Short title: Vasoregulation device

The present invention relates to a vasoregulation device for use during the phase prior to headache, in particular migraine, for applying pressure at least locally to one or more veins on the outside of the head, in order to restrict the flow of blood through the said veins, at least comprising pressure-exerting means.

Migraine is a periodically recurring headache which generally involves a very localized headache. Approximately 10% of the population suffers from a more or less serious form of migraine.

There are numerous forms of migraine, but generally a migraine attack consists of two important, distinct phases. There is a first pre-headache phase, often without pain, but with specific pre-headache symptoms, such as for example visual disturbances, including seeing coloured bubbles, lines and the like, or other disturbances, for example in hearing or the sense of taste or smell. Often, a spot of light, known as the "aura", is seen. Numbness or tingling of parts of the body, such as fingers, hands, lips and the like, also occurs.

In the case of the classical migraine attack, this pre-headache phase is accompanied by so-called vasoconstriction, which is a constriction of veins in the head, leading to a local increase in blood pressure.

In most cases, the pre-headache phase lasts for 5 to 30 minutes and disappears slowly together with the other pre-headache symptoms.

While these symptoms disappear slowly, they are replaced by the actual headache itself, which is often unbearable. This headache has a number of frequently occurring side-effects, such as nausea, increased sensitivity to light, noise or odour, visual disturbances, diarrhoea, yawning, sweating and the like. During this headache phase, a so-called vasodilatation occurs, namely a widening of blood vessels in the head, resulting in a reduction in blood pressure.

Numerous techniques and medicaments are known from the prior art for counteracting migraine, but these all act in the headache phase. Thus, it is known, for example, to arrange belts

or the like with increased tension around the head, possibly with discs positioned between them, during the headache, as is disclosed in US-A-5,419,758, or to administer medicaments which counteract the vasodilatation.

In this respect reference is also made to WO-A-9 907 323 of applicant which discloses a vasoregulation device using a bracket-like device with two arms as pressure-exerting means.

Applicant supprisingly has found that if the flow of blood to the head is reduced during the phase prior to the actual headache very little or no headache occurs during the subsequent headache phase. All other methods or medicaments actually do not suppress pain to a satisfactory extent. Also it is undesirable to carry out treatments to the head of a patient during the headache phase, owing to the oversensitivity to all external stimuli during the headache.

Applicant now has found that the pressure applied by the pressure-exerting means has to be very specific.

To that end the present invention is characterised in that said pressure-exerting means are designed to apply a pressure of 0,01-0,03 N/mm^2.

Preferably the pressure-exerting means are designed to apply a pressure of 0,015-0,025 N/mm^2 and more preferably a pressure of about 0,02 N/mm^2.

By applying this specific, relatively high pressure an optimal pain relieving effect is obtained.

By using the device according to the invention with the specific pressure it is possible, by restricting the flow of blood in certain veins on the outside of the head (on the outside of the skull) during the pre-headache phase, to substantially avoid pain completely during the subsequent headache phase. An important advantage of the device according to the invention is that headache is prevented without the use of a medicament.

In the present description, a vein is intended to mean both a blood vessel and an artery.

Preferably, the pressure-exerting means are designed to completely stop the flow of blood through the vein in question.

In particular, the pressure-exerting means are designed to apply pressure to at least one temporal vein, and preferably to both temporal veins.

Most preferably, the pressure-exerting means are designed to apply the pressure to the temporal vein just above the ear, before it branches off into two smaller veins.

The way in which pressure is applied to the vein(s) in question is in no way limited and may be carried out in a wide variety of ways.

In a particular embodiment, the pressure-exerting means comprise massaging means for allowing the pressure-exerting means to carry out a massaging movement.

In practice, it has been found that if, during the application of pressure, the pressure-exerting means carry out a massaging movement, which may comprise any known massaging movement, such as vibration, rotation, rolling and the like, a very effective action of the device is obtained.

The device according to the invention, may comprise a bracket with one or more pressure-exerting elements. Naturally, a bracket of this kind may be of any form which is suitable for allowing the pressure-exerting elements to apply the desired pressure. In particular, the bracket element forms part of a pair of spectacles, a set of headphones or a component thereof. Apart from these forms, consideration could also be given to a component of a face mask, shoulder supports, etc.

The number of pressure-exerting elements is not limited and may vary from 1 to even up to 10 pressure-exerting elements. Preferably, however, the device comprises two pressure-exerting elements, which are suitable for applying pressure to both temporal veins.

The form of the pressure-exerting surface of the pressure-exerting elements may vary as a function of the particular vein to which pressure is to be applied. In particular, the pressure-exerting elements comprise a rounded pressure-exerting surface with dimensions which are slightly greater than the diameter of the vein to which pressure is being applied.

The material of which the pressure-exerting means are made is not particularly critical, but advantageously that section of the pressure-exerting means which comes into contact with the

head at the location of the vein in question is made of soft, slightly resilient plastic material.

Particularly advantageously, that section of the pressure-exerting means which comes into contact with the head at the location of the vein in question, i.e. the pressure-exerting elements, are designed in such a manner that they are self-aligning. To this end, the pressure-exerting elements may, for example, be attached such that they can pivot in a number of directions.

In a particular embodiment of the device according to the invention, the pressure-exerting means comprise two hinged arms, which are optionally directly coupled to one another, having pressure-exerting elements, it being possible for the arms to interact with spring means in order to provide the necessary pressure. This embodiment will be explained in more detail below with reference to the drawing. This concerns a headphone-type device which can be worn over the head, behind the head or under the chin.

Preferably, the spring means comprise a so-called constant-force spring. These are springs which, under load, create an approximately constant reaction force, in this case the force exerted by the pressure-exerting means on the respective veins. The reaction force (and hence the pressure), is determined by the spring force, the arm of the spring force and the arm of the reaction force, and can be kept substantially equal for all practical displacements of the spring, i.e. for all practical sizes of the ordinary human head. This can be achieved by selecting fastening points for the spring with respect to the pressure-exerting means.

In the device according to the invention, the constant-force spring preferably is fastened to one of the hinged arms at a first fastening point and to the other of the hinged arms at a second fastening point, the angle between the line connecting the pivot of the first hinged arm and the first fastening point, and the line connecting the pivot of the second hinged arm and the second fastening point being larger than the angle between the line connecting the pivot of the first hinged arm and the pressure-exerting means of the first hinged arm and the line connecting the pivot of the second hinged arm and the pressure-

exerting means of the second hinged arm. This ensures that when the device is fit to a human head, the pressure exerted on the head by the pressure-exerting means is substantially equal for all ordinarily sized human heads. In practice a pressure difference of less than ± 1% can be obtained.

For example, assuming mirror-symmetry and both hinged arms being coupled to the same pivot, the fastening points of the spring are selected such that the line connecting each fastening point and the pivot intersects the line of symmetry of the device at a larger angle than does the line connecting the pressure-exerting means and the pivot. This has the effect that, for a changing angle between the hinged arms and thus a changing displacement of the spring, the change in the spring force is compensated by an opposite change of the arm of the spring force, such that its torque changes at substantially the same rate as the arm of the reaction force. Thus t
he reaction force remains substantially constant.

In a special embodiment, the constant-force spring of the device comprises a spring with a low spring constant but a relatively high prestress. In this case there will be only a relatively small change in the spring force when the spring is displaced when the device is adapted to fit a smaller or larger head.

Advantageously, the constant-force spring of the device has been prestressed with at least 20%, and preferably at least 50% of the maximum spring force that can be exerted with the device when fit on an ordinarily sized human head. This can be realized by using a long helical spring which has been prestressed.

Advantageously each arm further comprises a proximal arm portion and a distal arm portion pivotably connected to each other, said pressure-exerting element being connected to said distal arm portion and the proximal arm portion being hingedly connected to the proximal arm portion of the other arm. This embodiment will also be illustrated in the description of the drawing.

More advantageously said pressure-exerting element is connected to said distal arm portion at a point substantially opposite from the point of connection between said distal arm portion and said proximal arm portion.

In particular said device is substantial foldable by pivoting said distal arm portions to positions alongside said proximal arm portions. In this manner the device according to the invention can be stored in e.g. a case similar to a well known eye-glass case.

In a specific embodiment of the device according to the invention said arms further are hingedly connected to said spring means. In this embodiment both arms comprise distal and proximal pivotably connected arm portions which form the arms, said arms being hingedly connected to said spring means.

The invention will now be explained in more detail with reference to the appended drawing, in which:

FIG. 1 is a diagrammatic view of a human head, showing the typical relative positions of the temporal blood vessels;

FIG. 2 is a front elevation view of the device according to an embodiment of the present invention;

FIG. 3 is the device of FIG. 2 shown in partly folded position;

FIG. 4 is the device of FIG. 2 shown in a fully folded position;

FIG. 5 is the device of FIG. 2 shown with the arms slightly pulled apart, as in preparation for use by a user;

FIG. 6 shows a partially folded configuration of the device, suitable for wear by a user;

FIG. 7 is an exploded view of the device of FIG. 2;

FIG. 8 is a front elevation illustrating one mode in which a user may wear the device of FIG. 2;

FIG. 9 is a front elevation showing a second mode for wearing the device of FIG. 2;

FIG. 10 is a perspective view showing a third mode of wearing the device of FIG. 2; and

FIG. 11 is a flow diagram illustrating the method of using the device according to the invention.

The present invention will now be described more fully hereinafter with reference to the accompanying drawings, in which preferred embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the illustrated embodiments set forth herein. Rather, these illustrated

embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Like numbers refer to like elements throughout, and prime notation when used indicates similar elements in alternative embodiments.

FIG. 1 is a diagrammatic view of a typical human head showing the relative positions of the extracranial blood vessels flowing through the temporal area of the head. The blood vessel 21 typically runs anteriorly to the ear, and diverges into two smaller vessels 22 and 23 above the ear, the smaller vessels respectively running anteriorly and posteriorly on the head, as shown. The skilled artisan will know that this description refers primarily to the use of the invention generally over a temporal blood vessel 21. The invention may, however, be equally applicable to blood vessels positioned adjacently underlying the skin elsewhere in the body. Hence, the term "blood vessel" when used herein may apply to one or to a plurality of blood vessels lying along the temporal area or along other areas of the body.

The invention, shown in FIGS. 2 through 10, comprises a vasoregulation device 20 for aiding in compressing a blood vessel 21 adjacently underlying the skin. The device comprises spring means as known in the art, preferably a spring 25, and more specifically, a prestressed helical spring for producing a substantially constant force, an arm 27 connected to the spring 25 for transmitting the force, and a pressure element 29 connected to the arm for applying the force to the skin in the form of pressure to thereby aid in compressing the blood vessel 21. The device 20 may further preferably comprise a plurality of arms 27 connected to the spring 25, as shown in FIGS. 2-10, for transmitting the force in more than one direction. In addition, the device 20 may also comprise a plurality of pressure elements 29 for applying the force as pressure at more than one point on the skin, e.g. as seen in FIG. 2.

Advantageously, the pressure may be applied by the device 20 with motion to thereby provide a substantially massaging action. Those skilled in the art will recognize that pressure may be applied with motion in a variety of ways including, for example, in the form of vibrational force, rotational force, alternating pressure and release, or a combination thereof. The

skilled worker will also readily understand that known means such as small motors may be included in the device to produce such massaging motion.

In addition, in the device 20 the spring means, or spring 25 preferably produces a substantially constant force and transmits the force to apply a substantially constant pressure for aiding in compressing the blood vessel 21. Those skilled in the art will know that a biasing member (spring means) which produces a substantially constant force, and particularly a constant force spring, may be produced by known manufacturing methods. A constant force spring, for example, applies a substantially constant force regardless of displacement. Thus, the force applied by the device 20, and consequently the pressure, remains constant regardless of the head size of the user. Moreover, application of a substantially constant force provides the advantage of not requiring manual adjustment by the user, which may result either in insufficient pressure, or in excessive pressure being applied.

New reference is made to fig. FIG. 5. The torque (the force multiplied by the arm of the force) of the spring force of spring 28 around hinge 39 must be counterbalanced by an equal but opposite torque of the force exerted by the pressure-exerting elements 29 on the vein. For symmetry reasons only the right hand side of the device is considered. As shown in FIG. 5 the torque of the spring force depends on the angle α between its arm II and the line I of symmetry of the device 20. The torque of the force that causes the pressure in the pressure-exerting means depends on the angle β between its arm III and the line I of symmetry of the device.

Angles α and β change when the hinged arms 33 are rotated to adapt the device 20 for a smaller or larger head. Furthermore, the spring force depends on the length of the spring 25, and hence also on α. This extra angle dependence can be compensated by making α larger than β. In the device depicted in FIG. 5 $\alpha-\beta$ is about 40°. In this case, when the hinged arms are rotated, both α and β change at the same rate. The spring force increases with increasing α but its arm II decreases faster than the arm III (roughly a $\cos\alpha$ as compared to a $\cos\beta$, with α larger than β). The net effect is that the force and

hence the pressure as applied by the pressure-exerting elements 29 remains substantially the same for all normal human head sizes. In particular the difference in exerted pressure, as encountered with normal sized human heads, can be kept below 1%.

The pressure applied by the device 20 is preferably in the range of from about 0.01 to about 0.03 newtons per square millimeter. More preferably, the pressure comprises a range from about 0.015 to about 0.025 newtons per square millimeter, and most preferably of about 0.02 newtons per square millimeter. To apply such pressure, the applicator 29 preferably has a surface area of about 200 square millimeters, although the skilled will know that the surface area of the applicator may be of a different dimension.

In a preferred embodiment of the invention, the pressure application device comprises two arms 27 connected to the spring 25 for transmitting the substantially constant force, and a pressure element 29 connected to each arm 27 for applying the force to the skin in the form of pressure to thereby aid in compressing the blood vessel 21. The device having two arms 27, each having a pressure applicator 29, advantageously allows the user to position the device 20 so as to apply pressure to both temporal areas simultaneously, as illustrated in FIGS. 2-10.

The pressure application device 20 includes a folding embodiment, as shown in FIGS. 2-10, wherein each arm 27 further comprises a proximal arm portion 31 hingedly connected to the spring 25, a distal arm portion 33 pivotably connected to the proximal arm portion 31, and a pressure element 29 connected to the distal arm portion. The pivoting mechanism connecting the proximal and distal arm portions also includes a distal arm pivot click plate 34, shown in FIG. 7, which functions to allow the distal arm portion 33 to pivotably move in defined increments, or clicks. The proximal arm portion 31 also preferably includes a proximal arm cover 32, as shown in FIG. 7.

In this embodiment the pressure element 29 is preferably connected to the distal arm portion 33 at a point substantially opposite from the point of connection between the distal arm portion and the proximal arm portion 31, as seen in FIG. 7 The arms 27 of the device 20 are preferably also hingedly connected to each other, as shown in FIGS. 2-10. This embodiment of the

device also preferably may be disposed to apply pressure with motion to thereby provide a substantially massaging action.

In yet another preferred embodiment, the pressure application device 20 for aiding in compressing an extracranial blood vessel comprises a spring means, e.g. spring 25, for producing a force, and two elongated curved arms 27 connected to the biasing member for transmitting the force. The connected curved arms define a substantially elliptical curve having the spring means preferably positioned along a major axis of the elliptical curve, as seen in FIGS. 2 and 5. A pressure element 29 is connected to each curved arm for applying the force to the skin in the form of pressure, to thereby aid in compressing the blood vessel. The skilled practitioner will know that an extracranial blood vessel of the head lies outside the skull proper, or cranium, and adjacently underlies the skin so that it is positioned between the skin and the skull.

This embodiment of the invention also preferably comprises foldable curved arms 27, as shown in FIGS. 3, 4, and 6, wherein each arm further comprises a proximal arm portion 31 hingedly connected to the spring means (biasing member), or spring 25, a distal arm portion 33 pivotably connected to the proximal arm portion, and wherein the pressure element 29 is connected to the distal arm portion. A preferred hinge connection mechanism is illustrated in FIG. 7, and includes spring 25 positioned within a sleeve 35, and two pins 37 connecting the spring to the arms 27, preferably to the proximal arm portions 31, as shown. The spring 25 produces a force tending to bring the arms 27 together, a force which is applied as pressure when the device is properly worn on the head by a user, as illustrated in FIGS. 8-10. As shown in FIGS. 4-10, the arms 27 are also hingedly connected to each other, preferably by a hinge 39 comprising a resilient plastic material such as polypropylene. The pressure element 29, which is preferably connected to the distal arm portion 33 at a point substantially opposite from the point of connection between the distal arm portion and the proximal arm portion 31, as seen in FIG. 2, also preferably includes a cover 41. The cover 41 may be somewhat resilient to provide some distribution of pressure over the temporal area of the user. The cover 41 may also be easily replaceable for sanitary

purposes if the device 20 is to be shared among various users. The device is thus foldable by pivoting the distal arm portions 33 to positions alongside the proximal arm portions 31, as shown in FIGS. 3 and 4. This folding action is further aided by the arms 27 being hingedly connected to each other, as seen in FIG. 4, to allow more compact folding. As in other embodiments, the device 20 may preferably apply pressure with motion to thereby provide a massaging action.

The invention also includes a portable system for compressing an extracranial blood vessel underlying skin on a person's head. The system includes any of the folding embodiments of the pressure application device 20 and a substantially pocket sized carrying case wherein the folded pressure application device may be conveniently carried by the user, the case being somewhat similar to an eyeglass case.

The way in which the device according to the invention can be used for compressing an extracranial blood vessel is shown in FIG. 11 which from the start at Block 51 includes the step of producing a substantially constant force (Block 53) in a mechanical device by a constant force helical spring. The method then follows by applying the constant force (Block 55) on the temporal blood vessel by positioning the mechanical device adjacent thereto so as to apply the force as substantially constant pressure. A preferable pressure in this method is a substantially constant pressure of about 0,02 N/mm^2.

In the same way the development of a migraine headache, can be substantially arrested, which is also illustrated in FIG. 11. The method includes from the start (Block 51) using a biasing member in a mechanical device to produce a substantially constant pressure of about 0,02 N/mm^2, followed by applying the substantially constant force (Block 55) to a temporal blood vessel during the pre-headache stage of a migraine (Block 57) by positioning the mechanical device adjacent the temporal blood vessel so as to apply the force as substantially constant pressure thereon. The application of pressure is continued until the pre-headache phase ends, the method then stopping at Block 59.

CLAIMS

1. Vasoregulation device for use during the phase prior to headache, in particular migraine, for applying pressure at least locally to one or more veins on the outside of the head, in order to restrict the flow of blood through the said veins, at least comprising pressure-exerting means, characterised in that said pressure-exerting means are designed to apply a pressure of 0.01 - 0.03 N/mm^2 .

2. Device according to claim 1, characterised in that the pressure-exerting means are designed to apply a pressure of 0.015 - 0.025 N/mm^2.

3. Device according to claim 2, characterised in that the pressure-exerting means are designed to apply a pressure of about 0,02 N/mm^2.

4. Device according to one or more of the preceding claims, characterised in that the pressure-exerting means are designed to apply pressure to the temporal vein (21) just above the ear, before it branches off into two smaller veins (22, 23).

5. Device according to one or more of the preceding claims, characterised in that the pressure-exerting means comprise massage means for allowing the pressure-exerting means to carry out a massaging movement.

6. Device according to one or more of the preceding claims, characterised in that the pressure-exerting means comprise two hinged arms (27), which are optionally directly coupled to one another, having pressure-exerting elements (29), it being possible for the arms (27) to interact with spring means (25) in order to provide the necessary pressure.

7. Device according to claim 6, characterised in that the springs means (25) comprise so-called constant-force spring.

8. Device according to claims 6 or 7, characterised in that each arm (27) further comprises a proximal arm portion (31) and a distal arm portion (33) pivotably connected to each other, said pressure-exerting element (29) being connected to said distal arm portion (33) and the proximal arm portion (31) being hingedly connected to the proximal arm portion (31) of the other arm (27).

9. Device according to claim 8, characterised in that said pressure-exerting element (29) is connected to said distal arm portion (31) at a point substantially opposite from the point of connection between said distal arm portion (33) and said proximal arm portion (31).

10. Device according to claim 8 or 9, characterised in that said device is substantially foldable by pivoting said distal arm portions (33) to positions alongside said proximal arm portions (31).

11. Device according to one or more of claims 6-11, characterised in that said arms (27) further are hingedly connected to said spring means.