TITLE OF THE INVENTION:

ELECTRODE SYSTEM FOR VISION TREATMENT ~~AND METHOD~~

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority benefit, including under 35 U.S.C. §119(e), of U.S. Provisional Patent Application 63/025,987 filed May 15, 2020 by Thu-Ha Duncan, et al., titled "Electrode system for vision treatment and method," which is incorporated herein by reference in its entirety.

[0002] This application is related to:
U.S. Patent 10,391,312 issued on August 27, 2019 to Mowery et al. titled "Apparatus and method for ocular microcurrent stimulation therapy,"
PCT Patent Application No. PCT/US2016/051550, filed September 13, 2016 by Mowery et al. titled "Apparatus and method for ocular microcurrent stimulation therapy" (published as WO 2017/048731),
U.S. Provisional Patent Application No. 62/283,870, filed September 15, 2015 by Mowery et al., titled "Appliance for microcurrent stimulation therapy using a disposable material afixed to the upper and lower eye lid & other body parts,"
U.S. Provisional Patent Application No. 62/283,871, filed September 15, 2015 by Masko et al., titled "Apparatus for a method of application of microcurrent stimulation therapy, consisting of a goggle device affixed to & encircling the upper and/or lower eyelids, as well as other body parts,"
U.S. Provisional Patent Application No. 62/365,838, filed July 22, 2016 by Tapp et al., titled "Appliance for micro-current stimulation,"
PCT Application Serial Number PCT/US2019/063404 filed on November 26, 2019, by Masko et al., titled "APPARATUS AND METHOD FOR MICROCURRENT STIMULATION THERAPY" (published as WO 2020/131329),
PCT Application Serial Number PCT/US2019/067627 filed on December 19, 2019, by Masko et al., titled "MICROCURRENT-STIMULATION-THERAPY APPARATUS AND METHOD" (published as WO 2020/132337),
U.S. Provisional Patent Application 62/783,116 filed on December 20, 2018, by Masko et al., titled "APPARATUS AND METHOD FOR MICROCURRENT STIMULATION THERAPY," each of which is incorporated herein by reference in its entirety.

What is claimed is:CLAIMS

1. An apparatus comprising:

an electrode system for use in electrical-stimulation treatment, testing and monitoring of vision problems of eyes of a patient, the electrode system including:

a plurality of eyelid electrodes configured to be applied to one or more eyelids of the patient, and

a plurality of skin-contact return-electrode areas on an insulating polymer substrate, wherein the plurality of return-electrode areas is configured to be applied to a rear portion of the patient's head; and

an electrical controller operatively coupled to the plurality of eyelid electrodes and to the plurality of skin-contact return-electrode areas, and configured to control electrical currents applied through each one of the plurality of eyelid electrodes and to the skin-contact return-electrode areas so as to selectively alter a geometry of electric fields through the eyes of the patient.

2. The apparatus of claim 1, wherein the plurality of eyelid electrodes includes a first eyelid electrode on a first substrate strip configured to be applied to a first eyelid of a first eye of the patient and a second eyelid electrode on a second substrate strip configured to be applied to a first eyelid of a second eye of the patient.

3. The apparatus of claim 1, wherein the electrical controller is further configured to selectively alter the geometry of the electric fields through the eyes of the patient over a plurality of times during a single treatment session.

4. The apparatus of claim 1, wherein the plurality of skin-contact return-electrode areas are electrically connected to each other via an electrically conductive bridge.

5. The apparatus of claim 1, wherein the plurality of skin-contact return-electrode areas includes a first return-electrode area and a second return-electrode area, wherein the first return-electrode area is electrically isolated from the second return-electrode area, and wherein both the first return-electrode area and the second return-electrode area are driven with individually controlled signals from the electrical controller.

6. The apparatus of claim 1, wherein the plurality of skin-contact return-electrode areas includes a first return-electrode area placed on a first side of the rear portion of the patient's head across from a first eye of the patient, and a second return-electrode area placed on a second side of the rear portion of the patient's head across from a second eye of the patient, and

wherein the electrical controller is further configured to control the electrical currents applied through each one of the plurality of eyelid electrodes and to the plurality of skin-contact return-electrode areas so as to generate a first electric field that passes through the first eye of the patient and to both the first and second return-electrode areas.

7. The apparatus of claim 1, wherein the plurality of skin-contact return-electrode areas includes a first return-electrode area placed on a first side of the rear portion of the patient's head across from a first eye of the patient, and a second return-electrode area placed on a second side of the rear portion of the patient's head across from a second eye of the patient, and

wherein the electrical controller is further configured to control the electrical currents applied through each one of the plurality of eyelid electrodes and to the plurality of skin-contact return-electrode areas so as to generate a first electric field that passes through the first and second eye of the patient and to the first return-electrode area.

8. The apparatus of claim 1, wherein the plurality of skin-contact return-electrode areas includes a first return-electrode area placed on a first side of the rear portion of the patient's head across from a first eye of the patient, and a second return-electrode area placed on a second side of the rear portion of the patient's head across from a second eye of the patient, and

wherein the electrical controller is further configured to control the electrical currents applied through each one of the plurality of eyelid electrodes and to the plurality of skin-contact return-electrode areas so as to generate a first electric field that passes through the first eye of the patient and to the second return-electrode area.

9. The apparatus of claim 1, wherein the plurality of skin-contact return-electrode areas includes a first return-electrode area placed on a first side of the rear portion of the patient's head across from a first eye of the patient, and a second return-electrode area placed on a second side of the rear portion of the patient's head across from a second eye of the patient, and

wherein the electrical controller is further configured to control the electrical currents applied through each one of the plurality of eyelid electrodes and to the plurality of skin-contact return-electrode areas so as to generate a first electric field that passes through the first eye of

the patient and to the first return-electrode area.

10. A method for treating eyes of a patient, the method comprising:

providing an electrode system that includes:

a plurality of eyelid electrodes, and

a plurality of skin-contact return-electrode areas on an insulating polymer substrate;

applying the plurality of eyelid electrodes to one or more eyelids of the patient;

applying the plurality of skin-contact return-electrode areas to a rear portion of the patient's head; and

controlling electrical currents applied through each of one of the plurality of eyelid electrodes and to the plurality of skin-contact return-electrode areas in order to alter a geometry of electric fields through the eyes of the patient.

11. The method of claim 10, wherein the applying of the plurality of skin-contact return-electrode areas includes:

placing a first return-electrode area on a first side of the rear portion of the patient's head across from a first eye of the patient, and

placing a second return-electrode area on a second side of the rear portion of the patient's head across from a second eye of the patient;

wherein the controlling of the electrical currents includes generating a first electric field that passes through the first eye of the patient and to both the first and second return-electrode areas.

12. The method of claim 10, wherein the applying of the plurality of skin-contact return-electrode areas includes:

placing a first return-electrode area on a first side of the rear portion of the patient's head across from a first eye of the patient, and

placing a second return-electrode area on a second side of the rear portion of the patient's head across from a second eye of the patient;

wherein the controlling of the electrical currents includes generating a first electric field that passes through the first and second eye of the patient and to the first return-electrode area.

13. The method of claim 10, wherein the applying of the plurality of skin-contact return-electrode areas includes:

placing a first return-electrode area on a first side of the rear portion of the patient's head across from a first eye of the patient, and

placing a second return-electrode area on a second side of the rear portion of the patient's head across from a second eye of the patient;

wherein the controlling of the electrical currents includes generating a first electric field that passes through the first eye of the patient and to the second return-electrode area.

14. The method of claim 10, wherein the applying of the plurality of skin-contact return-electrode areas includes:

placing a first return-electrode area on a first side of the rear portion of the patient's head across from a first eye of the patient, and

placing a second return-electrode area on a second side of the rear portion of the patient's head across from a second eye of the patient;

wherein the controlling of the electrical currents includes generating a first electric field that passes through the first eye of the patient and to the first return-electrode area.

15. The method of claim 10, further comprising:

electrically connecting the plurality of skin-contact return-electrode areas to each other via an electrically conductive bridge.

16. The method of claim 10, wherein the plurality of skin-contact return-electrode areas includes a first return-electrode area and a second return-electrode area, the method further comprising:

electrically isolating the first return-electrode area from the second return-electrode area, wherein the controlling of the electrical currents includes driving both the first return-electrode area and the second return-electrode area with individually controlled signals.

1710. A system for monitoring vision characteristics of an eye of a patient, wherein the system comprises:

a personal electronic device, wherein the personal electronic device includes a processor, a memory operatively coupled to the processor, and a user interface operatively coupled to the processor;

an application that executes on the personal electronic device, wherein the application includes:

an output driver that executes on the processor and causes output of a transient light pattern to an eye of a patient,

a response unit that executes on the processor and is configured to elicit and receive an indication of a response of the patient to a perception by the patient of the visually perceptible light pattern, and

an assessment module that executes on the processor, wherein the assessment module is configured to perform a first vision analysis on the eye of the patient at a first temporal moment in order to produce a first vision-characteristic result, wherein the assessment module is further configured to perform the first vision analysis on the eye of the patient at a second temporal moment in order to produce a second vision-characteristic result, wherein the assessment module is further configured to store the first vision-characteristic result and the second vision-characteristic result in the memory, and wherein the assessment module is further configured to perform a first comparison between the first vision-characteristic result and the second vision-characteristic result, and

wherein the user interface is configured to output a first message based at least in part on the first comparison.

~~18~~11. A system for monitoring vision characteristics of an eye of a patient and for treating the eye of the patient, the system comprising:

a personal electronic device, wherein the personal electronic device includes:

a processor,

a memory operatively coupled to the processor, and

a user interface operatively coupled to the processor,

an electrode system operatively coupled to the personal electronic device, wherein the electrode system includes:

a plurality of eyelid electrodes configured to be applied to one or more eyelids of the patient, and

one or more return electrodes configured to be applied to a rear portion of the patient’s head to facilitate adjustment of the geometry of signal flow through tissues of the patient;

an application that executes on the personal electronic device, wherein the application includes:

an output driver that executes on the processor and causes output of a transient

light pattern to an eye of a patient,

a response unit that executes on the processor and is configured to elicit and receive an indication of a response of the patient to a perception by the patient of the visually perceptible light pattern,

an assessment module that executes on the processor, wherein the assessment module is configured to perform a first vision analysis on the eye of the patient at a first temporal moment in order to produce a first vision-characteristic result, and

a treatment module that executes on the processor, wherein the treatment module is configured to cause the electrode system to adjust a first treatment on the eye of the patient based at least in part on the first vision-characteristic result.

~~19~~12. The system of claim ~~18~~11, wherein the assessment module is further configured to perform the first vision analysis on the eye of the patient at a second temporal moment in order to produce a second vision-characteristic result, wherein the assessment module is further configured to store the first vision-characteristic result and the second vision-characteristic result in the memory, and wherein the assessment module is further configured to perform a first comparison between the first vision-characteristic result and the second vision-characteristic result, and

wherein the user interface is configured to output a first message based at least in part on the first comparison.

~~20~~13. The system of claim ~~18~~11, wherein the treatment module is further configured to cause the electrode system to adjust the first treatment such that a geometry of electric fields through the eye of the patient is selectively altered.

~~21~~14. The system of claim ~~18~~11, wherein the treatment module is further configured to cause the electrode system to adjust the first treatment such that the first treatment includes:

a first series of pulses that gradually increase in electrical-current amplitude until a patient-discomfort signal is received by the system,

a second series of pulses applied at a therapeutic electrical-current amplitude, wherein the therapeutic electrical-current amplitude is below a discomfort-level electrical-current amplitude that corresponds with the received patient-discomfort signal, and

a third series of pulses that gradually decrease in electrical-current amplitude from the therapeutic electrical-current amplitude.

22. A method for monitoring vision characteristics of an eye of a patient and for treating the eye of the patient, the method comprising:

providing a personal electronic device and an electrode system operatively coupled to the personal electronic device;

outputting, using the personal electronic device, a transient light pattern to an eye of a patient;

eliciting and receiving, into the personal electronic device, an indication of a response of the patient to a perception by the patient of the visually perceptible light pattern;

performing, using the personal electronic device, a first vision analysis on the eye of the patient at a first temporal moment in order to produce a first vision-characteristic result; and

adjusting a first treatment on the eye of the patient applied by the electrode system based at least in part on the first vision-characteristic result.

23. The method of claim 22, further comprising:

performing, using the personal electronic device, the first vision analysis on the eye of the patient at a second temporal moment in order to produce a second vision-characteristic result;

storing the first vision-characteristic result and the second vision-characteristic result into memory coupled to the personal electronic device;

performing, using the personal electronic device, a first comparison between the first vision-characteristic result and the second vision-characteristic result, and

outputting, using the personal electronic device, a first message based at least in part on the first comparison.

24. The method of claim 22, wherein the adjusting of the first treatment on the eye of the patient includes selectively altering a geometry of electric fields through the eye of the patient.

25. The method of claim 22, wherein the adjusting of the first treatment on the eye of the patient includes:

applying a first series of pulses to the eye of the patient, wherein the first series of pulses gradually increase in electrical-current amplitude until a patient-discomfort signal is received;

applying a second series of pulses to the eye of the patient at a therapeutic electrical-current amplitude, wherein the therapeutic electrical-current amplitude is below a discomfort-

level electrical-current amplitude that corresponds with the received patient-discomfort signal; and

applying a third series of pulses to the eye of the patient, wherein the third series of pulses gradually decrease in electrical-current amplitude from the therapeutic electrical-current amplitude.

26. The method of claim 22, wherein the electrode system includes a plurality of eyelid electrodes and plurality of skin-contact return-electrode areas, wherein the method further includes:

electrically connecting the plurality of skin-contact return-electrode areas to each other via an electrically conductive bridge;

applying the plurality of eyelid electrodes to one or more eyelids of each eye of the patient;

applying the plurality of skin-contact return-electrode areas to a rear portion of the patient's head, wherein the applying of the plurality of skin-contact return-electrode areas includes:

placing a first return-electrode area on a first side of the rear portion of the patient's head across from a first eye of the patient, and

placing a second return-electrode area on a second side of the rear portion of the patient's head across from a second eye of the patient;

wherein the adjusting of the first treatment on the eye of the patient includes generating a first electric field that passes through the first eye of the patient and to the second return-electrode area.

27<u>15</u>. An apparatus comprising:

an electrode system for use in electrical-stimulation treatment, testing and monitoring of vision problems of eyes of a patient, the electrode system including:

a plurality of eyelid electrodes configured to be applied to one or more eyelids of the patient, and

a plurality of skin-contact return-electrode areas on an insulating polymer substrate, wherein the plurality of return-electrode areas is configured to be applied to a location on the patient's skin other than the one or more eyelids of the patient; and

an electrical controller operatively coupled to the plurality of eyelid electrodes and to the

plurality of skin-contact return-electrode areas, and configured to control electrical currents applied through each one of the plurality of eyelid electrodes and to the skin-contact return-electrode areas so as to selectively alter a geometry of electric fields through the eyes of the patient.