Apparatus for Treatment of Living Tissue by Stimulation by means of Pulses of Electric Current and/or by means of Electro-Magnetic Waves.

The present invention relates to an apparatus for the therapeutic treatment of living tissue by stimulation by means of pulses of electric current and/or electro-magnetic waves.

Apparatus has already been proposed, for thereapeutic treatment by stimulation of living tissue by means of pulses of electric current and electro-magnetic waves, especially of electro-magnetic waves. In the known apparatus the transmission of the electric current or of the electro-magnetic waves to the tissue to be treated is carried out by means of devices such as electrodes or antennae, each adapted to the type of current or wave to be transmitted. Also, each apparatus is designed to enable a well defined type of treatment to be put into effect.

The present invention seeks to provide an apparatus which enables a new type of treatment, combining a plurality of stimulations by current or waves of different natures, which are applied in succession or simultaneously to a region of a living organism.

According to the invention there is provided an apparatus for the therapeutic treatment of living tissue by stimulation by means of pulses of electric current and/or by means of electro-magnetic waves, comprising: a generator for providing rectangular d.c. pulses having a pulse duration from 0.5 to 5 milliseconds at a voltage from 10 to 100 millivolts with a repetition frequency from 10 to 100 Hertz and a generator for providing alternating current having a frequency from 20 to 100 Megahertz modulated with a frequency of modulation from 2.5 to 6000 Hertz, and a futher generator for producing electromagnetic waves, and a common means for applying the electric current and/or the electro-magnetic waves output from the generators, in succession or simultaneously to a region of the living tissue to be treated.

The means of application of the generator outputs may be

an endonasal probe.

Preferably that a generator of a.c. pulses produces pulses in sinusoidal form or in a form having an equivalent effect (for example, in the form of square pulses).

Preferably the generator of electro-magnetic waves produces waves having a wavelength which corresponds with the visible band of the spectrum of electro-magnetic radiation, in the form of a beam of coherent light.

Preferred embodiments of the invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a general diagram of an apparatus in accordance with a first enbodiment,

Figure 2 shows an embodiment of an endonasal probe which may form part of the apparatus represented in Figure 1,

Figure 3 is a section on a scale enlarged with respect to that of Figure 2, of the front portion of the probe represented in Figure 2,

Figure 4 is a section on the same scale as that of Figure 3, of the rear portion of the probe represented in Figure 2,

Figure 5 shows another embodiment of an endonasal probe,

Figure 6 is a section of endonasal probe in accordance with a variant upon the embodiment illustrated in Figure 5,

Figure 7 represent an energy applicator in the form of a fork which may be employed in replacement of the endonasal probes illustrated in Figures 2 to 6,

Figure 7b represents a variant upon the energy applicator as Figure 7,

Figure 8 is a section of the applicator illustrated in Figure 7 along the plane indicated by the line VIII-VIII in Figure 7,

Figures 8b to 8d are sections similar to Figure 8, which illustrate variants upon the shape of the energy applicators represented in Figures 7, 7b and 8,

Figure 9 is a partial view of the applicator as Figure 7, along the plan IX-IX in Figure 7,

Figure 10 is a partial view of the applicator as Figure 7, along the plan X-X in Figure 7,

Figure 11 is a partial view of the applicator as Figure 7, along the plan XI-XI in Figure 7,

Figures 12a to 12c represent respectively a side elevation and a plan of a support for two endonasal probes as well as a diagrammatic view illustrating the method of use of this support, and

Figures 13a to 13c are diagrammatic views illustrating the method of use of a buccal energy applicator which may be employed in the apparatus in accordance with the invention.

The apparatus represented in Figure 1 comprises a low-frequency d.c. pulse generator 1 capable of producing current pulses in the form of a rectangular signal having, for example, a pulse width of the order of 0.5 to 5 milliseconds with a frequency of 10 to 100 Hertz at a voltage of the order of some tens of millivolts, preferably from 10 to 100 millivolts, a high-frequency a.c. generator

2, modulated at low-frequency, capable of producing an electrical signal formed of a sinusoidal wave or square pulses having a frequency of the order of some tens of Megahertz, preferably from 20 to 100 Megahertz, modulated in sinusoidal from with a frequency of modulation of the order of some tens of Hertz, preferably from 2.5 to 6000 Hertz, the power of this generator 2 being preferably of the order of 0.1 to 1 Watt and a generator 3 which is a laser emitter comprising, for example, a Helium-Neon tube capable of emitting a coherent and monochromatic red light beam having a wavelength of 632.8 nanometres in the form of a light signal modulated with a frequency variable from 1 to 160 Hertz. In replacement of the Helium-Neon tube one might equally employ any other suitable source of coherent monochomatic light, for example, a Gallium Arsenide photo-diode.

A control and display device 4 is connected to the generators 1 and 2, and to laser emitter 3 by respective control signal transmission lines 5, 6 and 7. The control and display device 4 enables the emission of energy by the generators and the laser emitter to be controlled in accordance with the needs of the treatment which it is desired to carry out by means of the apparatus in accordance with a pre-established programme in which the characteristics of the luminous electrical signals are made to vary as well as the duration of emission and the sequence of application of each of the signals, and the data of the programme so chosen to be displayed.

The generators 1 and 2 and the laser emitter 3 are respectively connected to a probe 8 for application of energy, by way of the lines 10 and 11 for transmission of electrical signals and of an optical fibre line 12 for transmission of signals and of a switch 9 (shown schematically in Figure 1) which is likewise controlled by the control and display device 4 by way of a control signal

transmission line 13.

The switch 9 is arranged so as to enable the signal transmission lines 10, 11 and 12 to be connected in succession or simultaneously to the probe 8 for application of energy, the connection between the probe 8 and the switch 9 being effected by means of a line 14 for mixed transmission of electrical and luminous signals. The return of the electric current is effected by means of an electrically conductive handle (not shown) which is held in the hand by the patient during the application of the electrical signals and is connected to the generators 1 and 2 by an electrically conductive line which is likewise not shown.

The endonasal probe 8 represented in Figure 2 comprises a middle portion 20 consisting of an electrically insulating sheath 15 which is flexible or semi-rigid and, for example, of plastics matter, surrounding an optical fibre line 16 for the tranmission of luminous signals, round which is wound in a spiral a line 17 for transmission of electrical signals, a front portion 18 intended for placing inside the endonasal cavity of a patient and a rear portion 19 for connection with the mixed transmission line 14.

The front portion 18 of the probe 8, shown in Figure 3, comprises a tubular piece 21 of a material which is a good electrical conductor, for example, copper or brass, formed of an elongated cylindrical portion 21a surrounded by an annular portion 21b, while these two portions may be in one piece as shown in Figure 3 they may equally well consist of two distinct pieces assembled together by any suitable means, for example, by brazing to enable easy flow of electricity from one portion to the other. The annular portion 21b is placed slightly nearer that end of the elongated portion 21a which is intended to be placed towards the front of the probe 8 so that the length of the tubular section 21'a of the portion 21a

overhanging towards the front is smaller than that, 21''a, which overhangs towards the rear. This latter tubular section 21''a is forced into the sheath 15 so as to ensure the integration of the piece 21 with this sheath 15. The line 16 for transmission of luminous signals may consist of a single optical fibre as shown in Figure 3, but it might equally well consist of a bundle of a number of optical fibres. This line 16 for transmission of luminous signals is preferably forced with light friction into the central bore in the piece 21 to project slightly towards the front of the probe.

The end of the line 17 for transmission of electrical signals, which consists, for example, of a copper wire, is connected electrically to the piece 21 by means, for example, of a spot of solder 22.

A rounded tip 23 of matter which is transparent or translucent at least for the radiation transmitted by the line 16, is attached to the tubular section 21'a to surround this section as well as the portion of the optical fibre line 16 for transmission of luminous signals, which project from the front of the piece 21, so that the sidewall of the annular portion 21b of the piece 21 is left bare and lies flush between the outer wall of the sheath 15 and the surface of the tip 23 to form an annular area conductive of electricity. The sidewall of the annular portion 21b remaining thus bare is advantageously covered with a coating which is a good electrical conductor and resistant to the action of physiological media, for example, with a thin layer of gold.

The rear portion 19 of the probe 8 comprises a tubular piece 24 of a material which is a good electrical conductor, for example, copper or brass. An elongated cylindrical portion 24a is forced into the sheath 15 in the same way and with the same object as the section 21''a of the tubular portion 21a of the piece 21 is forced in at the

other end of the sheath 15. The rear end of the line 16 for the transmission of luminous signals is forced partially inside the central bore in the piece 24 and the rear end of the conductor wire 17 is connected electrically to the piece 24 by a spot of solder 22'. The optical fibre transmission line 16 terminates in a plane cross-section 25 which is strictly perpendicular to the axis of the optical fibre (or fibres) so as to enable an optical joint of good quality with another optical fibre 16' forming the component for transmission of the luminous signal in the mixed transmission line 14 which connects the probe 8 to the remainder of the apparatus.

It will be understood that the front portion 18 of the probe 8 enables energy to be applied in succession or simultaneously in the form of electric current and in the form of luminous radiation in one and the same region of the same extent of the organism which is to be treated, which under the circumstances is the endonasal mucous membrane.

The endonasal probe represented in Figure 5 has the general shape of a stiletto or, more precisely, of a catheter. It is composed of a straight elongated middle portion 30, only the ends of which are shown in Figure 5 in order to facilitate its representation, as well as a front portion 28 of a shape which is rounded in order to facilitate the introduction of the probe into the endonasal cavum without risk of injury or of irritation of the mucous membrane, and of a rear portion 29 of cylindrical shape. As may be seen in Figure 5 the front portion 28 and rear portion 29 have a diameter slightly greater than that of the middle portion 30, the scale of Figure 5 corresponding approximately with a factor of enlargement of 10 with respect to the real dimensions. The body 58 of the probe represented in Figure 5 may consist, for example, of one single piece moulded from synthetic or natural plastics or elastomeric matter such as a synthetic resin like ABS or

hard rubber. This body 58 advantageously exhibits a certain flexibility in order to facilitate adaptation of its shape to that of the endonasal cavities and to contribute to reduction in the risk of injury to the mucous membrane at the time of placing the probe in position in these cavities.

The outer surface of the body 58 is covered with a layer 26 of electrically conductive matter consisting, for example, of a thin metallic layer formed by atomisation, etc... The function of this conductive layer 26 is to enable transmission of the electric current and/or the electro-magnetic waves proceeding from the energy generators of the apparatus in accordance with the invention, from the rear portion 29 of the probe which enables connection with the energy transmission line proceeding from these generators, up to the front portion 28 which forms the member which is the applicator of current or of the waves in the quite localised region of the surface of the endonasal mucous membrane with which it is in contact. The conductive layer 26 advantageously consists of a material having a high resistance to oxidation and to the action of the physiological media, for example, gold, silver, aluminium, chromium, etc... The cover of the surface of the body 58 by the layer 26 may be total or only partial, for example, in the form of continuous bands covering the middle portion 30 and connecting zones of wider area covering entirely the front portion 28 and the rear portion 29 of the probe. The rear portion 29 plays the part of connector piece similar to the rear portion 19 of the probe 8 of the embodiment illustrated in Figures 2 to 4. However, because in the embodiment illustrated in Figure 5 the probe does not comprise any line for transmission of luminous signals, it is suitable only for the application of energy in the form of an electric current and/or of electro-magnetic waves, to the exclusion of luminous waves.

On the contrary the probe in accordance with the

embodiment represented in Figure 6, the general shape and the arrangement of which are similar to those of the probe illustrated in Figure 5, comprises in addition a line 16 for transmission of luminous signals, which is placed on the axis of the body 68 of the probe and is similar to that which is designated by the same referecne number in the probe in accordance with the embodiment illustrated in Figures 2 to 4. Hence it likewise enables the application of energy in the form of luminous waves, for example, in the form of coherent light, in addition to that of electrical and/or electro-magnetic energy conveyed by the conductive layer 26 which covers entirely or partially the body 68.

It should be noted that the conductive layer 26 is represented in Figure 5 to have a thickness which is exaggerated with respect to the real proportions between this thickness and the diameter of the different portions of the probe, in order to facilitate understanding of the arrangement of the probe.

The energy applicator 78 represented in Figure 7 to 11 has the general shape of a fork composed of a middle portion 70, two curved arms 78a and 78b and a cylindrical connector rod 79 enabling electrical connection of the applicator to the generators of pulses of electric current and/or of electro-magnetic waves.

The section of the whole of the applicator 78 (Figure 8) and of different portions of it, that is, of the middle portion 70 (Figure 9) and of two cross-sections of the arms 78a and 78b (Figures 10 and 11) show details of the form of this applicator.

Apart from its particular shape, the aim of which is to guarantee great safety to the user by limiting the risks of injury and of irritation of the endonasal mucous membrane, the applicator 76 has an arrangement and operation similar to those of the probe illustrated in Figure 5. In particular it may consist of one single piece moulded from

plastics matter entirely or partially covered with an electrically conductive layer (not shown) having the same function as the layer 26 on the probe as Figure 5.

Numerous variations may be applied as illustrated, for example, in Figures 8b, 8c and 8d, to the form of the applicator 78, especially as far as the spacing, slope and radii of curvature of the arms 78a and 78b are concerned. The dimensions of the applicator may likewise vary, especially in order to allow adaptation to the dimensions of the users' nasal cavities as well as to the different exact points of application of the energy. On the other hand the applicator 78 might be equipped with one or more lines for transmission of energy in the form of luminous waves, to play the same part as the line 16 in the probes illustrated in Figures 2 to 4 and in Figure 6. For example, as shown in Figure 7b such a line for transmission of energy in the form of luminous waves might consist of a bundle of optical fibres 76, which is incorporated in the body of the applicator 78 and connects the connector rod 79 to the free ends of the arms 78a and 78b by dividing in the middle portion 70 into two distinct bundles 73a and 73b which continue respectively inside the arms 78a and 78b out to the free ends 80a and 80b of the latter, coming to lie flush with the rounded surfaces of these ends so as to enable there the outlet of the luminous rays conveyed by these bundles of optical fibres.

The support 81 represented in Figures 12a, 12b and 12c is composed of a central portion 82 and two side portions 83a and 83b arranged on opposite sides of the central portion 82 and movable in rotation with respect to it about an axis consisting of a screw 84.

The three portions 82, 83a and 83b of the support 81 are preferably realised in the form of pieces moulded from plastics matter, for example, of an ABS synthetic resin, the surface of which is at least partially covered

with an electrically conductive layer, for example, a layer of a metal such as silver, chromium of aluminium, formed or applied by any suitable technique such a metallisation under vacuum or thermal atomisation.

Two endonasal probes 8a and 8b similar to that which is represented in Figure 5, pass through respective bores 85a and 85b arranged in the side portions 83a and 83b respectively of the support 81. The middle portions 30a and 30b of the probes 8a and 8b are arranged so as to be able to slide against the inner walls of the bores 85a and 85b which are likewise covered with an electrically conductive layer connected electrically to that which covers the portions 83a and 83b. The conductive layer covering the portion 82 is likewise in electrical contact with that which covers the portions 83a and 83b. Thus the pulses of electric current or of electro-magnetic waves proceeding from the energy generators of the apparatus in accordance with the invention, by way of the transmission line 14 (Figure 1) may be transmitted to the rear portion 89 of the central portion 82, which serves for the electrical connection to the line 14, out to the conductive layers which cover the probes 8a and 8b. Thanks to the rotation of the side portions 83a and 83b as well as to the sliding of the probes 8a and 8b in the bores 85a and 85b the probes 8a and 8b may be placed in position with very great accuracy so that their front ends are in contact with the desired areas of the endonasal mucous membranes, as represented in Figure 12c. In addition, as shown diagrammatically in dotted lines in this Figure, the probes may be curled due to their flexibility, so as to adopt the shape of the endonasal cavum.

The buccal energy applicator 138 represented in Figures 13a, 13b and 13c has a shape which is partially similar to that of a dental prosthesis. The central portion 139 of it is arranged so as to be able to adopt the shape of the palate as far as the rear termination of the

cartilaginous portion of the soft palate. The front portion of it comprises a clip 140 arranged so as to be able to be placed on the incisors, so as to enable the position of the applicator 138 to be fixed. It may in addition be kept in place by the pressure of the tongue. The electrical and electro-magnetic connection of the energy applicator 138 with the energy transmission line 14 (Figure 1) is effected by way of a connector portion 141 playing the same part as the portion 79 of the energy applicator illustrated in Figures 7 to 11, the surface of the applicator 138 being entirely or partially covered with an electrically conductive layer.

The buccal energy applicator which has just been described might possibly be equipped with one or more lines for transmission of luminous signals, consisting, for example, of one or more optical fibres or bundles of optical fibres incorporated into the body of the applicator and lying flush with the surface of it at parts corresponding with the zones which are to be treated, in a similar manner to the case of the endonasal applicator illustrated in Figure 7b.

The invention is in no way restricted to the embodiments of the apparatus and of the probe or endonasal or buccal energy applicator which have just been described and it is clear that numerous other variants and combinations of these embodiments are possible as will easily appear to specialists.

In exerting effects by means of the apparatus which has just been described, of successive stimulations by a signal consisting of a series of rectangular d.c. pulses having a pulse width of 2 milliseconds with a frequency of 70 Hertz at a voltage of 0.03 volts, the duration of each series of pulses being 15 seconds, a signal modulated sinusoidally with a frequency of 50 Hertz, of high-frequency a.c. having a frequency of 27 Megahertz with a power of 500

milliwatts (alternating output voltage of the modulated signal: 50 Volts), the duration of application of this second signal being 25 seconds, and a luminous signal of coherent light consisting of a laser radiation having a wavelength of 632.8 nanometres with a power of 2.5 milliwatts, this radiation being modulated at very low frequency (1 to 160 Hertz), the duration of application of this third signal being 30 seconds, these three types of stimulation being linked alternately without intermediate stopping time, for a total duration of 5 to 20 minutes, a combination is obtained of a favourable action upon the nervous equilibrium, especially upon the neurovegetative equilibrium, resulting probably from the combination of stimulations by the rectangular d.c. electric pulses and by the high frequency a.c. modulated by the signal at very low frequency, and of an action which is anti-inflammatory and reconstituent of the cellular functions, which may be attributed to the effect of the stimulation by the radiation from the laser emitter.

Of course the apparatus in accordance with the invention may be employed for the application of combined stimulations by other additional forms of energy, especially by stimulations by fluxes from electro-magnetic of magnetic waves of very varying characteristics. Similarly the aplication of the stimulations may be carried out not only upon the endonasal mucous membrane or the buccal mucous membrane but likewise upon any other suitable portion of the organism which is to be treated.

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CLAIMS:

1. An apparatus for the therapeutic treatment of living tissue by stimulation by means of pulses of electric current and/or by means of electro-magnetic waves, comprising: a generator for providing rectangular d.c. pulses having a pulse duration from 0.5 to 5 milliseconds at a voltage from 10 to 100 millivolts with a repetition frequency from 10 to 100 Hertz and a generator for providing alternating current having a frequency from 20 to 100 Megahertz modulated with a frequency of modulation from 2.5 to 6000 Hertz, and a futher generator for producing electromagnetic waves, and a common means for applying the electric current and/or the electro-magnetic waves output from the generators, in succession or simultaneously to a region of the living tissue to be treated.

2. An apparatus as claimed in claim 1, wherein the generators are operatively connected to control means which can vary the characteristics of the outputs from the generators.

3. An apparatus as claimed in claim 2, wherein the generators are operatively connected to the means for applying the electric current and/or electro-magnetic waves by switching means which is controllable to provide the outputs from the generators in succession or simultaneously.

4. An apparatus as claimed in any one of claims 1 to 3, wherein the generator of electro-magnetic waves is for producing electromagnet waves having a wavelength which corresponds with the visible band of the spectrum of electro-magnetic radiation, in the form of a beam of coherent light.

5. An apparatus as claimed in any of claims 1 to 4, wherein the generator of electro-magnetic waves is a laser emitter which emits a beam of coherent light.

6. An apparatus as claimed in any preceding claim, wherein

the means for applying the pulses of electric current and/or the electro-magnetic waves consists of an endonasal probe having an elongate cylindrical shape with a blunt end.

7. An apparatus as claimed in claim 6, wherein the probe consists of one single piece moulded from plastics matter, the outer surface of which is at least partially covered with an electrically conductive layer arranged so as to enable transmission of an electric current between one rear end portion of the probe and a front end portion by way of a middle portion of the probe.

8. An apparatus as claimed in claim 6 or claim 7, wherein the probe has a line for transmission of luminous signals, which comprises at least one optical fibre incorporated into the body of the probe.

9. An apparatus as claimed in any one of claims 1 to 5, wherein the means for applying the pulses of electric current and/or the electro-magnetic waves is an endonasal applicator of fork shape.

10. An apparatus as claimed in claim 9, wherein the applicator consists of one single piece moulded from plastics matter, which is composed of a middle portion of two curved arms and a connector rod, the outer surface of which is at least partially covered with an electrically conductive layer enabling transmission of an electric current between the connector rod and the respective free ends of the arms.

11. An apparatus as claimed in claim 10, wherein the applicator has a line for transmission of luminous signals, which comprises a bundle of optical fibres incorporated into the body of the applicator and divided into two bundles which extend respectively into the arms, the free ends of these two bundles lying flush with the surfaces of the front faces of the free ends of the arms so as to enable the transmission of luminous rays between the

rear end of the connector rod and the front faces of the ends of the arms.

12. An apparatus as claimed in any one of claims 1 to 8, wherein there is a support which enables simultaneous application of two endonasal probes of stiletto shape in the endonasal cavum.

13. An apparatus as claimed in any one of claims 1 to 5, wherein the means for applying the electric current and/or the electro-magnetic waves consists of a buccal applicator which comprises a central portion arranged so as to be able to adopt the shape of the palate, a front portion comprising a clip for attachment to the incisors and a portion for connection to the generators of pulses of electric current and/or of electro-magnetic waves.

14. An apparatus as claimed in claim 13, wherein the buccal applicator has at least one line for transmission of luminous signals, which consists of at least one optical fibre incorporated into the body of the applicator and lying flush with the surface of the central portion so as to enable tranmsission of the luminous signals between the connector portion and the surface of the central portion.

15. An endonasal probe which forms in the apparatus as in claim 1, the means for applying the pulses of electric current and/or the electro-magnetic waves to the endonasal mucous membrane of a patient, comprising a middle portion which consists of an electrically insulating sheath surrounding at least one line for transmission of electrical signals and at least one line for tranmission of electro-magnetic waves in the form of a beam of coherent light, a front portion which comprises an electrically conductive tubular piece connected to a first end of the line for transmission of electrical signals and having passing through it a first end of the line for transmission of the beam of coherent light

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and a rounded tip of matter which is transparent or translucent to the radiation transmitted by the line for transmission of coherent light, this tubular piece exhibiting an annular wall which remains bare and lies flush between the wall of the insulating sheath and that of the tip, and a rear portion which comprises an electrically conductive tubular piece connected to the other end of the line for transmission of electrical signals and having passing through it partially the other end of the line for transmission of coherent light, this latter line terminating inside a central bore in the tubular piece in a plane cross-section perpendicular to its axis to enable an optical joint to be formed with another line for transmission of coherent light.

16. An apparatus for the therapeutic treatment of living tissue by stimulation by means of pulses of electric current and/or by means of electro-magnetic waves, substantially as herein described with reference to Figure 1, and Figures 2 to 4, Figures 5 and 6, Figures 7 to 11, Figure 12, or Figure 13 of the drawings.

17. A probe which forms the means for applying electric current and/or the electro-magnetic waves output from the generators of an apparatus for the therapeutic treatment of living tissue by stimulation by means of pulses of electric current and/or by means of electro-magnetic waves, substantially as herein described with reference to Figures 2 to 4, Figures 5 and 6, Figures 7 to 11, Figure 12 or Figure 13 of the drawings.