A SIMPLE CRYOSURGICAL INSTRUMENT*† AND ITS APPLICATION IN ETHIOPIA

BY

J. EDWARDS

National Institute for Medical Research, and University of Surrey

L. L. WOODGET

National Institute for Medical Research, London

F. O. MUELLER

Westminster Hospital, London

AND

R. LUDEK

Haile Selassie I Hospital, Addis Ababa, Ethiopia

Low temperature techniques were used in ophthalmic surgery more than 30 years ago (Bietti, 1933, 1934; Deutschmann, 1935) but interest in cryosurgery has become widespread only in the last 5 years. In the main, cryosurgical techniques are used to produce controlled necrosis and inflammation in selected areas of tissue. However, Krwawicz (1961) described a new application of cryogenics which involved freezing a small probe onto the lens to provide adhesion for cataract lens extraction. In the last few years, many ophthalmic surgeons have adopted this technique for routine cataract operations because it displays several advantages over other methods used up to this time. It is easier and safer than the conventional method of gripping the lens capsule with forceps, it virtually eliminates capsular rupture and it improves the clinical results (Kelman, 1965). Indeed, utilization of low temperature has been acclaimed the most important development of this decade in cataract surgery (Bellows, 1965).

The highest incidence of cataract occurs in the developing countries of Africa, India, and South America. In Kenya, for instance, 47 per cent. of all the blind or partially blind suffer from cataracts, while at one of the hospitals in Addis Ababa more than 450 near-blind persons sought treatment in 1965 alone (Bisley, 1964).

In 1965 and 1966 surgeons from the Westminster Hospital visited Addis Ababa to carry out corneal grafts in the ophthalmic department of the Haile Selassie I Hospital (Mueller, O'Neill, Trevor-Roper, Reiter, and Ludek, 1966). During this visit a series of cataract operations was undertaken using the cryogenic method of lens extraction. In selecting a cryogenic instrument for this work, the following criteria were laid down as desirable in view of the difficult surgical conditions anticipated.

It must be of simple design, solid construction, and reliable in the hands of different surgeons. There should be no trailing leads to interfere with surgical manipulation of the instrument and sterilization by any conventional method should be possible. If a coolant is used it should be available at low cost and capable of producing a

* Received for publication November 25, 1966.

† Address for reprints: Biomechanics Unit, Mechanical Engineering Department, University of Surrey, London, S.W.11.

satisfactory range of sub-zero temperatures. The complete instrument, including the refrigerant source, should be easy to transport and store.

Cryogenic instruments available on the commercial market, at the time when this work was started in August, 1965, did not entirely meet the above requirements. Most of them used liquid nitrogen or solid CO_2 which were difficult to obtain in Ethiopia and could not be stored long enough to be transported there (*i.e.* the Linde Cryogenic System described by Kelman and Cooper (1963), the two designs described by Bellows (1964, 1965), the Rubinstein Cryosurgical Unit and the Cryosystems Cryogenic Probe). The only other type of instrument available, the Kelman Cryostylet by Frigitronics (Kelman, 1964), required heavy electrical leads and water-cooling tubes, and could not be sterilized by boiling or autoclaving. Consequently, we designed and produced a new instrument specially for the occasion. In December, 1965, Mattis, Brady, and Sugana described a disposable cryophake developed by Sudarski in conjunction with Alcon Laboratories which, had it been available earlier, would probably have suited our purpose. Nevertheless, we consider that our design offers some very important advantages over the disposable cryophake. In particular, running costs are much lower.

A description of our instrument, together with the results of the clinical trial in Addis Ababa, are presented below.

Description and Working Principles of Cryoextractor

Several cryogenic instrument designs were tested and the instrument shown in Figs 1 and 2 includes several modifications that suggested themselves during the clinical trial. It consists of the main body, a small refrigerant container, an end-cap, and several interchangeable nose-pieces fitted with silver probes of different shapes and sizes (Fig. 1).

The overall length of the assembled instrument (Fig. 2) is 14 cm., the outside diameter of the body 1.7 cm., and the total weight 72 g.

FIG. 1.—Component parts of cryogenic instrument.

FIG. 2.—Assembled instrument, with a lens attached to the probe.

The working principles of the instrument are illustrated in Fig. 3 (opposite). Its method of creating a low temperature depends on the fact that when a liquid refrigerant vaporizes it takes in heat and cools the surroundings. During the clinical trial Freon 12 (CCl_2F_2) was used as the refrigerant, but performance tests carried out on the instrument have since shown that Freon 22 (CHClF_2) may offer some advantages (see p. 418).

FIG. 3.—Schematic cross-sectional diagram of cryogenic instrument.

(1) Refrigerant container.	(6) Nozzle of container.	(11) Exhaust channel.
(2) Main body.	(7) Filter.	(12) Vent holes.
(3) End Cap.	(8) Flow-restricting orifice.	(13) Cavity of nose cone.
(4) Control lever.	(9) Injection tube.	(14) Nose cone.
(5) Insert.	(10) Probe.	(15) Spring.

The refrigerant is supplied in a metal container of about 10 ml. capacity (1). This is inserted into the rear end of the main body (2) and held in position by the end-cap (3).

Depression of the lever (4) causes a movable spring-loaded insert (5) to be pushed against the nozzle of the container (6). This actuates a fluid release valve inside the container and allows refrigerant to be forced under pressure through a filter (7), a flow-restricting orifice (8), and a tube (9) into the hollow silver probe (10). At this point it vaporizes and cools the probe. The vapour escapes to atmosphere *via* the exhaust channel (11) and the vent holes (12).

As the probe cools, the rate of evaporation decreases and within seconds liquid refrigerant begins to accumulate in the nose-cone cavity (13). The level of the liquid can be seen through the plastic material of the cone (14).

The length of time the probe will remain at sub-zero temperatures depends on the amount of liquid accumulated in the nose cone and the thermal capacity of the probe. As soon as the lever is released, flow of liquid into the cone will stop. Therefore the period of cooling can be regulated by varying the time of lever depression.

Sterilization of the instrument can be achieved by conventional methods such as boiling and autoclaving.

During part of the clinical trial, the instrument was operated from a large cylinder of refrigerant by providing a connexion of thin nylon tubing between this large cylinder and the rear end of the refrigerant container. The surgeons in the trial preferred to work without this connexion, but thought that the choice of alternatives was a useful feature.

Instrument Performance Tests

The performance of the cryosurgical probe was investigated by conducting a series of experiments under surgical conditions. The main objective was to determine its temperature-time relationships, using Freon 12 and Freon 22 as refrigerants.

A temperature-sensing thermocouple was attached to the outer surface of the probe tip, just above the region where it makes contact with the lens.

During each experiment the output from the thermocouple was recorded while cryogenic lens extraction was being performed on a rabbit, immediately after it had been killed by air embolism. Typical temperature-time recordings obtained with Freons 12 and 22 are shown in Fig. 4. Time was measured from the instant when the coolant injection lever was first operated.

FIG. 4.—Typical temperature-time recordings, obtained during performance tests on the instrument (for a lever-actuation time of 10 seconds) using Freon 12 and Freon 22 as refrigerants. Zero time represents the instant when the control lever was first actuated.

In Fig. 4 the curve for Freon 12 with a lever-actuation time of 10 seconds is of particular interest because this was the average time adopted by the surgeons in the clinical trial. In this case, the probe became adherent to the lens (at point 'a') in less than one second and the lowest temperature attained was -16°C . in 14 seconds (point 'b'). The discontinuity on this curve at point 'c' represents the moment when the last drop of liquid remaining in the nose cone was finally vaporized.

Similar temperature-time curves were obtained for a range of lever actuation times, and a summary of the data derived from these is given in Table I. It is interesting to note that, by prolonging injection of Freon 12 to 15, 20, and 30 seconds, the time during which the probe remained adherent to the lens was extended to 80, 96, and 133 seconds respectively.

A 10-ml. cartridge contains sufficient refrigerant to provide adherence to the lens for a maximum period of 12 minutes.

The experiments using Freon 22 revealed two main advantages over Freon 12: a lower temperature was attained and the zone of ice formation was larger.

Thawing from the minimum temperature to the temperature at which the probe was separated from the lens usually took about 1 minute when the probe was left

TABLE I
SUMMARY OF PERFORMANCE TEST RESULTS

Performance	Refrigerant	Lever-actuation Time (sec.)				
		5	10	15	20	30
Lowest temperature attained ($^{\circ}\text{C}$.)	Freon 12	-7	-16	-17	-19	-20
	Freon 22	-15	-23	-28.5	-25.8	-31
Period of adhesion (sec.)	Freon 12	12	54	80	96	133
	Freon 22	33	58	106	121	142
Time at which probe became adherent to lens	Freons 12 and 22	Less than 1 second				
Maximum period of adhesion before 10-ml. cartridge became empty (min.)	Freon 12	12.5 min.				
	Freon 22	13 min.				

to rewarm on its own. Instantaneous separation, however, could be achieved by applying a jet of saline at body temperature (Mattis and others, 1965).

The above data were obtained with one particular setting of the instrument. In practice, the performance characteristics can be varied over a wide range by altering the size of the orifice and therefore the rate of the refrigerant flow, and the mass and dimensions of the probe and nose cone. Furthermore, different refrigerants can be used to obtain a wider range of temperatures.

The settings in the experimental instrument were as follows:

Size of orifice	=	0.05 mm.
Material of probe	=	Silver
Outside diameter of probe	=	1.5 mm.
Bore diameter of probe	=	1 mm.
Total length of probe	=	18 mm.
Projecting length of probe	=	6 mm.
Material of nose cone	=	Polypropylene
Volume of nose cone cavity	=	1.6 ml.

Surgical Methods

The cryoextractor was dismantled, boiled for 10 minutes, and dried with latex sponge pieces. A cartridge filled with Freon 12 was inserted into the rear of the instrument and the end-cap fixed over it. The injection tube (9) (Fig. 3) was cleared of water by passing a spray of coolant through it. Finally the nose cone was pushed into position and the instrument was ready for use.

The operations were carried out under local anaesthesia. The eye was anchored by sutures and the lids kept open by a light-weight speculum. After corneal section and peripheral or total iridectomy, the corneal flap was gently retracted and the cryoextractor at ambient temperature was brought into contact with the lens surface. Within one second after the lever was pressed down ice became visible, but extraction was not started until about 10 seconds later. The zonular ligaments were torn by rotary and side to side movements and the lens was delivered after a period varying from 10 to 40 seconds. The pre-placed sutures were tied, the iris pillars stroked back into position, and additional sutures inserted.

Surgical Experience and Results

The results of the 46 operations performed are summarized in Table II.

TABLE II
SUMMARY OF CLINICAL RESULTS

Type of cataract	Number of Cases	Iridectomy		Extraction		Number of Successes
		Basal	Total	Intra-capsular	Extra-capsular	
Mature	21	9	12	20	1	20/21
Hypermaturation	14	7	7	12	2	12/14
Nuclear and cortical	4		4	4		4/4
Congenital	2		2	2		2/2
Subluxated lenses	5		5	5		5/5

Mature Cataracts

Five of the 21 patients with mature cataracts were below 50 years of age. In nine cases the zonular fibres were found to be very resistant and up to 25 seconds were needed to break them. One capsule ruptured, but the rupture occurred at the zonule and not at the site of ice formation. During nine operations basal iridectomies were performed and in one of them the iris became adherent to the probe. Immediate re-warming with normal saline separated iris and lens from the probe and after re-application the lens was removed in its capsule.

Hypermature Cataracts

These fourteen extractions did not present difficulties and the amount of intra-ocular ice obtained at -16°C . proved to be sufficient in this type of cataract. In two cases the capsule ruptured. In one the bristles of a brush used to stroke the iris away from the lens pierced the capsule, so that here again the cryogenic tool could not be blamed for the failure to deliver the lens intra-capsularly.

The lenses of two hypermature cataracts were shrunk and the degenerated suspensory ligaments were partially ruptured before the lens extractor was applied. In one of them the vitreous presented itself immediately after the corneal flap had been retracted. However, careful application of the probe tip to the lens prevented vitreous adhesion. The lenses of nine patients were unusually large in size and the capsules were tight over the liquified lens material. In five of the nine cases below 45 years of age, the suspensory ligaments could not be torn with rotary movements and the proximity of the iris limited effective side-to-side movements; only gentle traction could be employed. In one case the capsule ruptured at the lens equator and not at the site of traction. In two other cases the lenses were considerably elongated and deformed during traction causing the zonular fibres to rupture simultaneously. The sudden release of the lenses caused the anterior vitreous faces to jerk forward and, in one instance, the capsule ruptured causing loss of some vitreous.

Nuclear and Cortical Cataracts

In one of these four cases the cornea froze onto the probe during extraction. After separation with warm saline, the probe was warmed to ambient temperatures by saline and reapplied. The lenses with nuclear cataracts became more deformed during traction than those with cortical cataracts. However, in no case did the capsule rupture.

Congenital Cataracts

Of particular interest are the two congenital cataracts in a young man aged 27 years. The zonular fibres were extremely resistant and the extraction lasted about 40 seconds. Vitreous appeared in both eyes, but careful delivery resulted in successful removal of both lenses without loss of vitreous or rupture of the capsule.

Subluxated Lenses

Three of the five lenses had reached the mid-pupillary line and in the remaining two patients the upper lens pole could just be seen. In one patient vitreous appeared

after the cornea had been sectioned and vitreous loss could not be prevented. All these lenses were removed intra-capsularly.

Discussion

The cryogenic instrument used during the clinical trial compared favourably with conventional lens extraction instruments such as capsule forceps and erisophakes. It is small in size, requires little routine attention, and, above all, can be sterilized by any standard hospital method. These features should make it particularly suitable for use in field hospitals set up in rural districts where there are no other surgical facilities. A trial in a mobile field unit is planned and we have good hopes that the instrument will prove its merit under these conditions.

During the trial the instrument was used only for cataract extraction. However, the design is such that it may well be adaptable to suit other surgical procedures. In recent years, cryogenic techniques have been used by neurosurgeons (Cooper, 1961), urologists (Stone, Soanes, and Gonder, 1966), ophthalmologists (Bellows, 1964), and otorhinologists (Cutt, Wolfson, and Ishiyama, 1966), as well as by general surgeons (Pouluseck, 1966). In most cases they require different sub-zero temperatures and probe shapes, and the range of temperatures needed is progressively widening as new applications for freezing are discovered. An adaptable instrument capable of producing all these temperatures, and yet of simple design, would offer distinct advantages over a single purpose instrument.

Modern refrigerants such as the chlorofluorocarbons (sold under trade names such as Freons and Arctons) are readily available with boiling points that provide good coverage of the temperature range which appears to be necessary for cryosurgery (*i.e.* -5.8° , -29.8° , -40.8° , -57.8° , -81.4° , and $-82^{\circ}\text{C}.$). Furthermore, they have a high latent heat, are non-corrosive and practically non-toxic, and not inflammable.

The instrument we have described was designed to take full advantage of these properties. By adapting it for use with lower boiling point refrigerants, its range of use might be capable of extension to other surgical procedures including the repair of retinal detachment.

Development work on this and other aspects of cryosurgical instrumentation is continuing in the Mechanical Engineering Department of Surrey University.

In Ethiopia, lens extraction is usually carried out under local anaesthesia and lack of co-operation on the part of the patient frequently leads to capsular rupture when the lens is extracted with forceps. By using the cryogenic method, the incidence of this complication was very much reduced, clinical results were improved, and it was possible to perform the operation without assistance from nursing staff.

One of the aims of the clinical trial was to note any difficulties experienced by surgeons who had not previously used cryogenic techniques. In general, they accommodated themselves to the new technique very quickly. The three cases in which the lens capsule was accidentally ruptured occurred early in the series and the instrument could not be blamed for any of these mishaps.

The entire work of cataract surgery in Ethiopia, with an estimated population of 22,000,000, lies in the hands of six surgeons, who are faced with a tremendous task in trying to treat the large number of patients. Since the cryogenic technique of

lens extraction is simpler and safer than other methods used at present, it may become possible to treat more patients by teaching the technique to general surgeons and perhaps even to skilled "dressers".

Summary

The technique of freezing a low temperature probe on to the lens to provide adhesion for cataract lens extraction has gained widespread acceptance in ophthalmic surgery. In 1965 and 1966 a team of surgeons undertook a series of cataract operations in Ethiopia to investigate any problems which might arise from using cryogenic methods of cataract extraction in the developing countries.

A cryogenic instrument for this work has to satisfy a particularly stringent specification. It must function satisfactorily not only under conventional hospital conditions, but also under the more difficult conditions of temporary field hospitals set up in rural districts. A description of an instrument developed for this purpose is presented together with the results of the clinical trial in Ethiopia.

The authors are indebted to the Haile Selassie I Foundation for their co-operation during the clinical work and to the Cooper Technical Bureau and the Aerosol Packaging Company Limited for supplying the refrigerant containers and Freon.

We also wish to thank Mr. W. C. Lister and Dr. B. M. Wright, of the National Institute for Medical Research, and Mr. P. D. Trevor-Roper, of the Westminster Hospital, for their help and advice.

REFERENCES

- BELLOWS, J. G. (1964). *Amer. J. Ophthalm.*, **57**, 29.
 — (1965). *Eye, Ear, Nose Thr. Mthly*, **44**, No. 4. (April), 39.
 BIETTI, G. (1933). *Boll. Oculist.*, **12**, 1427.
 — (1934). *Ibid.*, **13**, 576.
 BISLEY, G. G. (1964). *Trans. ophthalm. Soc. U.K.*, **84**, 55.
 COOPER, I. S. (1961). "Parkinsonism: Its Medical and Surgical Therapy". Thomas, Springfield, Ill.
 CUTT, R. A., WOLFSON, R. J., and ISHIYAMA, E. (1966). *Cryobiology*, **2**, 296.
 DEUTSCHMANN, R. (1935). *Klin. Mbl. Augenheilk.*, **94**, 349.
 KELMAN, C. D. (1964). In "Highlights of Ophthalmology", ed. B. F. Boyd, Vol. 7, No. 3, p. 181.
 — (1965). *Int. Ophthalm. Clin.*, **5**, No. 1, 81.
 — and COOPER, I. S. (1963). *Amer. J. Ophthalm.*, **56**, 731.
 KRZAWICZ, T. (1961). *Brit. J. Ophthalm.*, **45**, 279.
 MATTIS, R. D., BRADY, H. R., and SUGANA, T. (1965). *Arch. Ophthalm. (Chicago)*, **74**, 787.
 MUELLER, F. O., O'NEILL, P., TREVOR-ROPER, P. D., REITER, H., and LUDEK, R. (1966). *Brit. med. J.*, **2**, 17.
 POULUSECK, F. (1966). *Cryobiology*, **2**, 295.
 STONE, F., SOANES, W., and GONDER, M. (1966). *Ibid.*, **2**, 296.