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(54) Ultrasonic transducer for dispersal of haemorrhages in eyes

(57) Eye treatment apparatus for the in vivo dispersal of a haemorrhage (14) in the vitreous humour (15) of an eye (20) comprises a focussing ultrasonic transducer (10) adapted, when positioned adjacent the eye sclera (12), to emit an ultrasonic wave focussed within the vitreous humour (15) and sufficient to induce local micro-stirring to disperse the haemorrhage (14). The transducer is preferably housed in a hand-held proble (10). The beam is controlled to cause the micro-stirring or, at greater energies, cavitation of the vitreous humour, while leaving the other parts of the eye undamaged.

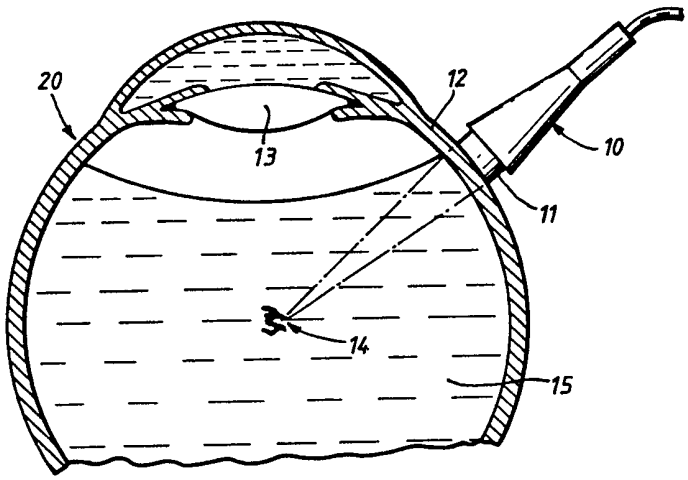


FIG. 2.

GB 2 167 305 A

The drawings originally filed were informal and the print here reproduced is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1982.

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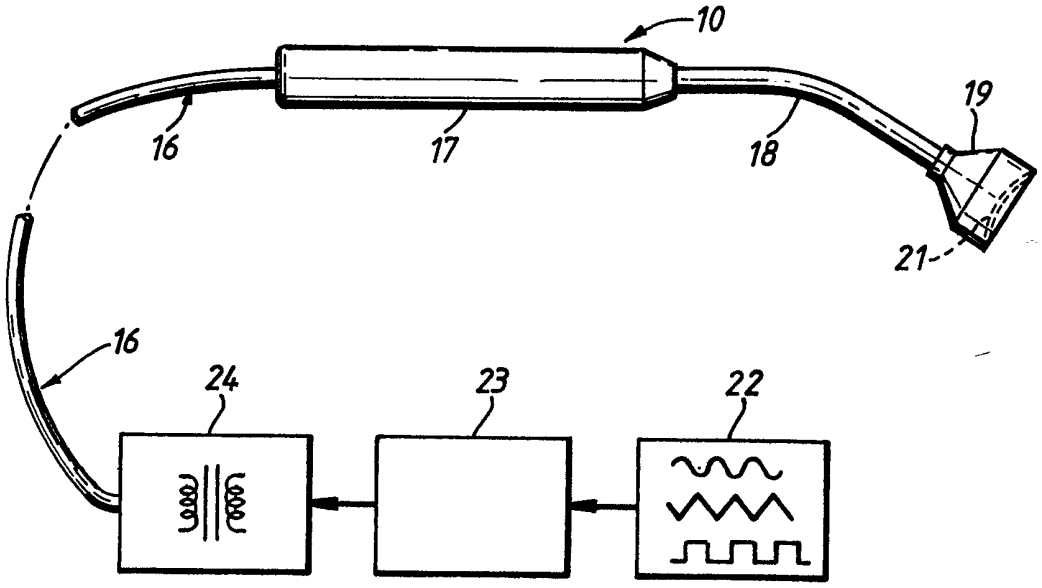


FIG. 1.

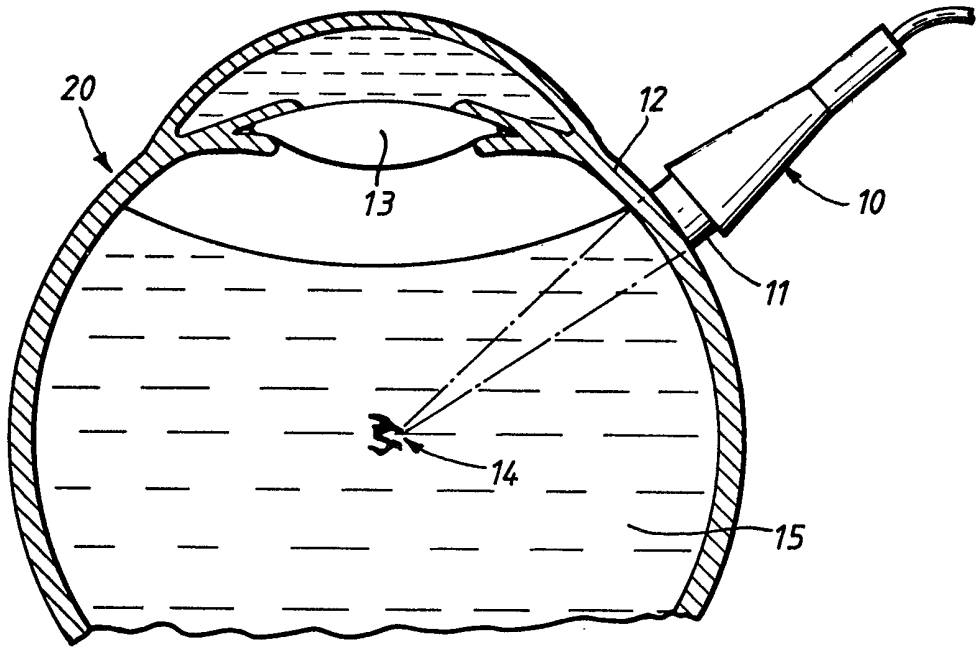


FIG. 2.

SPECIFICATION

Apparatus for dispersal of haemorrhages in eyes

The present invention relstes to eye treatment apparatus for the in vivo dispersal of haemorrhages and other lesions in the vitreous humour of eyes, especially useful in the treatment of human eyes. Vitreous haemorrhages have conventionally been treated either by drugs or by the surgical procedure of vitrectomy. Both methods have low success rates, and vitrectomy involves considerable risks to the eye. It is therefore an object of the invention to provide an apparatus for an alternative, non-invasive, treatment.

The invention, in a first aspect, provides an eye treatment apparatus for the in vivo dispersal of a haemorrhage in the vitreous humour of an eye, comprising focussing ultrasonic transducer means adapted, when positioned adjacent the eye sclera, to emit an ultrasonic wave focussed within the vitreous humour sufficient to induce local micro-stirring to disperse the haemorrhage. The transducer means preferably comprises a transducer housed at one end of a probe, advantageously hand-held, and adapted for engagement with a portion of the eye sclera by way of a coupling means.

The invention, in a second aspect, provides an eye treatment apparatus for the in vivo dispersal of a haemorrhage in the vitreous humour of an eye, comprising a focussing ultrasonic transducer having an emitter of ultrasonic waves, and a control system connected to the transducer for controlling the transducer so that the emitter, when positioned adjacent the eye sclera, emits an ultrasonic wave focussed within the vitreous humour sufficient to induce local micro-stirring to disperse the haemorrhage. The transducer and the emitter are preferably housed at one end of a probe.

The control system advantageously comprises an RF signal generator, a power amplifier for amplifying an RF signal therefrom, and an output transformer for matching the impedances of the power amplifier output and the transducer input so that the concentration of the ultrasonic waves at the focal point is sufficient to cause said dispersal.

The micro-stirring and, at rather larger energies, cavitation, of the vitreous humour have been found to disperse haemorrhages adequately.

The preferred frequency range of the transducer means is from about 1MHz to 3MHz. Within this range, the frequency is sufficiently high to produce a concentration of ultrasonic energy at the focal region to disperse haemorrhages, yet not so high that excessive energy is absorbed by the eye tissue outside the said region, or that the degree of cavitation is reduced due to the scarcity of small nuclei.

The preferred power range of the transducer means is from about 0.5w to 5w. The power in this range is sufficient to disperse the haemorrhage upon energization of the transducer means for a period of the order of 30 seconds. Moreover, such a power range produced an intensity at the surface of the transducer means adjacent the eye sclera well below that likely to destroy eye tissue.

Most haemorrhages which require operation occur close to the centre of the eye, i.e. some distance from the concentration of blood vessels near the back of the eye. In a human eye the centre is approximately 10mm from the sclera, so the preferred focal length of the transducer for application to the human eye is in the range of 8 to 14mm and advantageously approximately 11mm.

The transducer preferably has a fixed focus, and may take the form of a planar disc resonant in the thickness direction, or, more suitably, a part-spherical shell or bowl resonant in the thickness direction.

In order that the invention should be better understood, some preferred embodiments will now be described, by way of illustration, with reference to the accompanying schematic drawings, wherein:

Figure 1 is a diagram of an eye treatment apparatus for the in vivo dispersal of haemorrhages in eyes, including a hand-held probe and a control system; and

Figure 2 is a partial section through a human eye showing the apparatus of Figure 1 coupled to its outer surface.

As shown in Figure 1, the eye treatment apparatus comprises a the hand-held probe 10 and a control system 22, 23, 24. The probe 10 is capable of steam sterilization and comprises a handle 17 connected via a curved tube 18 to a head 19. The head 19 has a plastics flashover protection ring mounted in an internally-threaded ferrule; the ferrule being screwed on to the tube 18. A part-spherical, bowl-shaped, piezo-electric, ceramic, fixed-focus, ultrasonic transducer 21 is mounted within the probe head 19 for resonant vibration in the direction of its thickness, so that a spherical wave is, upon energization, emitted from a wave transmitting surface of the transducer which forms an emitter. The outer diameter of the head 19 is preferably about 10 mm, accommodating a transducer 21 having a chord diameter of about 7 mm. The resonant frequency of the transducer 21, which is preferably limited to the range of 1 MHz to 3 MHz, in one example is in a range of 1.5 to 2.5 MHz with a maximum output power of 5 watts, and the resultant beam is focussed with an acoustic focal length of 11mm. For use on human eyes, the focal length should lie in the range 8 to 14mm. The transducer 21 is air backed so as to give a high acoustic impedance to its rear face, concentrating the available acoustic energy in a forward direction.

With such a transducer, the beam intensity at the focal point is of the order of 100 times that at the emitting surface.

A coaxial RF cable 16, threaded through the handle 17 and the tube 18 connects the transducer 21 to the electronic control system 22,23,24 which is external to the probe.

The electronic control system comprises a variable frequency signal generator 22; a variable power, tuned, narrow-band RF amplifier 23; and an output matching transformer 24 for matching the impedance of the RF power amplifier 23 output to the probe transducer 21 input impedance. The control system further includes a control timer (not shown) with a range of 0-60 seconds, for initiating irradiation upon actuation of a footswitch (not shown) and automatically terminating irradiation after a predetermined interval. The control system also monitors the power applied to the transducer, and is set manually to switch the power off when the time-integrated power, i.e. total applied energy, reaches a preset threshold.

With reference to Figure 2, the apparatus described above with reference to Figure 1 finds greatest application in the treatment of the human eye. A human eye 20 has a cornea 13 which contains vitreous humour 15 bounded by sclera 12. It is possible for a haemorrhage, consisting of blood particles 14, to be localised at a region close to the centre of the eye and this will affect adversely the vision of the eye.

The apparatus described above is for dispersing such haemorrhages.

It has been found that above a certain energy ultrasonic waves in a liquid, such as the vitreous humour of a human eye cause microstirring, and this in itself can be sufficient to disperse a haemorrhage in the vitreous humour. Once dispersed, natural processes acting in the eye are able to carry away the dispersed matter and clear the vitreous humour.

Increased energy levels cause more vigorous microstirring and also the cavitation of the liquid. Cavitation is the developing of bubbles of vapour around microscopic nuclei, which expand and then suddenly contract releasing shock waves. These shock waves are particularly effective at dispersing a haemorrhage.

The apparatus described above with reference to Figure 1 operates on these principles.

In use, the probe 10 is held so that its outer, wavetransmitting surface lies adjacent the outer surface of the eye sclera 12, preferably in the pars plana region. A coupling medium 11, such as a diagnostic probe gel or a saline solution is placed between the transmitting surface and the sclera 12. The control timer is set at the required treatment time which, for may, for example, be 30 seconds, a time which has been found to be sufficient to disperse haemorrhages with no adverse effect on the sclera. The footswitch is then actuated to operate the transducer 21, which emits spherical ultrasonic waves focussed in the vitreous humour at the haemorrhage. As described above, these waves cause micro-stirring or, at increased energy levels, cavitation which disperses the haemorrhage. After the pre-set time, the timer halts the emission of ultrasonic waves and the treatment is halted.

The emitted beam does not damage the scleral tissue, since its effect is limited to the region of the eye close to the focal region of the transducer 21. In fact, for a bowl-shaped transducer 21 of the type described, the point of maximum beam intensity is located close to the centre of curvature, and on the side nearer the transducer. Since the cornea 13 is easily rendered opaque by ultrasonic radiation, and since it also absorbs and de-focusses the beam, this region of the eye should be avoided, even by the unfocussed portions of the beam. The probe may be moved over the eye to locate the precise point at which the focussed beam will most effectively disperse the haemorrhage.

An alternative to the bowl-shaped transducer is a planar disc transducer, also resonant in the thickness direction. The focussing of the emitted beam is then achieved with the provision of either a superimposed plastics lens, for use with liquid coupling means 11, or a liquid-filled acoustic cone acting itself as the coupling means 11. Variable focus transducers are also envisaged, the focal length being variable to suit the distance of the haemorrhage from the eye surface.

Clearly, the dimensions of the probe and the type of ultrasonic transducer means and the electronic control system are dictated by the nature of the haemorrhaged eye to be treated, and in particular the invention is not limited to a probe for the treatment of human eyes; animal eyes of different sizes may also be treated.

Although the invention has been illustrated in the form of a hand-held probe containing a transducer, it is envisaged that the transducer means could alternatively take the form of a fixed ultrasonic wave transmitter with a movable waveguide acting as the wave emitter. The transducer means is not necessarily hand-held, since the treatment could be performed by means of an automatically moveable probe or other ultrasonic wave emitter.

The invention has been described in relation to the dispersal of haemhorrhages in the eye. However, the apparatus of the invention is applicable also, in a similar manner, to the treatment of other lesions in the vitreous humour such as vitreous opacities due to massive vitreous retraction.

CLAIMS

1. Eye treatment apparatus for the *in vivo*

dispersal of a haemorrhage in the vitreous humour of an eye, comprising focussing ultrasonic transducer means adapted, when positioned adajcent the eye sclera, to emit an ultrasonic wave focussed within the vitreous humour sufficient to induce local microstirring to disperse the haemorrhage.

2. Apparatus according to claim 1, wherein the transducer means comprises a transducer housed at one end of a probe and adapted for engagement with a portion of the eye sclera by way of a coupling means.

3. Eye treatment apparatus for the *in vivo* dispersal of a haemorrhage in the vitreous humour of an eye, comprising a focussing ultrasonic transducer means having an emitter of ultrasonic waves, and a control system connected to the transducer means for controlling the transducer means so that the emitter, when positioned adjacent the eye sclera, emits an ultrasonic wave focussed within the vitreous humour sufficient to induce local microstirring to disperse the haemorrhage.

4. Apparatus according to claim 3, wherein the transducer means and the emitter are housed at one end of a probe.

5. Apparatus according to claim 3 or claim 4, wherein the control system comprises an RF signal generator, a power amplifier for amplifying an RF signal therefrom, and an output transformer for matching the impedances of the power amplifier output and the transducer input so that the concentration of the ultrasonic waves at the focal point is sufficient to cause said dispersal.

6. Apparatus according to claim 2 or 4, wherein the probe is a hand-held probe.

7. Apparatus according to any preceding claim, wherein the frequency range of the transducer means is from about 1MHz to 3MHz.

8. Apparatus according to any preceding claim, wherein the power range of the transducer means is from about 0.5W to 5W.

9. Apparatus according to any preceding claim, wherein the focal length of the transducer means is in the range of 8 to 14mm.

10. Apparatus according to claim 9, wherein the said focal length is approximately 11mm.

11. Apparatus according to claim 2 or any claim appendant thereto, wherein the transducer has a fixed focus.

12. Apparatus according to claim 11, wherein the transducer comprises a planar disc resonant in the thickness direction.

13. Apparatus according to claim 11, wherein the transducer comprises a part-spherical shell or bowl resonant in the thickness direction.

14. Eye treatment apparatus substantially as described herein with reference to the accompanying drawings.

CLAIMS

Amendments to the claims have been filed, and have the following effect:

Claims 1-3 above have been deleted or textually amended.

New or textually amended claims have been filed as follows:

1. Eye treatment apparatus for the non-invasive *in vivo* dispersal of a haemorrhage in the vitreous humour of an eye, comprising focussing ultrasonic transducer means adapted, when positioned adjacent and outside the eye sclera, to emit an ultrasonic wave focussed within the vitreous humour sufficient to induce local micro-stirring to disperse the haemorrhage.

2. Apparatus according to claim 1, wherein the transducer means comprises a transducer housed at one end of a probe and adapted for engagement with a portion of the eye sclera by way of a coupling means.

3. Eye treatment apparatus for the *in vivo* dispersal of a haemorrhage in the vitreous humour of an eye, comprising a focussing ultrasonic transducer means having an emitter of ultrasonic waves, and a control system connected to the transducer means for controlling the transducer means so that the emitter, when positioned adjacent and outside the eye sclera, emits an ultrasonic wave focussed within the vitreous humour sufficient to induce local micro-stirring to disperse the haemorrhage.

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