal, and is issued quarterly. This increases the shelf life of the technology because an individual can place these in his or her bookcase, and at the end of the year consult an index and refer back to the technology. It has been found, over the years, that people generally take about two years to actually get to use the technology they previously read.

If more information is needed to support the Tech Brief, technical support packages are available. These are notes that the innovator has written about the technology as he developed it. Figure 2 is a plot of the requests for technical support packages. Last year over 100,000 requests for technical support packages were received by NASA. This is significant. There are about 35,000 or 37,000 people who receive the Tech Brief Journal; and if over 100,000 people requested additional information, that is some indication that there is value in the Tech Brief Journal. For every Tech Brief published, there are about three to four people who request support packages.

Some examples of the uses of the Tech Brief Journal and also the information within the Tech Brief are discussed in the following paragraphs.

The first example is the technique for providing special types of plastic foams. Figure 3 shows an assortment of Scott's reticulating foam filters used in the automobiles, lawnmowers, motorcycles and other vehicles. A Scott engineer learned about NASA technology from reading one of our Tech Briefs and later requested a technical support package. This technology was instrumental in reducing the product development time.

REQUESTS FOR TECHNICAL SUPPORT PACKAGES (TSP's) ALL YEARS
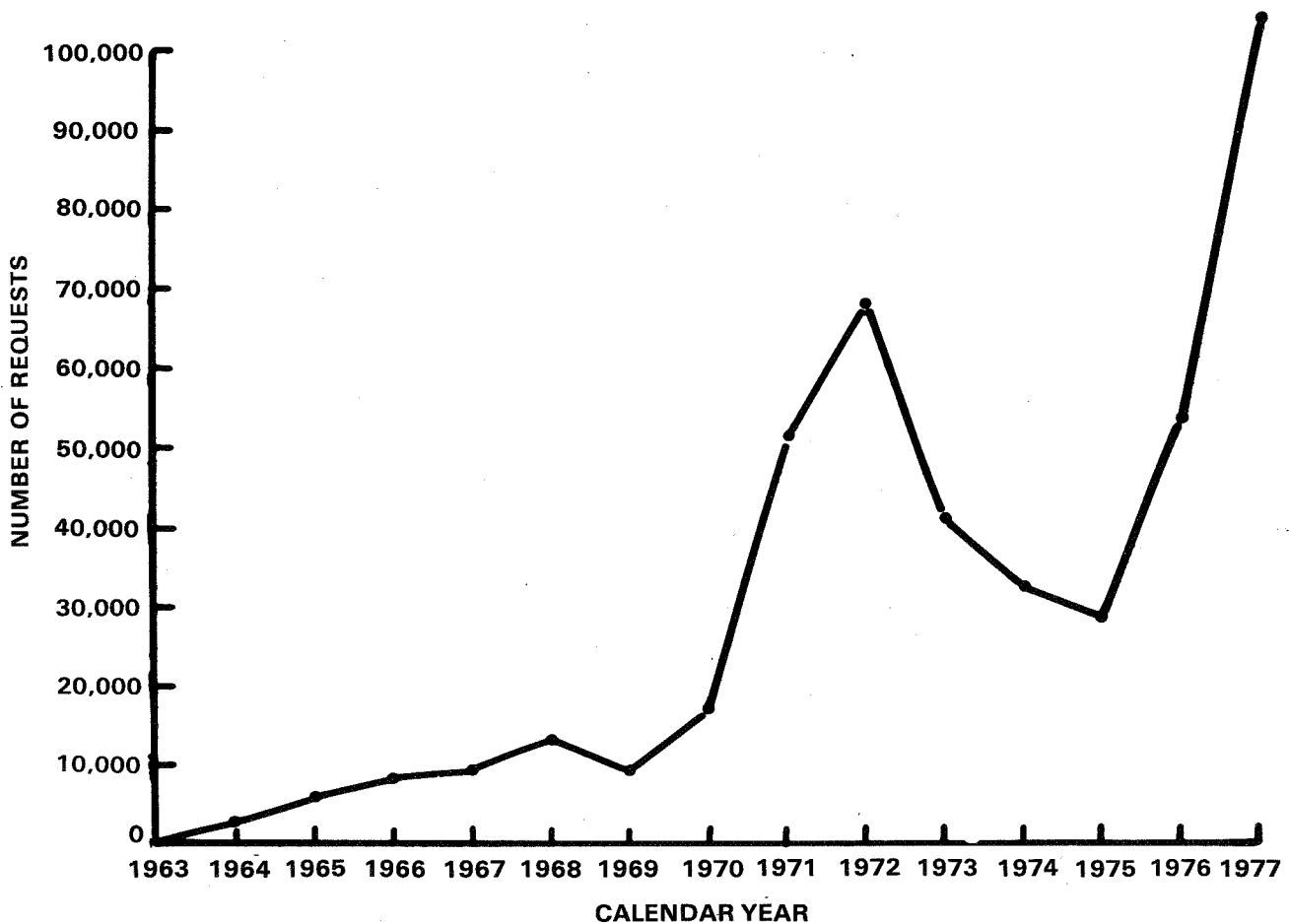
Figure 2. Plot of Requests for Technical Support Packages
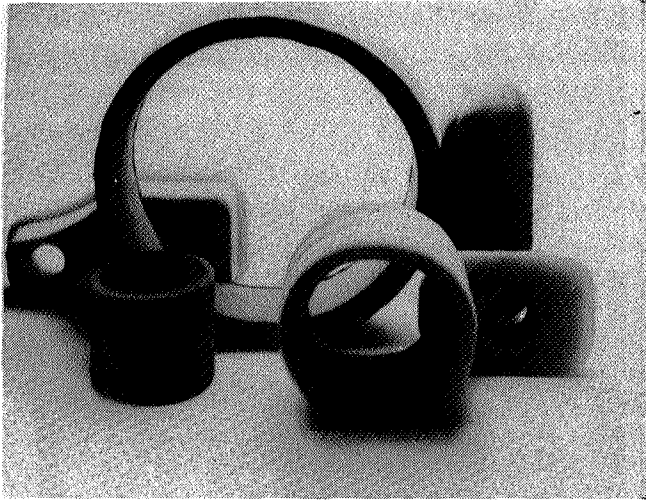
Figure 3. Reticulating Foam Filters

NASA has been asked by a number of people, particularly the Congress, to evaluate the benefits and the cost benefits of the tech briefs and the Tech Brief Journal. Denver Research Institute looked into this and randomly selected names from the list of people who requested technical support packages and questioned them about their uses, asking what the benefits were, and asking them to evaluate quantitatively the amount of dollars saved in one way or another.

As shown in Figure 4, there is a reported savings of $70 million dollars. When you consider that NASA puts $6.4 million dollars over that five-year period into the Tech Brief Journal program, you can see that there was an 11 to 1 return on the investment. That is to say, for every $1 NASA uses to publish the Tech Brief Journal, there was a reported $11 benefit to the user.

TECH BRIEF PROGRAM
Cost Benefit Analysis
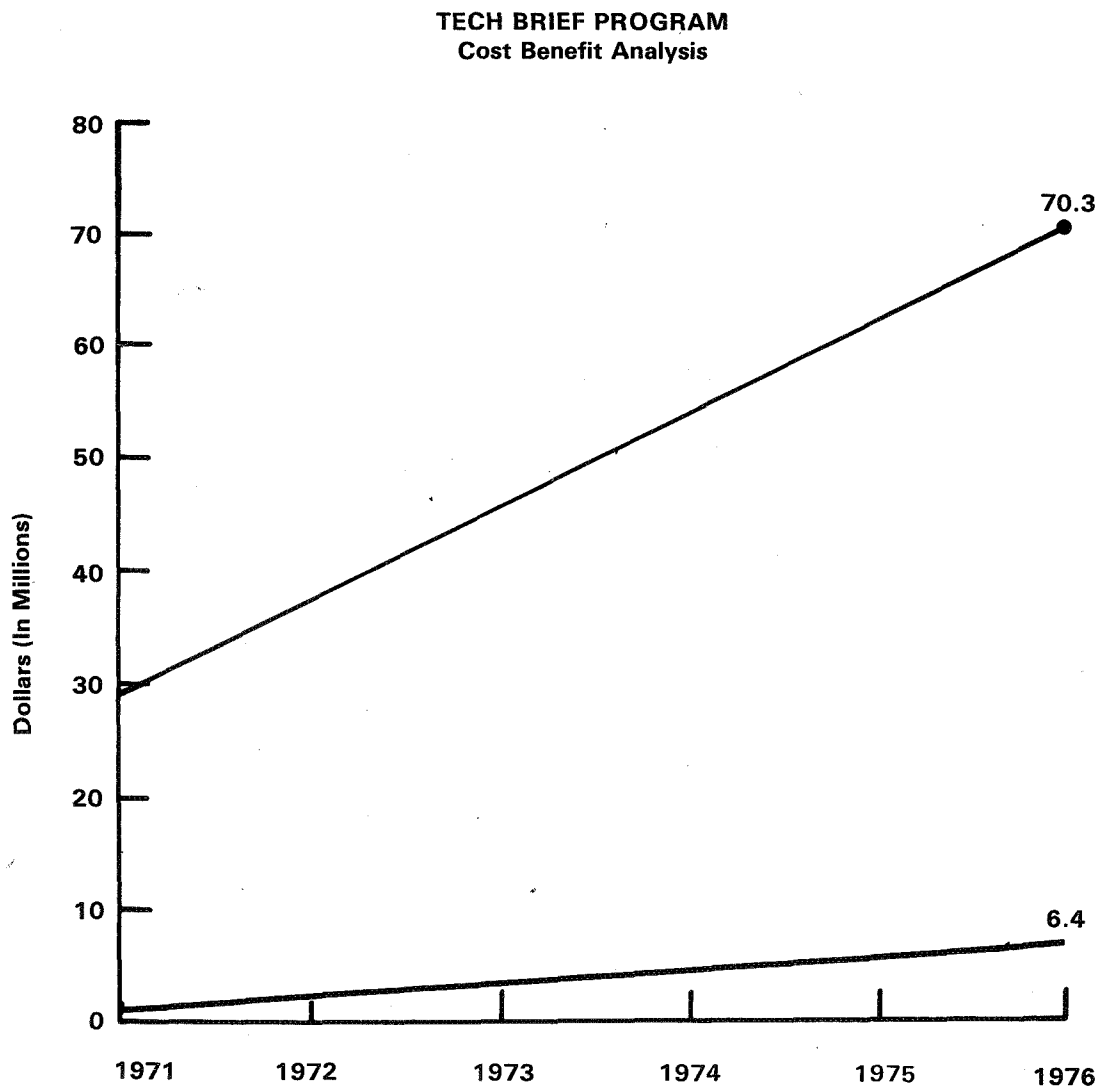
Figure 4. Cost Benefits of the Tech Briefs and the Tech Brief Journal

Another method used to disseminate NASA technology and accelerate its use is the Industrial Application Centers (IACs). These are listed on the chart in Figure 5. The IACs provide a face-to-face relationship between the manufacturer and the technologists. The IAC's have teams (most are universities or nonprofit organizations) that go out into industry, identify the industrialist who may have a problem, discuss the problem with the industrialist or the manufacturer, go back into the NASA data bank, search for information that may be useful to him, and turn the information over to the industrialist or the manufacturer and let him apply that technology to improve his product or processes or develop new products or new processes.

There is a charge for the service. The charge is not for the research and development; but for discussing the problem with the industrialist, identifying the problem, and searching for the technology and getting the *right* technology to him.

When you sit down and talk to the technologist face-to-face, many times a technologist is helping you define the problem. In act, 50 percent of the time the value of the face-to-face interchange of information helps the person with the problem to identify his real problem. For example, an aluminum casting manufacturer recently approached one of the Industrial Application Centers and said, "I would like to have some information on the temperature at which I should pour my aluminum. I think I am pouring it too hot. What temperature should I use to pour this aluminum?" After discussing it with the technologist, he quickly came to the conclusion that heat wasn't his problem. It was the resin he was using in his molds. He was using the wrong kind of resins. So the search was conducted for different kinds of resins for the kinds of molds he was using, not for pouring temperatures. That is an example of how the face-to-face interchange with the technologist helps identify the *real* problems.

The costs for this program are underwritten in part by the TU program in the Federal government, by the fees charged to the users, and support from the universities.

USER GROUPS

DEMONSTRATIONS

NASA
TECHNOLOGIST

APPLICATION
TEAMS

DESIGN, BUILD
TEST

FEDERAL
AGENCIES

MANUFACTURERS

NATIONAL
ORGANIZATIONS
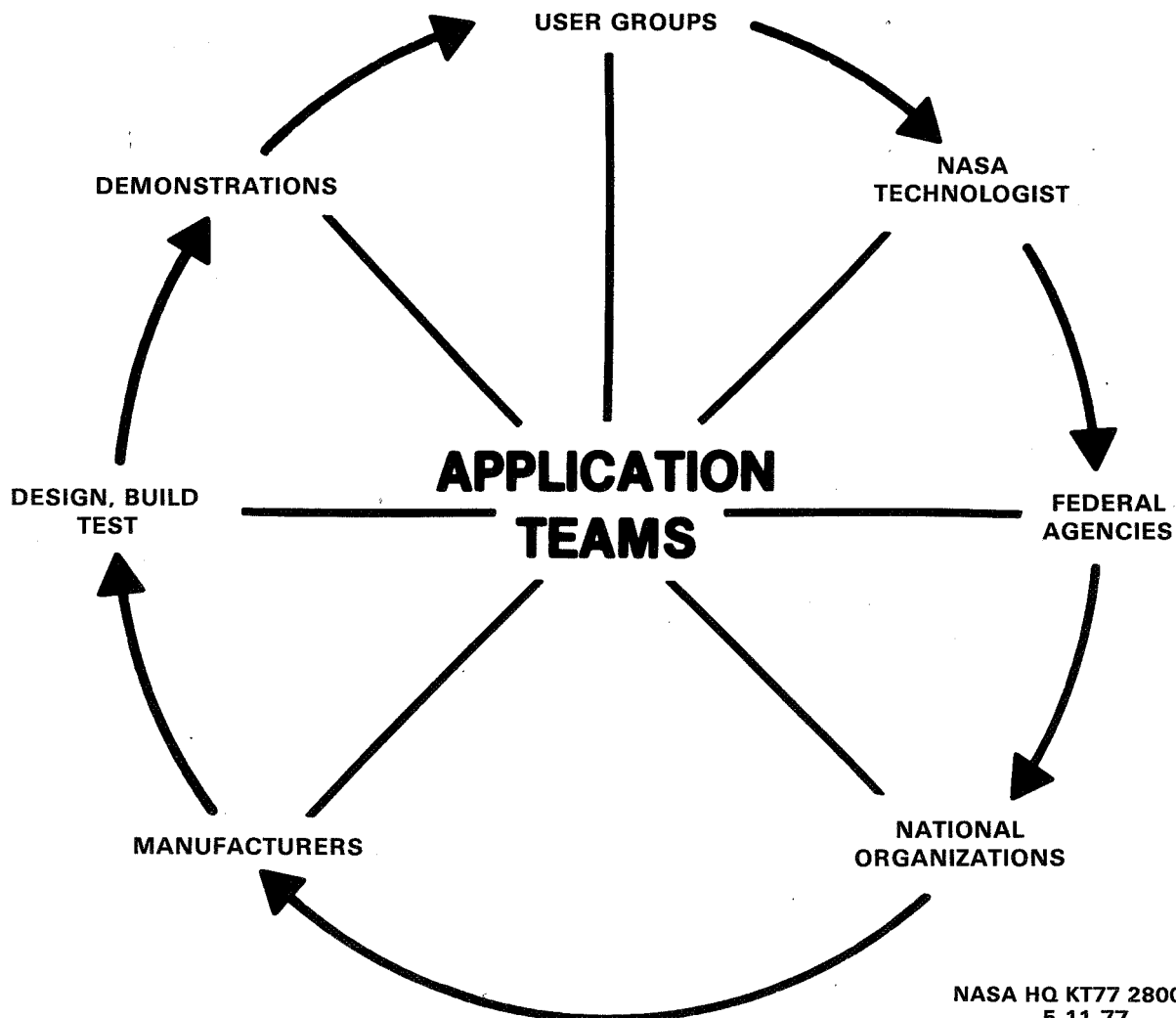
NASA HQ KT77 2800 (1)
5-11-77

Figure 5.   NASA Industrial Applications Centers

70

The data bank that these IACs have contains over a million technical reports that come from NASA's research and development programs plus an additional seven million reports worldwide. It is one of the largest data banks in the world, and it is growing at the rate of 50,000 documents per month.

Some examples of how this type of activity helped solve technical problems are described in the following paragraphs.

In a cooperative effort between our Industrial Applications Center in New Mexico and Goddard Space Flight Center, engineers applied heat pipe technology from NASA's Skylab program to construct the Alaska pipeline. The heat pipe anchors that are holding up the pipeline are shown in Figure 6. The heat pipes stabilized the underground temperature which prevents the supports from moving during the seasonal temperature change.

The heat pipes, called cryo-anchors, are placed in areas where there is an extreme change in temperature between summer and winter. If they were not there, the foundations would move, thereby causing ruptures in the oil pipe.

An example on a smaller scale, one of the Industrial Application Centers in California supplied information to a company on chlorate candles. A chlorate candle gives off oxygen when it burns; and this helped the company to develop a portable welding kit. These can be found in most hardware stores. It is portable, hand-held, and can deliver temperatures up to 5,000 degrees which means that one can weld and cut steel.

One of our Industrial Applications Centers provided information which led to the development of a device for recovering flue heat using heat pipe technology. This is shown in Figure 7. The right-hand corner shows the heat pipe that is placed in the flue. When the heat goes up the flue, the heat pipes transfer the heat to the other end of the heat pipe. A fan motor
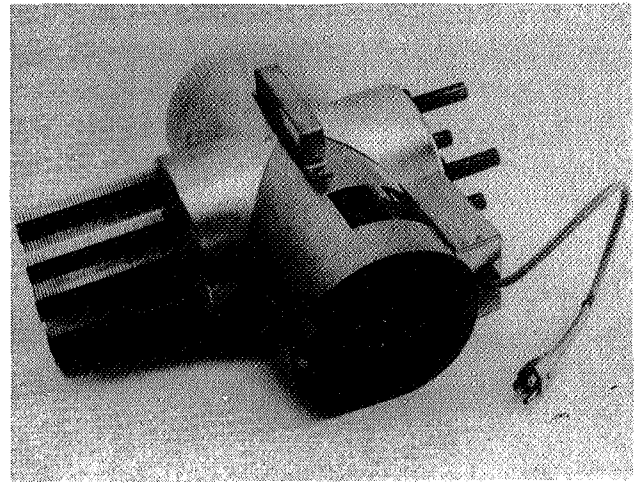
Figure 7. Device for Recovering Flue Heat

blows it back into the heating system and recovers it for use in the house.

Another Industrial Application Center is Cosmic, at the University of Georgia (see Figure 8). This is a repository of NASA's software programs. In that repository, they have over 1,600 computer programs. One example of the use of one of the computer programs is the NASTRAN, which stands for NASA STRuctural ANalysis program. This is one of the world's most sophisticated structural analysis computer programs in the world. Cadillac used the program to develop its Seville model. NASTRAN cut the engineering time for its dynamic structural analysis to a fraction of the normal time.

NASA uses another method of transferring technology to the public sector (see Figure 9). Transferring information and technology to the public sector is a somewhat different problem. In the public sector, you can't transfer information and then step aside. They need *solutions*. Public sector people are just no geared as the private sector is, to take on the Research and Development and apply it, do the prototype work, and taking it through to commercialization.

What the public sector needs is a demonstration; that is, they would like to expalin the problem, have NASA look for the technology, build the hardware, then demonstrate that the technology can be used to solve their problem. At this point, NASA puts the hardware into the commercial marketplace, has the private sector bit on it, and lets the commercial marketplace supply the product to the public sector. Some of the solutions that NASA has worked on and is working on now are described in the following paragraphs.

The Lixiscope shown in Figure 10 is an excellent example of one of these projects.

The United States Coast Guard is attempting,
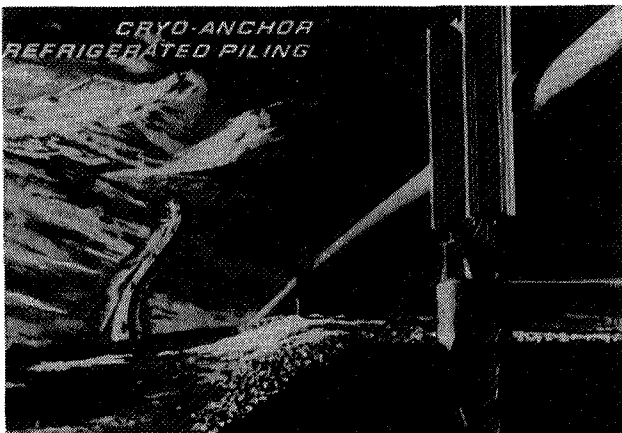
Figure 6. Heat Pipe Anchors

COSMIC®

(COMPUTER SOFTWARE MANAGEMENT AND INFORMATION CENTER)
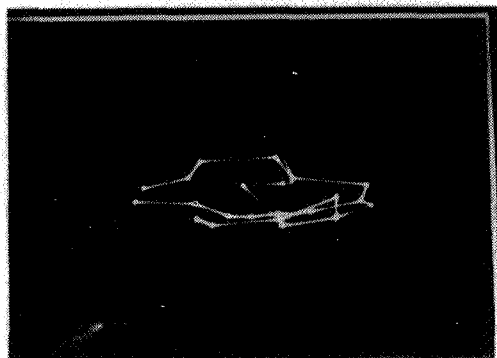
- **DISTRIBUTION CENTER FOR NASA COMPUTER PROGRAMS**

- **UNIVERSITY OF GEORGIA, IN ATHENS**

- **COMPLETE SOFTWARE PACKAGES IN ALMOST ANY TECHNICAL FIELD, INCLUDING MANAGEMENT**

- **MAINTENANCE/USER ASSISTANCE IS ALSO AVAILABLE IN SOME CASES**

- **LARGEST INVENTORY OF PROGRAMS AVAILABLE FROM A SINGLE SOURCE IN THE U. S.**

NASA HQ ET78-3108 (1)
8-9-78

Figure 8. Cosmic Industrial Application Center

to try to respond more quickly to harbor fires. What they were looking for is a lightweight, self-contained pump which can throw water farther and faster than most of their current pumps (Figure 11).

In this case, they are looking for 2,000 gallons per minute in a stream reaching 200 feet. This is about double what they can do now (Figure 12).

They would like to have the pump portable, to be transported by helicopter (Figure 13).

The boat can go out to the fire, while in the meantime, the fire fighting module can be picked up from the shore and carried to the boat, at the scene of the fire.

The pump is now going into its final testing by the Coast Guard, hopefully it will be in service next year.

While NASA was developing this prototype hardware for the Coast Guard, a manufacturer saw a commercial application and has put a different version of this kind of fire fighting equipment on the market. It is now on the market available for land fire fighting.

Figure 14 is a picture of a bolt stress monitor which is the final example to be presented. It was developed by NASA's Langley Research Center in Virginia and uses sound waves to give off a very highly accurate measure of the stress in a bolt. Current torque testing of bolts is an inaccurate measurement because it doesn't take into consideration the friction between the threads and the nut. In this case, the system acts somewhat like measuring the sound of a violin string. The tighter you stress the violin string, the higher the pitch.

The same principle applies here. Thus, the tighter you tighten the bolt, the more it stresses the bolt, which produces a different accoustical pitch. The instrument reads the accoustical signature and then

● MIC

▲ STAC

■ COSMIC

AEROSPACE RESEARCH
APPLICATION CENTER
ICFAR, INDIANAPOLIS, IN.

KNOWLEDGE AVAILABILITY
SYSTEMS CENTER, UNIV. OF PITT.

NEW ENGLAND RESEARCH
APPLICATION CENTER,
UNIV. OF CONN.

NERAC

KASC

ARAC

KY. STATE TECHNOLOGY
APPLICATIONS
CENTER, UNIV. OF KY.

NC/STRC

WESRAC

TAC

TUSC

COSMIC

NORTH CAROLINA SCIENCE &
TECHNOLOGY RESEARCH CENTER

WESTERN RESEARCH APPLICATION
CENTER, UNIV. OF SO. CAL.

COMPUTER SOFTWARE
MANAGEMENT & INFORMATION
CENTER, UNIV. OF GA.

TECHNOLOGY APPLICATION
CENTER, UNIV. OF NEW MEXICO

FLORIDA STATE TECHNOLOGY
APPLICATIONS CENTER
STATE UNIV. SYSTEM

TECHNOLOGY USE STUDIES
CENTER, SOUTHEASTERN
OKLAHOMA STATE UNIVERSITY

Figure 9. Technology Transfer to the Public Sector
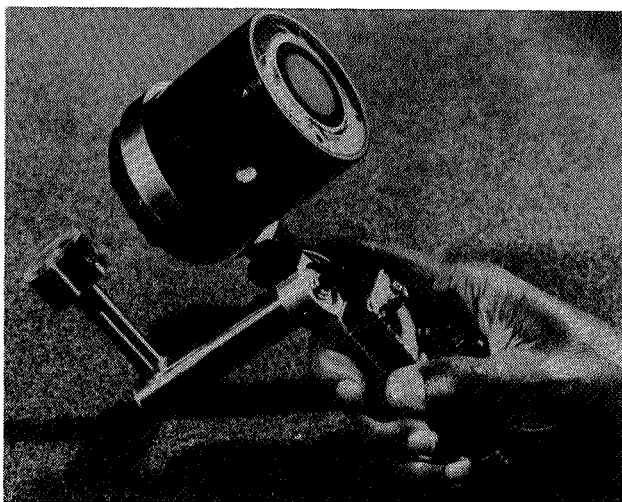
Figure 10. Photograph of the Lixiscope

reads out the stress on the bolt.

The preceding paragraphs have very briefly described the technology utilization program, the publications which are available for distribution, and the Industrial Applications Centers. Some programs were discussed which NASA developed to build prototype hardware to demonstrate that aerospace technology can be applied to public sector problems.

The primary questions often asked of NASA are: "Does technology utilization pay off? Does this system you are working with benefit anybody? And if so, can you measure the benefit?"

NASA commissioned Denver Research Institute last year to look at this method of transferring
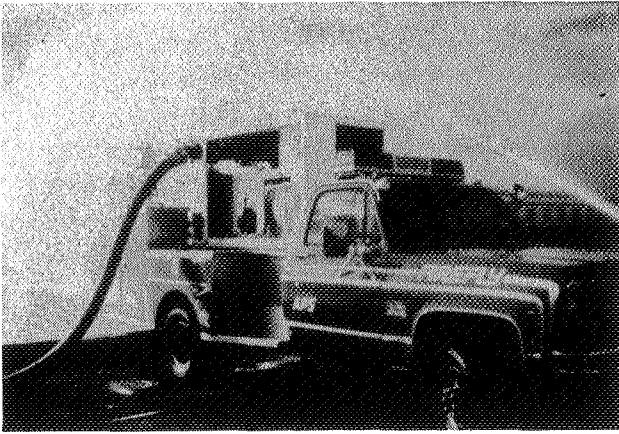
Figure 11. Photograph of a Water Pump

Figure 13. Transportation by Helicopter of Portable Pump to Boat
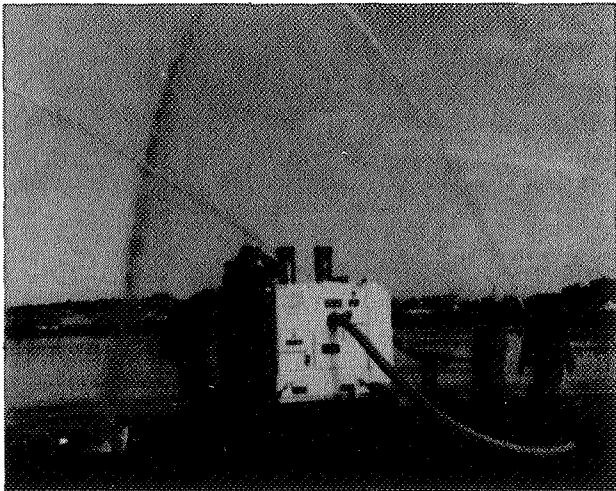
Figure 12. Water Pump
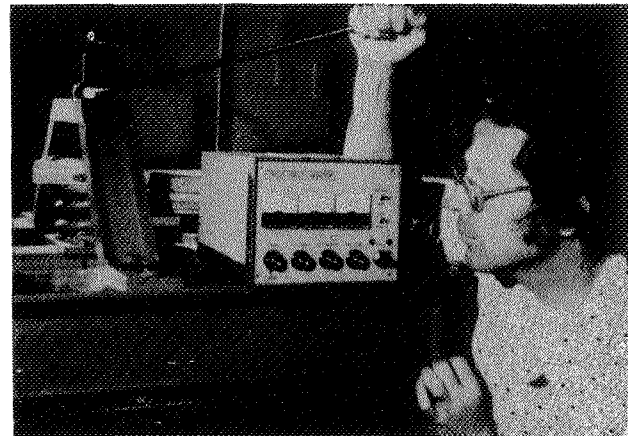
Figure 14. Photograph of a Bolt Stress Monitor

technology. They identified users of the technology and asked them to quantify the benefits. They returned with an analysis that showed there was a six to one return on the taxpayer's investment. That is to say, for the entire technology utilization program, every tax dollar NASA spent in the technology utilization program to bring aerospace technology to bear on problems in the private and public sector, there is a $6 return to the economy.

B. THE TECHNOLOGY UTILIZATION PROGRAM AT GODDARD

Mr. Donald S. Friedman
Head, Technology Utilization Office
Goddard Space Flight Center

The Technology Utilization (TU) Program has its genesis from the Space Act, which says that NASA will disseminate information from its space activities in the widest possible manner. To accomplish this, the major elements are through publications, Industrial Applications Centers, and application projects such as the Lixiscope. The TU Program is also involved in program evaluations.

To transfer this technology, GSFC is engaged in a series of activities, as shown in Figure 1. These include work in space sciences, applications, manned space flight programs, basic space technologies, power systems and control system development, limited work in energy with the Department of Energy, the tracking and data acquisition network at Goddard, and technology utilization.

Basically, the Technology Utilization Program is a technology transfer program; that is, performing basic space activities, and then applying some of this technology in a secondary application. One of these projects is the Lixiscope.

The NASA policy on transferring technology is to identify the technology and pass it on. As part of this effort, it is necessary to identify its significance. One

NASA ACTIVITIES

- ## SPACE SCIENCE

- ## APPLICATIONS

- ## MANNED SPACE FLIGHT

- ## AERONAUTICS AND SPACE TECH-NOLOGY

- ## ENERGY PROGRAMS

- ## TRACKING AND DATA ACQUISITION

- ## TECHNOLOGY UTILIZATION

Feb. 1975

Figure 1. Activities for Technology Transfer
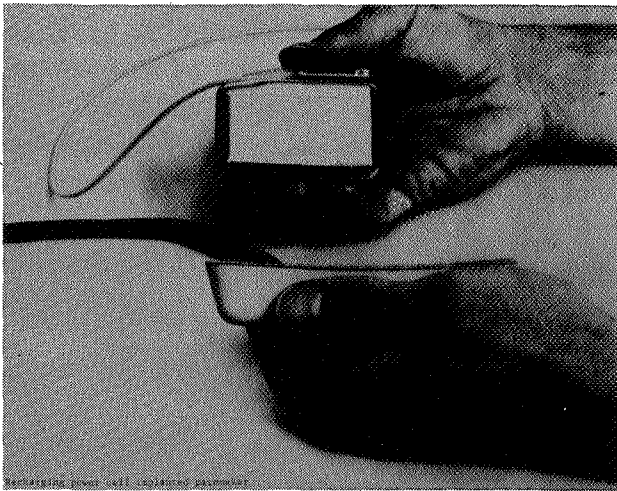
Figure 2. Rechargeable Heart Pacemaker

Figure 3. Photograph of First Heart Pacemaker Patient

of the primary objectives is to work with manufacturers to ultimately commercialize a particular product or project so it will get into the hands of the people and benefit the public.

To accomplish this, NASA assists in but does not perform market studies, and assists and helps to identify and work with manufacturers. In addition, NASA works with many Federal institutions, and either looks for co-funding or co-funds certain projects for develpment.

To illustrate NASA efforts in this regard, one project from the engineering spinoff that NASA started work on a few years ago, in collaboration with the Applied Physics Labs of Johns Hopkins Laboratory, was a rechargeable heart pacemaker shown in Figure 2. Johns Hopkins basically developed the pacemaker, but some of NASA's space technology was used, such as batteries, the electronics, and quality control techniques in the development.

Figure 3 is a picture of the first person who had the pacemaker implanted. This photograph was taken on the fifth anniversary of the implant. What makes this pacemaker unique is the fact that it is rechargeable and the batteries do not have to be replaced. The photograph also shows Bob Fischell and Dr. Lewis.

To continue this technology, GSFC is working with the Applied Physics Lab and the Johns Hopkins University on a device called the human tissue stimulator, which will be a rechargeable implantable device used to relieve pain as shown in Figure 4. This is another very good example of a spinoff. Figure 4 also shows a command telemetry system, which was developed on one of our astronomy satellites by the Applied Physics Lab. The system can be tied right to the doctor's office, through telephone lines, to control the various parameters. The stimulator is planned to be used to relieve back pains and similar ailments.

The preceding paragraphs have summarized some of the technology spinoffs of which GSFC has been a part. The Lixiscope represents another significant accomplishment in this regard. However, to find out more about the Technology Utilization Program, and what NASA is doing, NASA publishes a document entitled "Spinoff" which can be obtained from any NASA Technology Utilization Office at the nearest NASA Center.
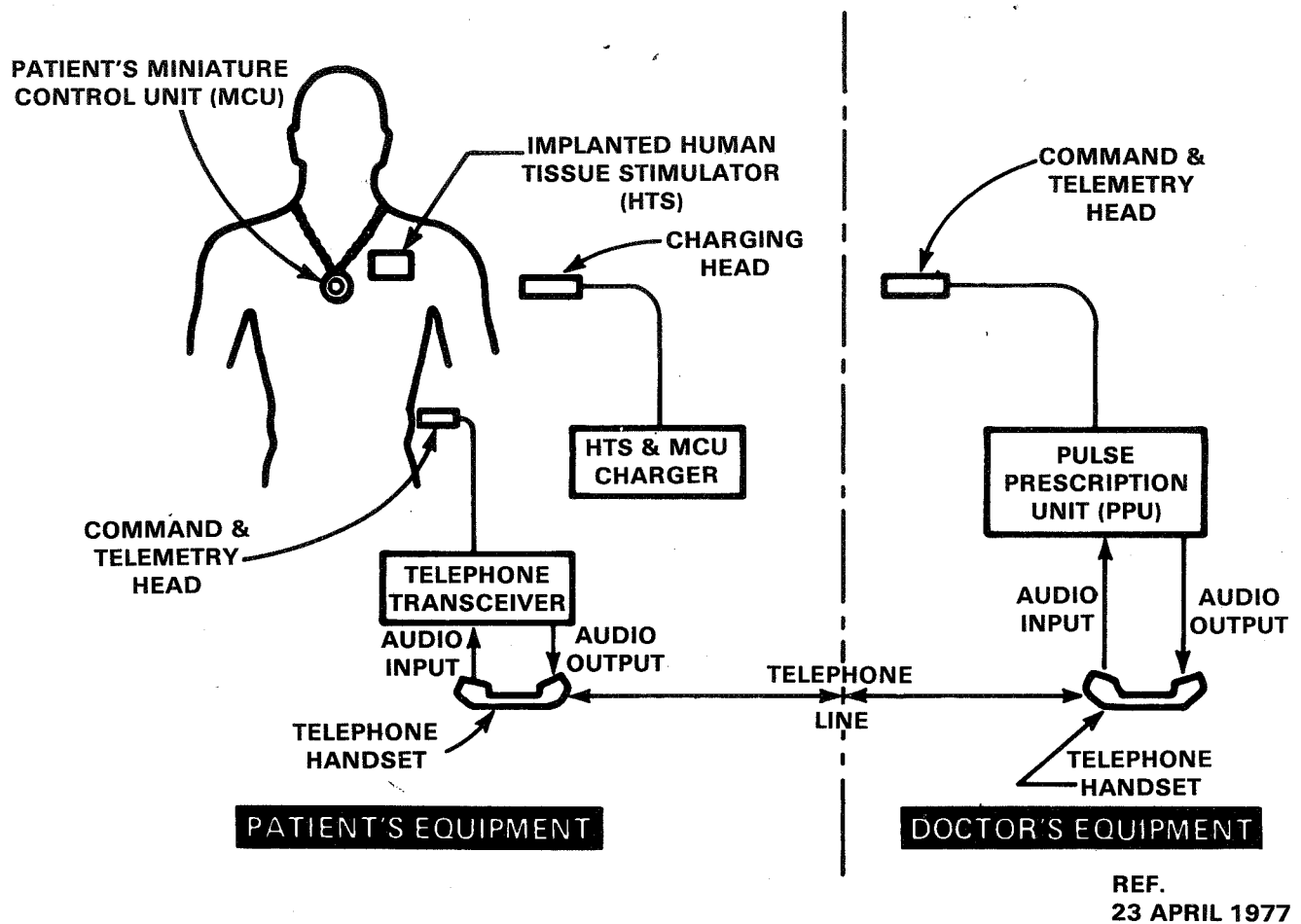
Figure 4. Human Tissue Stimulator

Page intentionally left blank

V. REGULATIONS & POLICY AFFECTING LIXISCOPE USE

A. REGULATIONS CONCERNING RADIOISOTOPE PROCUREMENT & HANDLING & CLINICAL USAGE

MEDICAL DEVICE AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

Marshall S. Little
Assistant Director for Standards and Regulations
Division of Compliance
Bureau of Radiological Health
Food and Drug Administration
Department of Health, Education, and Welfare

The Food and Drug Administration (FDA) has responsibility for the regulation of electronic product radiation and also for medical devices.

The authority over medical devices stems from the Food, Drug, and Cosmetic Act as it was recently revised by the 1976 Medical Device Amendments. The authority over electronic product radiation is derived from the Radiation Control for Health and Safety Act of 1968.

The Radiation Control for Health and Safety Act authorizes the Agency to establish a radiation control program for electronic products. This program is focused primarily on the development of mandatory, as well as voluntary, radiation safety performance standards for the products.

The Agency also has authority under this Act to take defect action against a manufacturer of a product which has a radiation safety defect that could cause a risk of injury, irrespective of whether there may be a radiation safety performance standard for that product.

Under the Radiation Control for Health and Safety Act, the Agency has standards for television sets, microwave ovens, cabinet X-ray machines used in industry as well as the baggage X-ray devices available at airports, diagnostic X-ray equipment, laser products, ultrasound therapy, and cold cathode gas discharge tubes. Other standards nearing completion are those for microwave diathermy, for mercury vapor lamps, and sunlamp products.

To get into the authorities under the Food, Drug, and Cosmetic Act, it would be best now to look at the definition of a device as defined in that Act:

DEFINITION

1. An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory

2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . or

3. Intended to affect the structure or any function of the body . . .

4. Does not achieve any of its principal intended purposes through chemical action within or on the body . . . and . . . is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

Figure 1. Definition of a "Medical Device"

This definition was introduced into the Act through the recent Medical Device Amendments which were passed on May 28, 1976. That date is quite important. It will be referred to later on.

Figure 2 is a list of authorities under the Food, Drug, and Cosmetic Act. The first one authorizes the Agency to classify or to categorize all of the existing medical devices into one of three classes: Class I being subject to general controls, Class II to performance standards, Class III to premarket approval.

In other words, the higher the class, the more potential for injury or the more important in terms of

life support and medical care and, therefore, it would be subject to greater controls.

- Classification
- Pre-market Approval
- Registration and Listing
- Good Manufacturing Practices
- Inspections
- Biennial Inspections
- Detention
- Banned Devices
- Repair, Replace, or Refund
- Restricted Devices
- Presumption of Interstate Commerce

Figure 2. FDA's New Medical Device Authority

The pre-market approval would apply to the Class III devices. Manufacturers would be required to register their establishment and list their products. They would be subject to good manufacturing practices regulations that would be issued by the Agency, and these regulations are about to be finalized. In fact, they were published in final form recently and should become effective in December 1978.

The Agency also has authority to inspect both the manufacturing facilities as well as the using facilities and would be required to inspect all Class II and Class III manufacturing establishments every two years.

The Field Inspectors would be authorized to detain medical devices suspected of being in violation of the Act for periods up to 30 days without any court action. The Agency would have authority to issue regulations banning a device that had a substantial risk of injury or was deceptive.

The authority to require manufacturers to repair, replace, or refund the purchase price of a product could also be taken by the Agency under the new Medical Device Amendments; and the Agency could issue regulations establishing certain restrictions on the manufacture or use of products. The only two types of devices for which restrictions are imposed at the present time are hearing aids and prescription-type devices.

And finally, there have been several court cases to determine whether a manufacturer was involved in interstate commerce, and the Agency could not take action unless that could be proven in courts. Now, under the Medical Device Amendments, it is presumed that interstate commerce is involved with respect to any medical device.

Some of the specific authorities of importance to a manufacturer of the Lixiscope include the following:

Every manufacturer of a medical device must register with the Agency and provide a list of the devices he manufactures. This is a relatively simple report that is sent to the Agency. He must register annually.

All devices are categorized into one of three levels, and the regulatory controls imposed on these levels would vary in the following way: Class I is subject to only the general controls such as prohibition on adulteration or misbranding, registration, and good manufacturing practices. The Agency could also require a manufacturer to maintain certain records or submit reports. The regulations pertaining to restrictions of devices or banning and so forth would also be part of the general controls.

If a device falls into Class II, this implies that a safety performance standard could be developed for the product and would eventually be mandatory. Class III would be subject to requirement that the manufacturer obtain pre-market approval prior to commercial distribution.

The procedures for classification are shown in Figure 3.

First, there are 13 advisory, classification panels. They have reviewed all of the devices and have recommended to the Agency which class should be assigned to each device.

CLASSIFICATION PROCEDURES

1. Device Panel Makes Recommendation
2. Federal Register Publication—Panel Report and Proposed Regulation Classifying Device
3. Federal Register Publication—Final Order Classifying Device
   *This starts the 30-month clock for Class III devices

   *At the end of 30 months, after publication of the final order for device classification, manufacturers must have filed a pre-market approval application or notice of completion of a product development protocol with FDA. Manufacturers may continue to market their devices during this 30-month period unless FDA declares otherwise.

4. Federal Register Publication—Proposed Regulation Requiring Submission of Pre-market Approval Applications (For Class III Device)
5. Federal Register Publication—Final Order Requiring Submission of Pre-market Approval Applications (For Class III Device)
   *This starts the 90-day clock for Class III devices

   *At the end of 90 days, after publication of the final order for submission of PAAs, manufacturers must have filed a pre-market approval application or notice of completion of a product development protocol with FDA. Manufacturers may continue to market their devices during this 90-day period unless FDA determines otherwise.

Figure 3. Classification Procedures

80

Roughly 60 percent have been recommended for Class I, about 20 percent for Class II, and the remainder for Class III.

These panel recommendations are now being considered by the Agency, and the Agency will then propose regulations in the FEDERAL REGISTER in the very near future which would include the panel recommendation and the Agency proposed classification.

In most cases, the proposed classification will agree with the panel recommendation, but in some cases, the Agency will propose a classification different from the panel recommendation and will so state the reasons for that difference.

When these classification regulations are made final, the manufacturer may petition for a reclassification if he has information not previously considered by the panel or Agency.

Class I devices are those for which general controls are sufficient or there is not adequate information to determine the full degree of possible risks associated with the product; and they do not appear to represent an unreasonable risk.

Class II devices are those for which there is sufficient information to develop a standard, or a standard presently exists and can be made applicable to this product.

Class III devices are those for which there is insufficient information to assure safety and effectiveness either through standards or general controls. Its use is important to human life or health or it represents an unreasonable risk of injury; or it is a device manufactured prior to the establishment of the 1976 Medical Device Amendments, and is intended for surgical implants. All surgical implants must be in Class III unless the Agency determines that pre-market approval is not necessary to assure the safety and effectiveness.

If is a device manufactured after May 28, 1976, it is considered a new device and automatically falls into Class III unless the manufacturer can provide evidence that the device is substantially equivalent to a device manufactured prior to May 28, 1976.

As mentioned previously, if the manufacturer feels that the classification of his device is for any reason an improper designation of a class and controls, he may petition for reclassification. This would have to be reviewed by one of the 13 Advisory Panels, and must be acted on by the Agency within 60 days.

For all devices introduced into commerce for the first time after May 28, 1976, the manufacturer would have to notify the Agency at least 90 days prior to commercial distribution of the device. This pre-market notification is a relatively simple report sent to the Agency.

The Agency has 90 days to act on that notification to determine whether the Agency agrees that it is substantially equivalent, in which case it would fall into the class already designated for that device. If the Agency determines that it is not substantially equivalent to a pre-1976 device, it automatically must fall into Class III and is subject then to pre-market approval.

Figure 4 summarizes the type of information included in the pre-market (or 510k) notification.

A 510k Notification Must Include:

1. Product Name (Proprietary and Common Names)
2. Registration Number for Your Establishment
3. Class in Which the Device is Classified
4. Action Taken to Meet Performance Standard or Pre-market Approval (Where Applicable)
5. Labels, Labeling, or Advertisements that Describe the Device and Identify Its Intended Use and Directions for Use
6. A Statement of How the Device is Similar to and Different from Other Devices on the Market
7. For Changed or Modified Devices, Data Must be Included to Show How This Affects the Safety and Effectiveness of the Device (This Also Applies to Devices Being Marketed with a New or Different Use.)

Figure 4. 510k Notification Information

The Agency determines whether a device is equivalent to a device marketed prior to May 28, 1976. If it is equivalent, it can be marketed. If it is not equivalent, then it is automatically subject to pre-market approval and falls into Class III.

Then the manufacturer has certain alternatives. He can petition for reclassification, and that petition is then reviewed by the Advisory Panel to decide whether or not it is appropriate for Class III; he can file an investigational device exemption application if it is going to be used for investigational purposes on humans; or he can submit a pre-market approval application or a product development protocol.

There is one other alternative not mentioned previously. If the manufacturer wants to use this device only for investigational purposes on animals and not humans, then he can so label the device and go ahead and distribute it for that purpose, but it must be labeled not for use on humans.

A pre-market approval application contains the information shown in Figure 5.

81

1. For all Devices Classified in Class III
2. Includes:
   - Full Reports of All Data (Both Supporting and Adverse)
   - Components, Ingredients, Properties, and Principle of Operation
   - Manufacturing, Processing, Packing, and Installation Information
   - Reference to Applicable Standards
   - Samples of the Device
   - Samples of the Labeling
   - Other Information

Figure 5. Pre-Market Approval—Applications

This is for all devices classified in Class III, and that would include the "new" devices. The manufacturer must make available samples for evaluation by the Agency and samples of the labeling and other information that might be germane.

There are alternatives to the pre-market approval. If a manufacturer does not want to submit the pre-market approval application or he does not have the necessary information, he can submit a product development protocol, which is a plan to indicate in detail how the manufacturer intends to collect the information necessary to assure safety and effectiveness of the product.

This is reviewed by the Agency, and if the Agency approves, the manufacturer begins collecting this information. When it is collected, the manufacturer submits a notification that he has completed his product development protocol. If the Agency agrees that the information is complete, the manufacturer may begin marketing the device.

This has an advantage over the pre-market approval, especially for something like the Lixiscope, because if the design of the device has not been rigidly fixed, it might be desirable to explore several different designs. The Agency is more likely to approve the data once it is collected if it has previously approved the protocol.

One could also obtain an investigational device exemption. This would be an exemption from any of the requirements of the Act to allow distribution for use in investigations on humans. The regulations for the investigational device exemption have been published as a tentative final rule and probably will be finalized before the end of the year. There is a public hearing scheduled for August 7, 1978, on these regulations at Rockville, Maryland.

Once the regulations become final, any investigations of devices to determine safety and effectiveness on humans must be approved as prescribed in the new investigational device exemption regulations.

How these regulations might apply to the Lixiscope device are as follows:

It has been indicated that there are two possible Lixiscope designs: one with the radioisotope source, the other with an X-ray tube. If it is manufactured with a radioisotope source, it is going to be subject to the licensing provisions of the Nuclear Regulatory Commission, or agreement states.

As far as the FDA regulations, the manufacturer must submit a pre-market notification at least 90 days prior to his commercial distribution of the device. It is likely that it would fall into Class III, requiring pre-market approval because it is a unique device.

It would also be desirable to obtain an investigational device exemption to permit investigation on humans. If the Lixiscope were designed with an X-ray tube, a pre-market notification also would be required. It is possible that the Agency would determine that it is equivalent to devices that were on the market prior to May 28, 1976, but this also is conjecture.

There have been devices manufactured prior to May 28, 1976 that use an intraoral X-ray tube. And, in fact, some are being marketed in the very near future. The FDA recently had a request for a variance from the diagnostic X-ray standard in order to manufacture these products. This brings up the point that the Lixiscope with an X-ray tube would be subject to the current diagnostic X-ray standard. It is doubtful that the product could meet all of the provisions of this standard. Thus, it would be necessary for the manufacturer to petition for a variance from that standard in order to be able to market it.

LICENSING OF DEVICES WITH RADIOACTIVE SOURCES

Dr. Leo Wade
Chief of Medical and Academic Section, Radioisotopes Licensing Branch
Nuclear Regulatory Commission (NRC)

The Nuclear Regulatory Commission's authority to regulate the use of radioactive materials derives from the Atomic Energy Act of 1954, and a subsequent reorganization act which created the Nuclear Regulatory Commission when the Atomic Energy Commission was abolished.

For any Lixiscope that does not utilize a radioactive source, that is, one that utilizes an X-ray tube, NRC is not involved in any way whatsoever, whether for human use or not. It is only those versions which might involve a radioactive source in which the Nuclear Regulatory Commission is involved.

The Nuclear Regulatory Commission regulates the possession and use of source material, special nuclear material, and by-product material; that is, radioactive material that can be produced as a by-product of a reactor. That includes iodine 125. There are some radioactive materials that the Nuclear Regulatory Commission does not regulate: naturally occurring radioactive materials such as radium, accelerator-produced radioisotopes such as cobalt 57, and radiation-producing machines.

The Nuclear Regulatory Commission also has the authority, as did the Atomic Energy Commission, to enter into agreements with state governments whereby the states assume some of the regulatory responsibility for certain radioactive material. This complicates the matter a little bit with respect to the Lixiscope because those states that have assumed the regulatory responsibility also regulate radium and accelerator produced radioisotopes and usually radiation producing machines.

So the type and the exact nature of the regulations to which the manufacturer and the user of the Lixiscope may be subjected depends upon whether it contains an X-ray source or a radioisotope source, whether it is to be used in humans or not, and whether it happens to be used in an agreement state or not.

There are currently 25 agreement states, and so the odds are about 50/50 as to whether someone is regulated by the Nuclear Regulatory Commission or one of the states.

A Lixiscope using I-125 specifically would come under Nuclear Regulatory Commission regulations if the manufacturer were in a non-agreement state. If he were in an agreement state, it would come under state regulations but they would probably be pretty much equivalent.

There are three types of licenses issued by the Nuclear Regulatory Commission. The first is a specific license of limited scope. This license may be issued by the Nuclear Regulatory Commission or by one of the agreement states for any type of specific use. It may include research and development, manufacturing and distribution, clinical evaluation of experimental devices, routine use of clinical devices and animal use. It is written specifically for a particular use and usually limits the type of radioactive material that can be used and specifically names the individuals that are authorized to use that radioactive material. This is the type of license that is held, for instance, by most medical institutions who use radioisotopes, either in drugs or in sealed sources for human diagnosis and therapy.

The second type of license for consideration is a specific license of broad scope. This may also authorize a number of uses, either human or non-human. The difference between it and the limited scope license is that the broad scope license normally authorizes a broad range of radioactive materials, and neither the users nor the uses are specifically designated. It is normally issued to institutions that have a lot of experienced and well-trained people.

The institution normally has a radioisotope committee, consisting of people in various specialities with experience in the use of radioactive material. That committee authorizes specific individuals to use the radioactive material. They take over part of the function of the Nuclear Regulatory Commission. They evaluate the individual's training and the specific uses for which the radioactive material will be used. For example, such a license might authorize an institution for any radioactive material with atomic numbers from 3 to 83, and it would state that the users are to be designated by the radioisotope committee. For authorized uses, it might say "research and development" or "medical research, diagnosis and therapy." These type of licenses may be issued to a large manufacturer or a large research firm. The Goddard Space Flight Center probably has a broad license of that type. Broad licenses are also issued to universities, to medical schools and to hospitals.

The third type of license is a general license. A

general license is one in which the regulations state that anyone is licensed to use a particular type of radioactive material, and it may subject them to certain requirements, but an application is not required. Some types of general licenses require registration, but they do not require an application, and most do not require even a registration.

For instance, there are general licenses for static elimination devices, certain measuring and gauging devices, luminous safety devices for aircraft, calibration and reference sources, ice detection devices, and *in vitro* diagnosis of certain diseases.

There is also one general license for *in vivo* diagnostic procedures involving very small quantities. As an example of what might be conducted under any of these licenses, a manufacturing firm might manufacture and distribute an item such as a Lixiscope under either a specific license of limited scope or a broad license. Someone who would use the Lixiscope might do so under a license of limited scope or a license of broad scope. It is also possible that a Lixiscope could be used under a general license; that is, if the NRC saw fit to issue a general license for use of the Lixiscope.

It would be unlikely that it would ever be used for human purposes under a general license. That is the author's personal speculation and not the agency position.

A broad scope license, for example, would normally be issued to a medical school or a hospital and would be the type of license under which investigative protocols would normally be carried out. For example, the National Institute of Dental Research operates under a broad license issued to the National Institutes of Health for human research, diagnosis and therapy. The University of Connecticut also holds a broad license for medical research, diagnosis and therapy.

It is normally at institutions like this that clinical evaluations are carried out, although it is not absolutely required. A specific license could be issued for clinical evaluation. That is true for drugs and it is true for devices such as this that might contain sealed sources.

The steps that might be required if the Lixiscope is ever to receive wide-scale use will be discussed in the following paragraphs. It should be noted that this concerns a Lixiscope that utilizes a radioactive source, not one that utilizes an X-ray tube.

First of all, the manufacturer must hold a license either from the Nuclear Regulatory Commission or an agreement state to even manufacture the instrument. There are several steps that could all be taken at once or could be taken sequentially. First, for instance, one might obtain a license for research and development of the Lixiscope; not for use at all, not for distribution or manufacture, but just for research and development. One application of that type has been submitted.

The second step might be a license, after the research and development work was completed, for manufacturing and distributing the device. Assuming that distribution is to specific licensees, a license for manufacturing doesn't really require a lot more than a license for research and development other than an additional fee.

But the third step that has to be taken either simultaneously or very close to the manufacturing and distributing license is a product evaluation. Whenever a specific license is issued to anybody to use a sealed source or device, that sealed source or device must be evaluated from the standpoint of its safety, not only to the individual using it, but to the general public.

Rather than evaluate every one of these on an individual case, they are evaluated once. The information submitted by the manufacturer or the distributor is evaluated so that when an individual or institution wants to use that sealed source or device, all of the information is in the files. The Nuclear Regulatory Commission knows that it has passed all of the necessary tests, that it is safe to use, and what special precautions might be needed to be imposed on the individual user.

Concurrently with the manufacturing and distributing license, there must be a submission to the Nuclear Regulatory Commission or to the agreement state of a description of the product and device. There may be one or two evaluations. For instance, some manufacturers may buy a sealed source as an off-the-shelf item from somebody and put it in their device and market it that way. In that case, the sealed source may have already been evaluated separately.

In that case, however, the Nuclear Regulatory Commission would still have to evaluate the device containing the sealed source that is intended to be marketed.

In some cases, the same manufacturer manufactures the sealed source, puts it in the device, and it is sold as a unit. In that case, it would only be one product evaluation. But in either case, whether it is done in one step or two steps, the sealed source and the device both have to be evaluated.

For evaluation of sealed sources, the Nuclear Regulatory Commission wants to know how it is going to be used, what it contains, how it is labeled, what type of encapsulation is around the sealed source, what type of testing it has been through to determine its integrity, and what type of quality control procedures are used.

Basically, all these are from the standpoint of determining that it is safe for the user and does not present any hazard to the public in its use.

For evaluation of the device, information is sought on things like radiation profiles and how it is installed. Is it something that is bolted to the floor or is it something that is extremely portable?

This leads to one of the potential problem areas of overlap between the Nuclear Regulatory Commission and the Food and Drug Administration, because the Food and Drug Administration is also involved in product evaluation. The two agencies are in the process of negotiating a memorandum of understanding that may eliminate overlap between the two agencies and eliminate those areas where people might be subject to regulation by both agencies.

An agreement is in effect with the Food and Drug Administration for radioactive drugs. For many years, radioactive drugs were exempted from some of the Food and Drug Administration Regulations but now they have removed those exemptions, and as they did, the Nuclear Regulatory Commission backed out of certain areas in drug evaluation and determination of the safety and efficacy. It is believed that most of the overlap has been eliminated in those two areas.

It is anticipated that a final memorandum of understanding would operate in much the same way, and by knowing the function of the two agencies, one can take a guess at approximately where that dividing line might be. With respect to areas of potential overlap, the primary responsibility of the Food and Drug Administration is the safety and effectiveness of the drug or device with respect to the patient, whether it is able to do what the manufacturer claims it can do, whether it is labeled properly, and that sort of thing. Simply, it deals primarily with safety to the patient.

The Nuclear Regulatory Commission's responsibility, however, deals primarily with safey of the user and handler and the public. Now, that is an oversimplification, and there is a lot to be negotiated between the two agencies and a lot that is difficult to understand and might take us a while to work out between ourselves. In simplistic terms that is how such an agreement might finally take place.

Now suppose the manufacturer has completed his research and development. He has obtained a license to do that. He has obtained a license to manufacture and distribute this device. NRC has completed its product evaluation or, if the manufacturer is in an agreement state, the agreement state has completed it; in either case, information is exchanged so he doesn't have to go through this twice. But suppose all that is done and it is all ready to go. Unfortunately, he couldn't sell it because he has nobody to sell it to. He has nobody authorized to receive it. So that is the next step. Whoever wants to use it has to obtain a license to use it.

Now assume that the user is an industrial firm who wants to use it for quality control or nondestructive testing. Then it is analogous to a lot of other types of licenses that the Nuclear Regulatory Commission has. He has to submit an application to the Nuclear Regulatory Commission, demonstrating that he has the training and experience that is necessary to use whatever it is that he wants to use and has implemented whatever controls may be appropriate. What that might mean depends upon the final form that the device might take. Once that individual user has submitted an application and received a license, then the manufacturer is free to sell to the user and no more is involved. If the user is located in an agreement state, the same thing would apply there.

However, there is another possibility. It could be determined that sufficient controls can be published in the regulation so that the Commission feels that public health and safety could be adequately protected through a general license, and the Commission could then conceivably issue a general license for its use. In this case, the individual users would not have to submit an application before they could use it. That type of license normally would require a petition for rulemaking to the Nuclear Regulatory Commission, asking to place the device under a general license. It would then have to be evaluated in terms of the potential threat to the public health and safety.

If it is just for industrial use, then that is all that is involved. If it is for medical use, however, there are a few more steps involved. If the user is a potential medical user wanting to use for clinical evaluation, he must meet all the FDA requirements, and a copy of his letter from the FDA saying that he has met their requirements should be submitted to the Nuclear Regulatory Commission. Once that is done, then licensing would proceed just like for any other radioactive drug or any other device. For example, the University of Connecticut and the National Institute of Dental Research have broad licenses under which their own committees are enabled to approve protocols. Some restrictions are placed on those licenses, but not many. For instance, one of the restraints placed on those broad licenses says that any use of radioactive material in or on humans must be under the supervision of a physician. That would rule out the primary investigator being a dentist, for instance, if it were used on humans. That is not to say those things couldn't be changed. That is normally the way a license is issued now. But within the terms of their license, then these institutions are free, assuming they meet FDA requirements, to conduct their clinical evaluation.

A hospital that did not have a broad license could apply for a specific license to do that clinical evaluation, in which case the same question would be asked: Has the user met FDA requirements and submitted evidence that he has. If that evidence is submitted it would be evaluated strictly from a stand-

point of the qualifications of the user: Does he know how to use radioactive material, whether it be this source or any other source, and have appropriate procedures been set up. If it is determined that he had, then a specific license would be issued for that clinical evaluation.

As long as that individual user were a physician, it is straightforward; however, if he is not a physician, a change to the regulations would be required. The present regulations do not allow the use of radioactive material in or on humans by either a dentist or a podiatrist.

Finally, assume that all the clinical evaluations had been completed and all FDA requirements had been met, and that approval had been given for distribution for routine use. There are two options to make its use widespread. Considering only medical uses, not dental or podiatry uses, there are two options:

1) To issue a license to each individual physician or institution that wants to use the radioactive material.

2) To place it in one of our designated groups.

Most of the radioactive materials that are in common usage are divided into six groups, and one of these groups is a group for sealed sources. It includes sealed sources for both diagnosis and therapy.

If the Lixiscope is placed in that group, then all those licensees who are already authorized for group six would automatically be authorized to use it, and they wouldn't have to submit any additional application.

The preceding paragraphs gave a brief summary of the requirements. At this point it is not known which direction the Lixiscope is going, so it is complicated because all potential options must be covered. As the device gets refined, and more definitive information is known about how it is going to be used and what form it will take, then more definitive information can be provided about the regulatory requirements.

B. PATENT POLICY & LICENSING

John O. Tresansky
Patent Counsel's Office
Goddard Space Flight Center

Patent coverage on the Lixiscope and the NASA policy regarding licensing of private parties to practice the Lixiscope invention will be discussed in the following paragraphs of this paper. To set the stage for NASA policy in this regard, it is necessary to go back about 20 years to when NASA was established after the Russians had launched their Sputnik. There was a lot of concern about the Russians getting the jump on the U. S. in space. The Congress reacted uncustomarily rapidly by legislation which created NASA to conduct space exploration. In this legislation, two concerns of Congress were rather evident. The first concern was Congressional fear that in this new area of technology there would likely be inventions resulting from the work being performed in the space exploration area, and Congress wanted to be assured that no particular segment of American industry would get a broad monopoly over this field of space technology.

So in the enacting legislation, the Congress provided that any invention made relating to space and aeronautical activity sponsored by NASA belonged to the government.

The second concern of Congress was that inventions resulting from the space exploration effort should benefit the American public whose tax dollars were paying for the efforts in space and aeronautics. So the legislation expressly authorized NASA to license inventions which resulted from space exploration, and NASA has gone ahead for 20 years in implementing this Congressional provision.

NASA, from its earliest days, has had patent licensing regulations which provide for the availability of inventions owned by NASA to be licensed either on a nonexclusive or on an exclusive basis. The patent licensing program is both domestic and foreign in its scope. Thus, NASA is in a position to license both under U. S. patents and under foreign patents in those foreign countries in which NASA elects to file patent applications on our inventions.

Generally speaking, NASA's inventions are initially made available on a nonexclusive basis, and only if there are no interested parties willing to undertake the risk involved in developing an invention for the marketplace on a nonexclusive basis will the invention become available on an exclusive basis. If there are some interested parties willing to undertake development on a nonexclusive basis but are unsuccessful within a particular time frame, these nonexclusive licensees are revoked and the invention is made available for licensing on an exclusive basis. Basically, this is the NASA licensing program.

NASA recognized very early the commercial significance and potential of the Lixiscope invention, and quickly filed an application for patent in the United States Patent Office. This was filed in July 1977. For those interested in obtaining licenses under it, the key information which is needed in applying for a license is given as follows: the NASA case number is GSC12,263 and the patent number is 4,142,101.

NASA has received notice from the United States Patent Office that a patent will be issued on the application. Now, for those of us who have been in this patent business for a long time, we remember the days not too long ago when it would take on the average of three and a half to five years to get a patent issued on an application. In fact, there was kind of a cynical truism uttered in the profession that if an invention is patented, it must be obsolete.

However, in this case a patent was issued in about a year from the time the application was filed. The patent has 37 claims which define the scope of the patent monopoly in various degrees. The claims fall into two categories: 1) the structure of the Lixiscope, and 2) claims related to a method of radiation imaging. Both the apparatus and the process associated with its use are covered by the patent application.

There is one peculiarity of the American patent system which should be noted. It is one that apparently is not widely understood by the American public, including some in industry. For some reason, the patent profession doesn't recognize the need to get this message across to American industry. Under the United States patent system, the granting of a patent only grants to the patentee a negative right and not a positive right. The nature of this negative right is merely the right to exclude anyone else from making, using or selling the patented invention. Under U. S. patents, the patentee does not get the positive right to make, use or sell his invention.

Thus, it should be understood by anyone interested in licensing under the Lixiscope patent that you are not free and clear of any possible patent infringement

liability just because one obtains this license. This is not to say that any such liability exists..

Based on a review of the Patent Office prosecution, there does not appear to be any dominating patents covering the broad combination of structure involved in the Lixiscope. However, it is understood that the Lixiscope is primarily composed of a combination of commercially available components.

If, in fact, any of these components which are utilized in the Lixiscope are covered by privately owned patents, anyone who wants to manufacture a Lixiscope must either procure that patented component from the patent owner or a licensee of the patent owner; or, in turn, procure from the patent owner a license to manufacture under the patent. It is not known whether or not the components used in the Lixiscope are privately patented.

As a consequence, those who do become licensees under the patent on the Lixiscope will notice in the license that NASA does not warrant that a licensee who practices, makes, uses or sells the Lixiscope, will be free of infringement liability. This is standard practice in U. S. patent licensing procedures.

Six applications have been received from American corporations applying for nonexclusive licenses under the Lixiscope. As of now, the Lixiscope is only available for licensing on a nonexclusive basis and to date, NASA has granted four nonexclusive licenses. The four licenses are Electronic Relays Incorporated of Niles, Ohio; Pfizer Medical Systems from Columbia, Maryland; Narco McKesson Company of North Charleston, South Carolina; and IPCO Hospital Supply Company from White Plains, New York.

The earliest licensee is Electronic Relays of Niles, Ohio. Their license was granted in April of 1978. Thus, there has only been a short time period within which these licensees could apply efforts to develop the Lixiscope.

In addition to the U. S. patent application, NASA has also filed patent applications in 13 foreign countries. These countries are: Australia, Belgium, Canada, Denmark, Finland, France, Great Britain, Japan, Mexico, the Netherlands, Norway, Sweden, and West Germany. These applications were filed in November 1977.

As part of NASA's patent licensing program, NASA also licenses under foreign patents. Normally, NASA makes foreign patents available for anyone in the world to license and manufacture abroad. However, in the case of the Lixiscope, NASA headquarters made a policy determination that licenses to manufacture, use and sell the Lixiscope in any foreign country will be limited to U. S. industry.

However, NASA will license foreign industry under other patents to make, manufacture, and sell our inventions abroad. In the case of the Lixiscope, NASA will only license American manufacturers to manufacture and sell abroad. Insofar as the American manufacturers are concerned, those American manufacturers who indicate that they are interested in manufacturing the Lixiscope in the United States for sale and use abroad will be given preferential consideration. This may be viewed as NASA's contribution to re-establishing a favorable balance of payments situation.

The key question is, "How does an American manufacturer apply for a nonexclusive license to the Lixiscope?" First, it is a rather simple process as far as the nonexclusive license is concerned. A standard form, called Form 1495, must be filled out. The kind of information that Form 1495 seeks is as follows: 1) describe the applicant's production and development capabilities; 2) identify the applicant's technical skills; 3) describe the applicant's marketing and distribution channels; and 4) identify the financial resources that will be available for the further development of the Lixiscope.

In regard to the financial resources, it is not necessary to disclose secret business or confidential information. In addition to the above information, NASA would like to know the applicant's plans and intentions as to the Lixiscope; such as what development and marketing are being contemplated, and the geographic areas for marketing. In other words, are you just interested in the northeastern market or the southwestern market? This information is desired because NASA will grant nonexclusive licenses on a geographic basis. NASA would also like to know what technological fields of use of the invention are you particularly interested in?

As far as the internal processing of any application or nonexclusive license is concerned, the application should be sent to the Patent Office at Goddard. It will be reviewed, a questionnaire will be filled out and then it will be sent to NASA Headquarters, where, by statute, NASA's Inventions and Contributions Board is charged with the responsibility for passing on the question of whether or not the license should be granted or rejected. It is believed that nonexclusive licenses are granted to American corporations pretty much as a matter of form.

What are the conditions of the grant of a nonexclusive license from NASA? Insofar as an American corporation is concerned, NASA does not charge royalties, so the license is royalty free. The government will realize its return from the employment opportunities that are created and the corporate taxes that are paid by a corporation manufacturing a Lixiscope.

It should be pointed out again that the license grant does not warrant freedom from any patent infringement. This is a responsibility that should be assumed by the commercial licensees.

The license grant does require a licensee to submit

annual reports on what progress has been made to bring the invention to the marketplace. Again, the primary interest is to get the inventions made with taxpayer dollars back to the taxpayers so they can realize the benefits resulting from the invention.

The licenses are not assignable by the licensee. NASA requests that a licensee who is successful in developing a product for the marketplace indicate that the product was licensed by NASA. In turn, NASA prohibits the licensees from using the name of NASA or the name of the inventor for promotional purposes. NASA has to maintain a neutral position in this area.

To encourage licensees to be more expeditious in their efforts to bring the invention to the marketplace, the nonexclusive licenses usually set a target date for the licensee to get that invention to the marketplace. At this time, that target date is two years from the date of the grant. If the licensee is unsuccessful after that two-year period, NASA may revoke the license.

Normally, a nonexclusive license expires after seven years; however, it is understood that if there are cogent reasons to extend the license period, NASA will do so. Insofar as any revocation by NASA is concerned, NASA gives prior notice to licensees that revocation is being considered, thereby providing the licensees with an opportunity to come before the Inventions and Contributions Board to justify why the license should not be revoked.

Finally, two questions are often asked by industry regarding licensing. These are: 1) Why it is that the government goes through the exercise of making its patents and inventions available initially on a nonexclusive basis; and 2) What does a licensee get if he knows that he and anybody else can come in and obtain a nonexclusive license under a government patent?

The answer to this is that the Justice Department, Antitrust Division, insists that inventions are made available on a nonexclusive basis initially. If that doesn't entice a company to invest risk capital to bring the invention to the marketplace, the invention can be made available on an exclusive basis. Thus, the grant of unnecessary exclusive monopolies is avoided, and in a broad sense, a patent is a negative monopoly.

What advantage is there for a manufacturer to come into NASA and request a nonexclusive license? First, by asking for a nonexclusive license, the manufacturer is assuring himself that some other manufacturer will not get an exclusive license to practice the Lixiscope invention. This may happen if there are no applicants or no successful nonexclusive licensees. Second, it should be pointed out that the Lixiscope is in a rather early stage of development. When NASA grants a nonexclusive license, NASA does not require its licensees to grant back to NASA any rights under any improvement patents that the licensee may obtain.

In other words, it is rather evident that improvements are needed in the Lixiscope to make it more commercially saleable. Any nonexclusive licensee who makes such an improvement can obtain a private patent on the improvement, and he alone owns that patent. The government gets nothing. Thus, a nonexclusive licensee of NASA may end up suing the government for infringement of his improvement patent.

In closing, it should be pointed out that under the United States patent laws, patents can be obtained on improvements in the Lixiscope design, as well as for some kind of unobvious application of the Lixiscope which may be developed by a nonexclusive licensee. Thus, one can obtain a patent for a new use of an existing device, and, if anyone, including the United States government, should use a Lixiscope for this new use, that nonexclusive licensee can hold the government to paying reasonable compensation.