Lens extraction with ultrasound
Experiments in rabbits

DOUGLAS McG. CLARKSON*
Departments of Medical Physics and Ophthalmology
AND
CALBERT I. PHILLIPS
Department of Ophthalmology, University of Edinburgh and Princess Alexandra Eye Pavilion, Royal Infirmary, Edinburgh

As a step in the development of a system for the removal of hard cataracts in humans using ultrasonic vibrations, a prototype device has been used to extract the (normal) rabbit lens.

Various methods of using ultrasonic vibrations for cataract extraction have been reported (Kelman, 1969; Girard and Hawkins, 1974; Kuwahara, 1970).

An essential feature of the procedure is the insertion into the anterior chamber of a small vibrating needle at the tip of which lens fragmentation occurs.

Method

IRRIGATION-ASPIRATION SYSTEM

General description

The hollow needle portion of the aspirator-fragmentor (22 G) is inserted into the anterior chamber at the limbus temporarily through a self-sealing incision. Inclined to this first needle at about 90 to 100°, a 25 G standard disposable syringe needle is similarly inserted at the limbus at around 6 o'clock (Fig. 1). Each needle is connected with a push-pull machine (Phillips and Wang, 1971) by 150 cm lengths of Portex manometer tubing: 'disposable manometer line', luer fitting, length 150 cm, type 200/490/150.† The push-pull machine allows the simultaneous irrigation of fresh saline into the anterior chamber and aspiration of saline along with lens fragments at equal rates. Two 50-ml Plastipak syringes, the plungers of which are secured in fixed brackets, lie on either side of a central threaded rod facing in opposite directions. Rotation of the rod moves the common transverse piece which grips the barrels of the syringes (Fig. 2). The motion of the syringe barrels relative to their respective plungers is therefore equal but in opposite directions. This equalizes the irrigation and aspiration flows because the cross-sectional areas of the syringes are identical. The grips for the plungers allow independent control of the syringe volumes when required so that an adequate depth of anterior chamber can be maintained if leakage occurs at entry points of the needles.

Preliminary settings

Initially the irrigation syringe with attached manometer tubing is filled with about 55 ml of saline. Trapped air bubbles are expelled and the syringe with attached tubing is fixed to the irrigation arm of the push-pull machine with the associated plunger control set for maximum independent fluid input (about 55 ml). The aspiration syringe and attached manometer tubing are filled only to the extent required to eliminate air bubbles; with a small amount in the syringe the tubing is then fitted into the aspiration arm of the push-pull machine where the plunger control is used to expel most of the residual contents of the syringe.

The elimination of air bubbles from the irrigation limb prevents their entering the anterior chamber to obscure the operator's view. Also, in both the

FIG. 1 Initial insertion of needles at limbus
irrigation and the aspiration limbs careful elimination of air bubbles ensures that the associated positive and negative pressures are maintained at optimum values. The negative pressure at the aspirator-fragmentor needle aids fragmentation of the lens.

THE LENS FRAGMENTOR/ASPIRATOR

The lens aspirator/fragmentor (Clarkson and Phillips, 1975) employed in these experiments (Fig. 3) comprises two main parts:

- the outer case with associated power socket
- the vibrator which undergoes longitudinal vibrations.

The device is powered by an oscillating signal from an electrical generator at a specific resonant frequency of the vibrational assembly. Piezoelectric crystals* are alternately expanded and compressed (mainly longitudinally) by the voltage signal and in so doing supply vibrational energy to the vibrator assembly. This vibrator is specifically designed to produce a significantly greater amplitude of vibration at the active tip of the instrument compared with that at other points along its axis, a result which is achieved by using an ‘acoustic horn’ (Eisner, 1967; Merkulov, 1957; Merkulov and Kharitonov, 1959; Neppiras, 1963). It is at the active tip that lens material can be fragmented.

This active tip is at the bevelled end of a 3 cm length of stainless steel tubing, typically of 22 G or 21 G specification (less than 1 mm outside diameter). This tubing, through which fragmented lens matter is sucked, exits from the side of a cone portion of the vibrator, where it is soldered (Magnat type) to a larger-diameter stainless steel tube. This tube runs parallel with the axis of the vibrator inside the case towards the face of the power socket. From there it protrudes about 4 cm where it terminates in a luer lock attachment. To that attachment is connected the disposable manometer tubing.

THE ELECTRICAL GENERATOR

General description

The electrical generator shown schematically in Fig. 4 delivers to the vibrator a sinusoidally varying voltage signal which can be altered both in frequency and amplitude, permitting optimum tuning of the mechanical vibrator and control of amplitude.

*Vernitorn Ltd, Thorn Hill, Southampton
of vibration at the active needle tip. Of the two frequency ranges available, the lower one which extends from about 25 to 45 kHz is employed. The voltage output is continuously variable between 0 and 125 V root mean square.

Mode of operation
An oscillator (Wein bridge type) inputs a signal of controllable frequency and amplitude to the power amplifier. The output of this amplifier is some 50 times greater and this is further increased by a factor of 10 with an output transformer, making available to the crystal elements in the vibrator an oscillating voltage of sufficient amplitude to produce the necessary active vibration at the tip of the needle. At the resonant frequency of the vibrator, the current drawn from the generator is at a local maximum, and a voltage signal proportional to the generator current is observed on an oscilloscope in order to monitor this resonance. The oscillator draws power from a ±15 V power supply while the amplifier is powered from a source delivering 45 V DC. This in turn is supplied with 45 V AC from the secondary windings of a mains transformer. The generator draws no more than about 7 W from the mains under normal operating conditions; of these about 2 W at most will be supplied to the fragmentor itself.

IN VIVO RABBIT LENS EXTRACTION
To date, eight experiments on rabbits have been done, two with survival.

Preliminary
Atropine was administered topically at five-minute intervals beginning 30 minutes before the start of the procedure, while an intravenous injection of nembutal given in conjunction with an ether mask was used to produce a sufficiently deep state of anaesthesia. Phenylephrine 10 per cent and cocaine hydrochloride 4 per cent were administered once, five minutes before the operation. (Some deaths early in the anaesthetic were probably due to systemic absorption of too frequently administered phenylephrine 10 per cent, cocaine 4 per cent, or atropine 1 per cent.) Lid sutures were used. Two limbal traction sutures were inserted, one temporally and one at 6 o'clock, to allow firm fixation of the eyeball so that accurate incisions of half-thickness of cornea just anterior to the limbus could be made.

Needle insertion and anterior capsule incision
Against countertraction on the limbal fixation sutures, the needle-fragmentor and the irrigation needles were easily inserted through the deeper half of the cornea. The bevel at the fragmenting tip must be sufficiently sharp to allow penetration with minimal corneal trauma. The resulting punctures should be small enough to minimize loss of aqueous humour during and after the operation. The irrigation needle and the aspirator-fragmentor needle, which are reasonably manoeuvrable in the anterior chamber, are used to incise the anterior lens capsule in a cruciate pattern.

Lens fragmentation and aspiration
The process of lens removal is initiated by passing saline through the eye at a rate of about 2 ml a minute and then switching on power to the tuned lens fragmentor. Typically 1.5 W of electrical power at a root mean square voltage of 120 V is supplied at an oscillating frequency of about 35 kHz. Lens material sucked on to the active tip is 'shredded' by the ultrasonic vibrations, and drawn down the suction pathway of the lens fragmentor-aspirator into the collecting syringe. In the absence of ultrasonic vibrations, however, no lens cutting is achieved.

The aspiration flow serves also to stabilize the temperature of the fragmentor which tends to heat up because of mechanical losses in the metal which experiences large cyclic stressing forces. To avoid over-heating, power must be cut off when aspiration flow ceases and not turned on again until aspiration flow is re-established.

The lens material tends to prolapse into the anterior chamber and becomes more accessible, hence improving the cutting rate. Material can be scavenged from beneath the iris by aspiration in...
the absence of fragmentation while any leakage at the limbal incisions can be replaced by the use of the independent plunger control in the irrigation limb. All visible lens fragments with the exception of the posterior capsule and peripheral parts of the anterior capsule were generally removed in about 12 minutes, during which time about 25 ml of fluid had been used. Flow (and power) should be intermittent, otherwise the saline passes directly from the irrigator to the aspirator and avoids lens matter; during pauses in the flow of fluid, the tip of the aspirator-fragmentor should be positioned on lumps of lens matter which can then be scavenged and pulverized as soon as flow starts again. The fragmentor needle is then withdrawn. The anterior chamber is deepened by injection of saline through the irrigation needle which is also then withdrawn. On account of the small size of limbal wounds, there is usually no subsequent loss of anterior chamber and no need for suturing.

SUBSEQUENT OBSERVATIONS

Terminal experiments

In several experiments at the end of which the rabbit was killed, the condition of the vitreous face was assessed directly after the extraction procedure. It was generally found that the ruptured anterior capsule was inconspicuous. An intact posterior capsule always remained so that there was no loss of vitreous, although all lens material had been removed. There seemed to be no danger of vitreous aspiration, presumably because the irrigating fluid tends to go directly from the irrigation to the aspiration needle.

Survival experiments

Ethylene oxide gas has proved an effective agent for sterilizing the lens fragmentor. Any traumatized region at the limbus caused initially by a relatively forceful entry of the aspiration needle into the anterior chamber steadily decreases in extent until after three weeks only a small greyish opacity about 1 to 1·5 mm in diameter remains (Fig. 5). With care the needles can be inserted at right-angles to the surface of the cornea, and trauma can be minimized; if the tip of the needle is pointing even slightly towards the apex of the cornea, a rather long intracorneal track results with a larger area of traumatized cornea. With appropriate initial penetration, however, no such opacity was observed, initially or subsequently, which would seem to imply that the contact between the needle vibrating along its long axis and cornea does not, at the levels of vibration being used and with sufficient aspiration flow, contribute towards corneal opacity.

FIG. 5 Corneal opacity at 12 o’clock (over pupil margin)—that is, at entry point caused by passage of aspiration needle along layers of cornea before entering anterior chamber

TEMPERATURE STUDIES OF VIBRATING ASPIRATION NEEDLE

An experiment was done to measure the temperature variation of points along the powered vibrator while aspiration was carried out at carefully controlled rates using an infusion pump. A thermister (type STC U14) of about 0·5 mm diameter was carefully encapsulated using only sufficient epoxy resin to insulate it electrically from, and ensure excellent thermal contact with, the metallic surface of the vibrator. The thermister was wired in series with a 400 mV DC voltage source and a resistor of value similar to that of the thermister at room temperature. In the range of temperatures investigated (15 to 60°C) the voltage across the constant value resistor increased linearly with the thermister temperature, and in subsequent measurements an electrocardiogram chart recorder was used to measure the variation of this voltage with time.

General observations

Significant heating of the vibrator is produced only in the region between the needle tip and side exit of the aspiration duct on the cone portion. The heating is caused by mechanical losses in the structure which is undergoing large stressing forces. Equalization of temperatures occurs along the needle itself owing to thermal conduction and the temperature from apex to base of the cone portion falls because heat is conducted to regions where less is produced because stress forces are smaller. Important factors in determining the needle temperature are the input power and the rate of aspiration; however, overall design, especially the size of needle used, as well as the degree of acoustic
coupling between the cone and needle sections, are also relevant.

Results

The excess rise of the outer surface of the needle at the cone-needle junction for two different fragmentors at various aspiration rates is shown in Fig. 6. The 22 G needle fragmentor was powered at 1.2 W and compared with a 21 G needle fragmentor powered at 1.4 W. Significant heating would seem to occur only at the higher input powers for aspiration rates of less than 1 ml/min. For a given input power the 21 G needle, with its slightly larger annular area, tends to heat up more readily compared with the 22 G needle.

Fig. 7 shows the variation in thermister temperature. A steady aspiration only is first established. This is followed by a period of combined aspiration and power which in turn is followed by a period of power with no aspiration. The aspiration is then resumed, and finally the power is switched off. The fast response of the system is indicated by the rapid changes in temperature at the various steps.

Provided therefore, that the aspiration rate is maintained at a level of at least 1 ml/min, there should occur no thermally induced corneal trauma. The Kelman probe (Kelman, 1969, 1973, 1974) differs somewhat in its thermal properties (Benolken, Emery, and Landis, 1974) in that irrigating fluid flows over the vibrating probe before it enters the anterior chamber. This may tend to increase the heat input into the anterior chamber compared with the independent irrigation-aspiration design.

ADVANTAGES OF PROCEDURE

Manoeuvrability of the cutting needle in the eye is enhanced because of its small outer diameter (an angle of about 135° can be swept out). Also associated with size is increased access to the eye which simplifies for example scavenging under the iris.

The limbal wounds do not usually require suturing.

PROPOSED USE IN HUMANS

It is intended, in the first place, to extract soft cataracts in humans using the general procedures outlined above—that is, to extract the lens material using small needles through an aperture in the anterior capsule. A new improved instrument is being constructed.

Capsule consideration: human capsule fragmentation studies in vitro

Even with a maximum tip amplitude of about 0.06 mm peak to peak excursion, no significant ultrasound-induced breakdown of human capsule has so far been observed. This is in contrast with the softer rabbit capsule. The fronds of human capsule must not be allowed, however, to block the aspiration needle, which is an occurrence usually caused by the capsule impaling itself on the needle tip. Aspiration of capsule is facilitated by use of large-bore needles and well-developed bevelled needle tips. These features will encourage the
capsule to be drawn into the aspiration duct rather than becoming lodged at the needle tip.

The capsule behaves in effect like a thin, tough polythene sheet which because of its small overall volume, can be drawn along the aspiration duct. Flaps of capsule 3 x 7 mm may be aspirated successfully by a needle of inner bore corresponding to a 20 gauge needle.

Procurement of suitable needles

While the use of larger-bore needles would ordinarily imply the disadvantage of decreased manoeuvrability and increased wound size, a process of electrolytic erosion may be employed by the manufacturer* to produce economically a needle of a given bore yet with any required thickness of wall. In this process, metal is evenly removed at a controlled rate from the outer surface of the needle while the inner diameter of the needle is unchanged.

*Cooper's needle works, 261-265 Aston Lane, Birmingham B20 3HS

It is also intended to use syringes of up to 100 ml capacity† in order to increase reserves of fluid in the irrigation/aspiration system.

Summary

The extraction of the rabbit lens is described using a 25 G irrigating needle and a 22 G aspirating needle; at the latter's bevelled tip lens fragmentation occurs due to the longitudinal ultrasonic vibrations generated there—an 'acoustic horn' causes the tip to vibrate with large amplitudes. The use of small needles allows considerable manoeuvrability in the anterior chamber and usually eliminates the need for corneal suturing. Push-pull coupled syringes equate the volume of irrigation with that of aspiration. This procedure makes possible lens extraction through an aperture in the anterior capsule of the rabbit's lens and a similar machine is being constructed for trial on human cataract.

†Everett Medical Products Ltd, Mitcham, Surrey

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