This invention is an apparatus (10, 12) for treatment of migraines or headaches comprising a headset (10) and transducers (80), mounted on the headset (10), for periodically applying noninvasive pressure to multiple locations on the head of a user. The noninvasive pressure may be applied with or without concomitant application of a gel on the head of a user.
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APPARATUS FOR TREATMENT OF MIGRAINE

FIELD OF THE INVENTION

The present invention relates generally to apparatus and techniques for non-invasive treatment of migraine and headache.

BACKGROUND OF THE INVENTION

Substantial efforts have been made over the years to cure or treat migraine and headaches. Various attempts have been made to establish a single mechanism for the cause of migraine.

The mechanism has been postulated to be, inter alia: a disorder of platelets (Hannington E, Jones RJ, Amess JA, Wachowicz B. Migraine: a platelet disorder. Lancet, ii 720-723, 1981), a cerebrovascular spasm (Wolff HG. Headache and other head pain, Oxford University Press, New York, 1963) and central dysnociception (Sicuteri F. Migraine, a central biochemical dysnociception, Headache, 16:145-149, 1986).

Generally, there are known two types of migraine: 1. migraine without aura, attacks of severe pulsating head pain, lasting up to 72 hours, associated with nausea and/or photophobia or phono-phobia, and aggravated by physical activity; and 2. migraine with aura: a similar pain phase heralded by an aura, characterized by gradually spreading neurological symptoms taking the form of spreading paresthesias and numbness in a hemiform pattern.
Tension-type headache is characterized by mild to moderate pain occurring in episodes of variable duration or continuously.

Based on the facts that migraine pain is usually pulsating and is relieved by vasoactive drugs, and often by vascular compression it has been determined that migraine pain is vascular in origin. Regional cerebral blood flow is markedly reduced, indicating that primary vasoconstriction is involved. (See: Olesen J. Some clinical features of the acute migraine attack. An analysis of 760 patients. Headache, 18:268-211, 1978; Blau, JN, Dexter SL. The site of pain origin during migraine attacks. Cephalalgia 1: 143-147, 1981.; Drummond PD, Lance JW. Extracranial vascular changes and the source of pain in migraine headache. Ann. Neurol. 13: 32-37, 1983; Tunis MM, Wolff MG. Long term observations of the reactivity of the cranial arteries in subjects with vascular headache of the migraine headache type.


Migraine pain is known to be aggravated by physical activity and may be triggered or aggravated by vasoactive drugs. (See Iversen HK, Langemark M, Andersson PG, Hansen PE, Olesen J. Clinical characteristics of migraine and episodic tension type headache in relation to old and new diagnostic criteria. Headache, 30:514-519, 1990); Krabbe AE, Olesen J. Headache provocation by continuous intravenous infusion of histamine: clinical results and receptor mechanism. Pain,

In the area of reduced regional cerebral blood flow, vasoreactivity is impaired or abolished (Lauritzen M, Skyhoj Olsen T, Lassen NA, Paulson OB. The regulation of regional cerebral blood flow during and between migraine attacks. Ann. Neurol. 14:569-572, 1983). Regional cerebral blood flow is markedly reduced, indicating that primary vasoconstriction must be involved (Olsen TS, Friberg L, Lassen NA. Ischemia may be the primary cause of the neurologic deficits in classic migraine. Arch. Neurol. 44 :258-161, 1987), and there is evidence of a stop-go flow pattern (Friberg L, Skyhoj Olsen T, Roland PE, Lassen NA. Cerebrovascular tone instability causing focal ischemia during attacks of hemiplegic migraine. Brain, 110: 917-934, 1987).

It has been reported that a posterior focal reduction in regional cerebral blood flow is observed first, followed by the symptoms of migrainous aura, which always precedes the headache. (See: Olesen J, Friberg L, Olsen TS,
Iversen HK, Lassen NA, Andersen AR, Karle A. Timing and
topography of cerebral blood flow, aura and headache during

Support for vascular nociception is the marked
tendency of patients suffering from migraine without aura to
develop headache after histamine and nitroglycerine, drugs
with a presumed vascular site of action. The pain and
associated symptoms are identical in both forms of migraine,
and both respond to the same drugs (See: Sicuteri, F, Bene
ED, Poggioni M, Bonnazzi A. Unmasking latent dysnociception in
JJ. Headache. In: Bonica (Ed), The management of pain, Lea and

Marked tenderness of pericranial muscles during
migraine attacks has been described. (See: Hay KM. Pain
thresholds in migraine, Practitioner, 222:827-833, 1979). The
muscles of migraine patients during attack-free periods are
more tender than those of headache free individuals (See:
Jensen K, Tuxen C, Olesen J. Pericranial muscle tenderness and
pressure-pain threshold in the temporal region during common

It has been found that in migraine, extracranial
vascular compression relieves the pain in less than half the
patients (See: Drummond PD, Lance JW. Extracranial vascular
changes and the source of pain in migraine headache, Ann.

The trigeminal ganglion is the sensory nerve of the
head, and its fibers are particularly important for head pain. (See: Moskowitz MA. The neurobiology of vascular head pain, Ann. Neurol. 16:157-168, 1984).

These fibers are projections from neurons mostly in the first division of the trigeminal ganglion and located in close proximity to, but discrete from, cells projecting to the forehead (See: O'Connor TP, Van der Kooy D. Pattern of intracranial and extracranial projections of trigeminal ganglion cells, J. Neurosci. 6: 2200-2207, 1986).

Some nociceptive specific neurons in the trigeminal nucleus caudalis receive input from nerve fibers around blood vessels via the trigeminal ganglion and also respond to stimulation of both intracranial and extracranial blood vessels. The above mentioned findings form the basis for our cranial programmed pulsating pressure (CPPP), treatment of cranial and forehead tissues.
SUMMARY OF THE INVENTION

The present invention seeks to provide apparatus and an improved technique for treatment of headache and migraine.

There is thus provided in accordance with a preferred embodiment of the present invention apparatus for treatment of migraine or headache comprising:

- a headset; and
- transducers, mounted on the headset, for periodically applying noninvasive pressure to multiple locations on the head of a user.

The noninvasive pressure may be applied with or without concomitant application of a gel on the head of the user.

There is also provided in accordance with a preferred embodiment of the present invention a method for treatment of migraine or headache comprising:

- mounting a headset onto a user; and
- employing transducers mounted on the headset for periodically applying noninvasive pressure to multiple locations on the head of a user.

In accordance with a preferred embodiment of the present invention, a conductivity sensor is employed for determining preferred locations on the user's head for application of pressure.

Preferably, the preferred locations are on the scalp and forehead of the user.

In accordance with a preferred embodiment of the
present invention, the transducers are operated by pressurized fluid. In accordance with an alternative preferred embodiment of the invention, the transducers are operated electrically.
BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

Fig. 1 is a pictorial illustration of apparatus for treating headache and migraine mounted in operative engagement with the head of a user;

Fig. 2 is a block diagram illustration of the apparatus shown in Fig. 1 in accordance with one embodiment of the present invention;

Fig. 3 is a block diagram illustration of the apparatus shown in Fig. 1 in accordance with another embodiment of the present invention;

Fig. 4A is a simplified perspective view of a fluid operated head engagement assembly constructed and operative in accordance with the present invention;

Figs. 4B, 4C, 4D and 4E are simplified illustrations of fluid operated head engagement assemblies constructed and operative in accordance with the present invention; and

Figs. 5A, 5B, 5C, 5D and 5E are simplified illustrations of electrically-operated head engagement assemblies constructed and operative in accordance with the present invention.
DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Reference is now made to Fig. 1, which is a pictorial illustration of apparatus for treating headache and migraine mounted in operative engagement with the head of a user. The apparatus comprises a head engagement subsystem, generally indicated by reference numeral 10 and a remote subsystem, generally indicated by reference numeral 12, which is coupled to the head engagement assembly 10 by means of an umbilical cord 14.

The head engagement subsystem 10 typically comprises a head engagement element 16, which may be rigid, semi-rigid or soft and may be made of any suitable structural material. A chin strap 18 may be associated with element 16 for holding it securely in place on a user's head. Mounted on head engagement element 10 are a plurality of head engagement assemblies 20 and a gel injector 68, the operation of which will be described in greater detail hereinbelow with reference to Figs. 4A - 5E.

The remote subsystem 12 typically comprises a housing 22 in which are disposed, inter alia, a pneumatic fluid reservoir 24 and a pneumatic fluid pressure controller 26 in fluid communication therewith, and an electrical power unit 28 which may be coupled to a source of mains power by means of a line cord 36.

Pressure controller 26 preferably comprises a pressure relief valve (not shown) which maintains fluid pressure within pressure controller 26 in a fluid pressure...
range between 0.5 to 3.0 atmosphere and preferably at about 1 atmosphere.

The electrical power unit 28 powers electric valves 30, as described hereinbelow, in response to signals from a controller 32. The controller 32 may comprise any suitably programmed microcomputer. The controller 32 is programmed for various treatment schedules and receives inputs from a skin conductivity sensing unit 34 for determining treatment sites.

Remote subsystem 12 communicates via umbilical cord 14 with the head engagement subsystem 10. The umbilical cord includes multiple fluidic conduits as well as low voltage electrical conductors for activating electrically operated transducers and or transmitting skin conductivity sensor outputs to the remote subsystem 12.

Reference is now made to Fig. 2, which is a block diagram illustration of the electrical control system of the apparatus shown in Fig. 1 in accordance with one embodiment of the present invention. In the illustrated embodiment of Fig. 2, the head engagement subsystem 12 includes a plurality of pneumatic transducers 50, which are operative to provide pressure pulses to selected locations on a user’s head, as well as a plurality of tissue conductivity sensors 52, which are associated with the pneumatic transducers.

The remainder of the apparatus shown in Fig. 2, forms part of the remote subsystem 12 (Fig. 1). It is seen that a manual operation switch 60 and an electrical operation switch 62 are both provided. The electrical operation switch 62
couples the apparatus to a source of mains power. For activation of the transducers under manual control, the manual operation switch directly operates electric valves 30, which are also controllable by an transducer schedule controller 64, which may be embodied in controller 32 (Fig. 1). Controller 64 receives electrical power via power unit 28, which is operated by switch 62.

Controller 64 interfaces with conductivity measurement system 34, which interfaces with tissue conductivity sensors 52.

Electric valves 30 are operative to provide pneumatic pulses to pneumatic transducers 50 and communicate via pressure controller 26 with pneumatic fluid reservoir 24. A gel injector 68 may be provided to inject gel to the transducers. The gel injector 68 may be a conventional pressurized container similar to a conventional can of shaving gel. A valve may be operatively associated with the gel injector 68 to control the flow of gel from the gel injector in response to commands from the transducer schedule controller 64. The gel may have a viscosity and consistency similar to that of a conventional shaving gel. The gel may be applied in conjunction with pulsed pressure treatment.

Reference is now made to Fig. 3, which is a block diagram illustration of the apparatus shown in Fig. 1 in accordance with one embodiment of the present invention. In the illustrated embodiment of Fig. 3, the head engagement subsystem 12 includes a plurality of electrical transducers
80, which are operative to provide pressure pulses to selected locations on a user's head, as well as a plurality of tissue conductivity sensors 82, which are associated with the electrical transducers 80.

The remainder of the apparatus shown in Fig. 3, forms part of the remote subsystem 12 (Fig. 1). It is seen that a manual operation switch 90 and a mains switch 92 are both provided. The manual operation switch provides inputs to a transducer schedule controller 94, which may be embodied in controller 32 (Fig. 1). Controller 94 receives electrical power via power unit 28, which is operated by switch 92.

Controller 94 interfaces with conductivity measurement system 34, which interfaces with tissue conductivity sensors 82. A gel injector 98 may be provided to inject gel to transducers 80. The gel injector 98 may be a conventional pressurized container similar to a conventional can of shaving gel. A valve (not shown) may be operatively associated with the gel injector 98 to control the flow of gel from the gel injector in response to commands from the transducer schedule controller 94. The gel may have a viscosity and consistency similar to that of a conventional shaving gel. The gel may be applied in conjunction with the pulsed pressure treatment, as described hereinbelow.

Reference is now made to Figs. 4A, 4B, 4C, 4D and 4E which are simplified illustrations of fluid operated head engagement assemblies constructed and operative in accordance with the present invention.

Fig. 4A illustrates a head engagement assembly,
fixedly attached to head engaging element 16, comprising a fluid operated piston, such as a pneumatic piston 100 which is coupled via a conduit 102 to a source of pressurized fluid (not shown) for controlling movement of piston 100. Fixed to piston 100 via a shaft 104 is a transducer head 106, typically including a plurality of pointed elements 108, typically formed of an elastic material to substantially conform to the contours of the head of the user. A typical diameter of the transducer head is approximately between a diameter between 20 to 80 mm and is preferably 40mm. According to a preferred embodiment of the present invention, a tissue conductivity sensor 110, such as a Bio-Tech AWQ-104, available from Mitan, Israel Center for Advanced Therapeutic Equipment Ltd., 15 Chen Blvd., Tel-Aviv, Israel, is mounted on one of the pointed elements 108.

The diameter of piston 100 and the pressure applied are such that the force exerted by each of the pointed elements 108 is between 0.5 Newton to 3 Newton and is preferably about 1 Newton.

Fig. 4B illustrates an alternative embodiment of head engagement assembly wherein a plurality of pointed elements 120 are each associated with a separate fluid operated piston assembly 122, supplied with pressurized fluid via a plurality of conduits 124. The pistons 122 move in cylinders 118 which are fixedly mounted on a common base 126, supported on a shaft 128.

The diameter of pistons 122 and the pressure applied
are such that a force between 0.5 to 3.0 N preferably about 1 N is exerted by each of the pointed elements 120.

Fig. 4C illustrates a composite head engagement assembly which comprises a fluid operated piston 130 which supports a common pusher element 134 within a housing 136. Disposed within housing 136 are a plurality of spring loaded pointed elements 138, one of which has associated therewith a tissue conductivity sensor 140.

The diameter of piston 130 and the pressure applied are such that a force between 0.5 to 3.0 N and preferably about 1 N is exerted by each of the pointed elements 138.

Fig. 4D illustrates a composite head engagement assembly 105 which comprises a fluid operated piston, such as a piston 100 which is coupled via a conduit 102 to a source of pressurized fluid (not shown). Fixed to piston 100 via a shaft 104 is a transducer head 106, typically including a plurality of pointed elements 108, typically formed of an elastic material, to substantially conform to the contours of the head of the user. According to a preferred embodiment of the present invention, a tissue conductivity sensor 110, such as a Bio-Tech AWQ-104, available from Mitar, Israel Center for Advanced Therapeutic Equipment Ltd., 15 Chen Blvd., Tel-Aviv, Israel, is mounted on one of the pointed elements 108.

The assembly 105 is coupled via a conduit 130 to a gel injector 68 as shown in Fig. 2. Injector 68 is activated by controller 64 or 94 to inject gel via conduit 130 into hollow volume 107 of the base of transducer head 106. Upon activation of piston 100, gel injected into volume 107 is
forced through orifices 140 on the head of the user and simultaneously pressure pulses are applied by means of elements 108.

The diameter of piston 100 and the pressure applied are such that a force between 0.5 to 3.0 N and preferably about 1 N is exerted by each of the pointed elements 108.

Fig. 4E illustrates an alternative embodiment of a head engagement assembly 705 wherein a plurality of pointed elements 720 are each associated with a separately operated piston 722 supplied with pressurized fluid via a conduit 724. The pistons 722 move in cylinders 728 which are fixedly mounted on a common base 726, supported on a shaft 728. According to a preferred embodiment of the present invention, a tissue conductivity sensor 110, such as a Bio-Tech AWQ-104, available from Mitar, Israel Center for Advanced Therapeutic Equipment Ltd., 15 Chen Blvd., Tel-Aviv, Israel, is mounted on one of the pointed elements 720.

The assembly is coupled via a conduit 730 to a gel injector 68 shown in Fig. 2. Injector 68 is activated by controller 64 or 94 to inject gel via conduit 730 into hollow volume 727 of the base 726. Upon activation of pistons 722, gel injected into the volume 727 is forced through orifices 740 on the head of the user and simultaneously pressure pulses are applied by means of elements 720.

The diameter of pistons 722 and the pressure applied are such that a force between 0.5 to 3.0 N preferably about 1 N is exerted by each of the pointed elements 720.
Reference is now made to Figs. 5A, 5B, 5C, 5D and 5E which are simplified illustrations of electrically-operated head engagement assemblies constructed and operative in accordance with the present invention.

Fig. 5A illustrates a head engagement assembly comprising an electrically operated transducer, such as a solenoid 150 which is coupled to an electrical power source (not shown). Fixed to solenoid 150 via a shaft 154 is a transducer head 156, typically including a plurality of pointed elements 158, typically formed of elastic material to substantially conform to the contours of the head of the user. According to a preferred embodiment of the present invention, a tissue conductivity sensor 160, such as a Bio-Tech AWQ-104, available from Mitar, Israel Center for Advanced Therapeutic Equipment Ltd., 15 Chen Blvd., Tel-Aviv, Israel, is mounted on one of the pointed elements 158.

The voltage applied to solenoid 150 is such that a force between 0.5 N and 3 N and preferably about 1 N is exerted by each of the pointed elements 158.

Solenoid 150 may be replaced by a linear motor such as manufactured by SAIA, Industrie/Electronik und Komponenten, CH-3280 Murten, Switzerland.

Fig. 5B illustrates an alternative embodiment of head engagement assembly wherein a plurality of pointed elements 170 are each associated with a separate solenoid 172, supplied with electricity via conductors 175. The solenoids 172 are fixedly mounted on a common base 176, supported on a shaft
The voltage applied to the solenoids 172 is such that a force between 0.5 to 3.0 N preferably 1 N is exerted by each of the pointed elements 170.

The solenoids 172 may be replaced by linear motors such as manufactured by SAIA, Industrie/Electronik und Komponenten, CH-3280 Murten, Switzerland.

Fig. 5C illustrates a composite head engagement assembly which comprises a solenoid 180 which supports a common pusher element 184 within a housing 186. Disposed within housing 186 are a plurality of spring loaded pointed elements 188, one of which has associated therewith a tissue conductivity sensor 190.

The voltage applied to the solenoid 180 is such that a force between 0.5 to 3.0 N preferably 1 N is exerted by each of the pointed elements 188.

The solenoid 180 may be replaced by linear motors such as manufactured by SAIA, Industrie/Electronik und Komponenten, CH-3280 Murten, Switzerland.

Fig. 5D illustrates a composite head engagement assembly 855 which comprises an electrically operated transducer, such as a solenoid 850 which is coupled to an electric power source (not shown). Fixed to solenoid 850 via a shaft 854 is a transducer head 856, typically including a plurality of pointed elements 858, typically formed of an elastic material, to substantially conform to the contours of
the head of the user. According to a preferred embodiment of the present invention, a tissue conductivity sensor 860, such as a Bio-Tech AWQ-104, available from Mitar, Israel Center for Advanced Therapeutic Equipment Ltd., 15 Chen Blvd., Tel-Aviv, Israel, is mounted on one of the pointed elements 858.

The assembly 855 is coupled via a conduit 870 to a gel injector 68 is shown in Fig. 3. Injector 68 is activated by controller 64 or 94 to inject gel via conduit 870 into hollow volume 857 in the base 856. Upon activation of solenoid 850, gel injected into the volume 857 is forced through orifices 875 on the head of the user and simultaneously pressure pulses are applied by means of elements 858.

The voltage applied to the solenoid 850 is such that a force between 0.5 to 3.0 N preferably about 1 N is exerted by each of the pointed elements 858.

The solenoid 850 may be replaced by a linear motor such as manufactured by SAIA, Industrie/Electronik und Komponenten, CH-3280 Murten, Switzerland.

Fig. 5E illustrates an alternative embodiment of a head engagement assembly 792 wherein a plurality of pointed elements 770 are each associated with a separately operated solenoids 772, supplied with electricity via conductors 775. The solenoids 772 are fixedly mounted on a common base 776, supported on a shaft 778 fixedly attached to head engaging element 16. According to a preferred embodiment of the present invention, a tissue conductivity sensor 780, such as a Bio-Tech AWQ-104, available from Mitar, Israel Center for Advanced Therapeutic Equipment Ltd., 15 Chen Blvd., Tel-Aviv,
Israel, is mounted on one of the pointed elements 770.

The assembly is coupled via a conduit 785 to a gel injector 68 is shown in Fig. 3. Injector 68 is activated by controller 64 or 94 to inject gel via conduit 785 into volume 794 of the base 776. Upon activation of pistons 772, gel injected into the volume 794 is forced through orifices 790 on the head of the user and simultaneously pressure pulses are applied by means of elements 770.

The voltage applied to the solenoids 772 is such that a force between 0.5 to 3.0 N preferably 1 N is exerted by each of the pointed elements 770.

The solenoids 772 may be replaced by linear motors such as manufactured by SAIA, Industrie/Electronik und Komponenten, CH-3280 Murten, Switzerland.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the present invention is defined only by the claims which follow:
CLAIMS

1. Apparatus for treatment of migraine or headache comprising:
   a headset; and
   transducers, mounted on the headset, for periodically applying pressure to multiple locations on the head of a user.

2. Apparatus according to claim 1 and wherein said pressure is applied with concomitant application of a gel on the head of a user.

3. Apparatus according to either claims 1 and 2 and also comprising a tissue conductivity sensor.

4. Apparatus according to any of claims 1 - 3 and wherein said transducers comprise pneumatic transducers.

5. Apparatus according to any of claims 1 - 3 and wherein said transducers comprise solenoids.

6. Apparatus according to any of claims 1 - 3 and wherein said transducers comprise linear motors.

7. A method for treatment of migraine or headache comprising:
   mounting a headset onto a user; and
   employing transducers mounted on the headset for
periodically applying pressure to multiple locations on the head of a user.

8. A method according to claim 7 and wherein said pressure is applied with concomitant application of a gel on the head of said user.

9. A method according to either of claims 7 and 8 and also comprising measuring tissue conductivity and employing the measurements for determining preferred locations on the user's head for application of pressure.

10. A method according to claim 9 and wherein the preferred locations are on the scalp and forehead of the user.
### INTERNATIONAL SEARCH REPORT

**International application No.**
PCT/US95/15083

#### A. CLASSIFICATION OF SUBJECT MATTER

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According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)


Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

#### C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of Box C. See patent family annex.

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Date of mailing of the international search report: 08 MAR 1996

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<td>US, A, 3,968,789 (SIMONCINI) 13 July 1976.</td>
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<td>A</td>
<td>WO, A, 79/00974 (MARKER) 29 November 1979.</td>
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<td>CH, B, 557 679 (LUTHER) 15 January 1975.</td>
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