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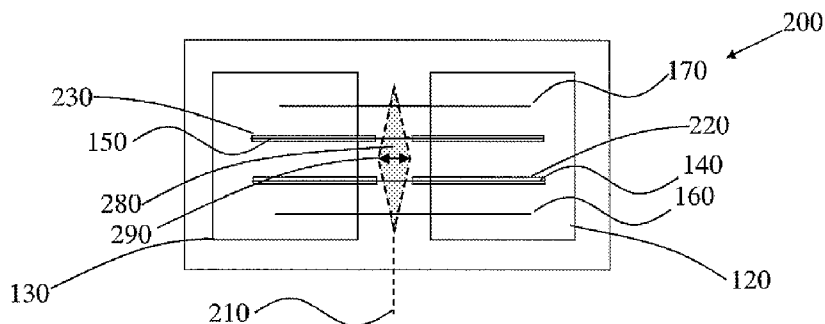


FIG. 2

(57) Abstract: A system for prevention of hypertrophic scars is disclosed, the system includes a first patch configured to be affixed to a first portion of skin proximate to a first side of a skin irregularity, a second patch configured to be affixed to a second portion of skin proximate to a second side of the skin irregularity, and a first actuation wire positioned between the first patch and the second patch and selectively placed in (i) a contracted state when an electrical current passes through the first actuation wire and (ii) a relaxed state when the electrical current ceases to pass through the first actuation wire.

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**System and Method for Prevention of
Hypertrophic Scars by Actuatable Patch**

PRIORITY

[0001] The present U.S. application is related to, and claims the priority benefit of U.S. Provisional Patent Application Serial No. 61/358,442, filed June 25, 2010, the contents of which is hereby incorporated by reference in its entirety into this disclosure.

TECHNICAL FIELD

[0002] The present disclosure generally relates to wound closure systems and particularly to wound closure systems aimed at prevention of hypertrophic scars.

BACKGROUND

[0003] Hypertrophic scars occur at incision locations after a disturbance to skin, e.g., resulting from a surgical procedure. In addition to cosmetic concerns, such scars could also limit a patient's function, particularly the patient's joint mobility. Formation of hypertrophic scars is largely driven by tension at the wound site. Generally, scars are fibrous tissues that replace skin, after an incision has been made in the surgical procedure or after suffering an injury. Hypertrophic scars form as a result of body's overproduction of collagen which causes the scar to be raised above the surrounding skin near where the injury or incision had taken place. Although there are several products and treatments that may assist in reducing the

effects of hypertrophic scars after the scars are formed, a better way to treat hypertrophic scars is to avoid or at least minimize the formation of excess collagen.

[0004] Different approaches for repairing wounds have been investigated. Skin grafts are now often utilized in many clinical situations, e.g., burns, open/gaping wounds, and ulcers. Besides the closure of fresh wounds and burns, skin grafts become essential to reconstructing inappropriately healed skin with hypertrophic or keloid scars (be it due to a past burn or surgery). A skin graft can be an autograft (i.e., the donor is the subject/patient himself/herself) or allograft (harvesting skin from another donor). Autograft procedures require operations on other locations in the body. Such donor locations are susceptible to a host of morbidities, such as bleeding, pain, lack of healing or scar formation. Alternatively, allograft usually presents immunologic challenges while disease transmission remains a potential risk. An alternative to skin grafts is use of biomaterials. An ideal biomaterial that is to replace skin at an injury site has yet to be developed. Most biomaterials are useful only at the early onset phase of an injury and usually serve the mere function of wound dressing.

[0005] No matter what material or method is used, excessive scars may be formed proximate the area of repair. Such excessive scars, besides the cosmetic concerns and associated impact on patient psychology, also present challenges in terms of affecting ambulation when located near joints. Therefore, technology which can regenerate patients own skin as part of the healing process is of great use. Patient's own skin is far superior to any other option in terms of immunological response, matching of complexion, presence of hair follicles and sebaceous glands.

[0006] Therefore, there is a need for a system and a method that avoids or minimizes formation of hypertrophic scars. Further, there is a need for an alternative approach to skin grafting in clinical applications.

SUMMARY

[0007] In one form, a system for prevention of hypertrophic scars is disclosed. The system includes a first patch configured to be affixed to a first portion of skin proximate to a first side of a skin irregularity. The system further includes a second patch configured to be affixed to a second portion of skin proximate to a second side of the skin irregularity. The system also includes a first actuation wire positioned between the first patch and the second patch and is selectively placed in (i) a contracted state when an electrical current passes through the first actuation wire and (ii) a relaxed state when the electrical current ceases to pass through the first actuation wire.

[0008] In another form, a method of prevention of hypertrophic scars is disclosed. The method includes affixing a first patch to a first portion of skin proximate to a first side of a skin irregularity. The method also includes affixing a second patch to a second portion of skin proximate to a second side of the skin irregularity. The method further includes fixedly coupling a first actuation wire to the first patch. The method also includes fixedly coupling the first actuation wire to the second patch. The first actuation wire is configured to be selectively placed in (i) a contracted state when an electrical current passes through the first actuation wire and (ii) a relaxed state when the electrical current ceases to pass through the first actuation wire.

BRIEF DESCRIPTION OF DRAWINGS

[0009] FIG. 1 is a block diagram of a system for prevention of hypertrophic scars by actuatable patches that can be used for wound healing.

[0010] FIG. 2 is a schematic of a system similar to that depicted in FIG. 1 in use in a noncontracted position.

[0011] FIG. 3 is a schematic of a system similar to that depicted in FIG. 1 in use in a contracted position.

[0012] FIG. 4 is a photograph of a system similar to that depicted in FIG. 1 in use in a noncontracted position.

[0013] FIG. 5 is a photograph of a system similar to that depicted in FIG. 1 in use in a contracted position.

[0014] FIG. 6 is a schematic of an excitation circuit used in a system similar to that depicted in FIG. 1, in accordance with one embodiment.

[0015] FIG. 7 is a circuit board layout of the excitation circuit of FIG. 6.

[0016] FIG. 8 is an exemplary cyclic waveform generated by the excitation circuit of FIG. 6.

DETAILED DESCRIPTION

[0017] For the purposes of promoting an understanding of the principles of the present disclosure, reference will now be made to the embodiments illustrated in the drawings, and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of this disclosure is thereby intended.

[0018] A novel arrangement and method of using the arrangement for prevention of hypertrophic scars by actuatable patches have been disclosed. The system utilizes actuatable patches to promote healthy wound closure and healing with no or minimum formation of hypertrophic scars.

[0019] Referring to FIG. 1, a block diagram of a wound closure system 100 is provided. The system 100 includes an excitation circuit 110 which is in communication with a first patch 120 (identified as Patch 1). The first patch 120 is in communication with a second patch 130 (identified as Patch 2). The circuit loop between the excitation circuit 110, the first patch 120, and the second patch 130 are completed by a pair of actuation wires 140 and 150, and by a pair of excitation wires 112 and 114. The excitation wire 112 is connected to the actuation wire 140 and the excitation wire 114 is connected to the actuation wire 150. As a result of this connectivity, the system 100 is configured to provide electrical current from the excitation circuit 110 to the actuation wire 140 through the excitation wire 112 and through the first patch 120 and back to the excitation circuit 110 through the actuation wire 150 through the excitation wire 114 and through the second patch 130.

[0020] A first electrical conduction path (not shown) can be provided, as part of the first patch 120, between the excitation wire 112 and the actuation wire 140. The first conduction path (not shown) can be connected to the excitation wire 112 via a terminal or other connections known to a person of ordinary skill in the art. The first conduction path (not

shown) can also be connected to the actuation wire 140 via a terminal or other connections known to a person of ordinary skill in the art. The first electrical conduction path (not shown) is configured to provide electrical connectivity between the excitation wire 112 and the actuation wire 140.

[0021] A second electrical conduction path (not shown) can also be provided, as part of the first patch 120, between the excitation wire 114 and the actuation wire 150. The second conduction path (not shown) can be connected to the excitation wire 114 via a terminal or other connections known to a person of ordinary skill in the art. The second conduction path (not shown) can also be connected to actuation wire 150 via a terminal or other connections known to a person of ordinary skill in the art. The second electrical conduction path (not shown) is configured to provide electrical connectivity between the excitation wire 114 and the actuation wire 150.

[0022] A third electrical conduction path (not shown) can also be provided, as part of the second patch 130, between the actuation wire 140 and the actuation wire 150. The third conduction path (not shown) can be connected to the actuation wire 140 via a terminal or other connections known to a person of ordinary skill in the art. The third conduction path (not shown) can also be connected to actuation wire 150 via a terminal or other connections known to a person of ordinary skill in the art. The third electrical conduction path (not shown) is configured to provide electrical connectivity between the actuation wire 140 and the actuation wire 150.

[0023] It should be appreciated that while the actuation wires 140 and 150, as will be described further below, are constructed from a material that are configured to contract (i.e., shorten) when electrical current is applied and then to return to a noncontracted state (i.e., a relaxed state) when the electrical current is ceased, the first conduction path (not shown), the

second conduction path (not shown), and the third conduction path (not shown) are not configured to contract or relax when electrical current is applied and removed.

[0024] The first patch 120 and the second patch 130 are also coupled by deformation limiters 160 and 170. These deformation limiters 160 and 170 are provided to limit the separation between the first patch 120 with respect to the second patch 130 to a maximum separation. The deformation limiters 160 and 170 are members which can fold or flex inwardly as the first and second patches 120 and 130 move toward each other, however, provide a solid limit in travel as the first and second patches 120 and 130 move away from each other. The deformation limiters 160 and 170 are coupled to the respective first and second patches 120 and 130 by fasteners, known to a person of ordinary skill in the art.

[0025] Referring to FIG. 2, a schematic of the wound closure system 200 is shown in a noncontracted position. A wound 280 having a centerline 210 is shown. The first and second patches 120 and 130 are placed on the two sides of the wound 280 with medical adhesive (not shown). The medical adhesive (not shown) ensures no relative motion between the first and second patches 120 and 130 and the skin. The wound 280 is shown in a noncontracted state. Therefore, the spacing between the first and second patches 120 and 130 is such that the wound 280 defines the widest point (shown at the middle) which has a width of 290. The actuation wires are fixedly coupled to the respective first and second patches 120 and 130 via connectors (not shown). Therefore, as the actuation wires contract or relax (i.e., with the application of electrical current or after removal of the electrical current), the first and second patches 120 and 130 move according to the contraction and relaxing of the actuation wires 140 and 150. Sheathings 220 and 230 are provided to protect the actuation wires 140 and 150 during the deformation of these wires.

[0026] Through application of continuous cyclic contractions, and via the ability of skin to undergo viscoelastic deformations, the systems according to the present disclosure can bring

the edges of the wound 280 together and expedite the healing process. The forces generating contraction of the skin near the wound 280 resulting from contraction of the actuation wire 140 and 150 are countered by forces generated from local tensile stresses which tend to separate edges of the wound 280. The forces generated by the local tensile stresses, in the absence of the systems of the present disclosure, result in formation of hypertrophic scars.

[0027] In accordance with one embodiment, the wound closure system includes a bandage containing nitinol (a nickel/titanium alloy) actuation wires 140 and 150 crossing the incisions centerline 210 at about 90 degrees. The actuation wires 140 and 150 contract upon application of current. The current is preferably defined by a cyclic waveform, where the current is on for an on period of time and off for an off period of time. Frequency and amount of contractions of the actuation wires are according to frequency and amplitude of current passing through the actuation wires 140 and 150. The frequency and amplitude can be adjusted by a controller circuit (shown in FIG. 6).

[0028] Also shown in FIG. 2 are the deformation limiters 160 and 170. As described above, the deformation limiters are made from a material that can flex/bend inwardly as the patches are moved toward each other. In addition, the deformation limiters are configured to provide a limitation as to how far the wound 280 can open up once the forces responsible for contraction of the wound 280 are absent.

[0029] Also as described above, the excitation wires 112 and 114 (see FIG. 1) are connected to the actuation wires 140 and 150. The excitation wire 112 and 114 can be connected directly to the actuation wires 140 and 150 or via the first and second electrical conduction paths (not shown). In one case (i.e., where the excitation wires 112 and 114 are directly connected to the actuation wires 140 and 150), the connectivity between the excitation wires 112 and 114 and the actuation wires 140 and 150 have to be such that cyclic and frequent movement (i.e., the contraction and relaxing) of the actuation wires 140 and 150 do not

negatively affect the connectivity. In the other case (i.e., where the excitation wires 112 and 114 are not directly connected to the actuation wires 140 and 150, but rather connected via the first and second electrical conduction paths (not shown)), the excitation wires 112 and 114 are connected to the first and second patches 120 and 130, and the first and second electrical conduction paths (not shown) are instead connected to actuation wires 140 and 150. This intra-type of connectivity can be more robust, however, it will require the additional first and second electrical conduction paths (not shown).

[0030] Referring to FIG. 3, a schematic of the wound closure system 300 is shown in a contracted position. A wound 380 having a centerline 310 is shown. Sheathings 320 and 330 are provided to protect the actuation wires 140 and 150. The wound 380 is shown in a contracted manner. The wound 380 at its widest point has a width that is smaller than the noncontracted wound width 290 shown in FIG. 2. The contraction is further shown by the buckling of the deformation limiters 360 and 370 as shown by the deformation 390 of the deformation limiters 360 and 370. The actuation wires 340 and 350 in sheathings 320 and 330 are contracted to provide the contractions seen in FIG. 3.

[0031] Referring to FIG. 4, a photograph of a wound closure system 400 in accordance with one embodiment is shown in a noncontracted position. Cyclic electrical current is provided by clips 440 and 450 to the system 400. Two representative wounds 410 are shown in FIG. 4. Applying the electrical current causes three actuation wires (not referenced) to contract during the on cycles. FIG. 4 is a proof of concept using a latex material to simulate the resiliency of skin. In this proof of concept embodiment, the wound closure system was adhered to a stretched latex membrane.

[0032] The contractions are shown by reference numerals 520 and 530 when comparing FIGs. 4 and 5. Referring to FIG. 5, a photograph of a wound closure system 500 in accordance with one embodiment is shown in a contracted position. In FIG. 5, the two

wounds are shown with reference numeral 510. As can be seen in FIG. 5 the wounds 510 contract as the electrical current is applied during the on cycles. The repetitive contraction can assist in quicker healing of the wound.

[0033] Referring to FIG. 6, a schematic of the actuation circuit 600 is shown for the excitation circuit used to excite the actuation wires 140 and 150. Power is supplied by two 9VDC batteries connected in series to generate an 18VDC power source 610 (identified as P1). The 18VDC power source is provided to the rest of the circuit 600 via a connector 620 (identified as Conn1). One side of the 18VDC power source, e.g., the positive side is connected to one side of the connector 620 and the other side of the 18VDC power source 610 is connected to the other side of the connector 620. An ON/OFF power switch 630 (identified as S1) is used to turn on or off the actuation circuit 600. The positive side of the 18VDC power source 610 is connected to one side of the ON/OFF power switch 630. The other side of the ON/OFF power switch 630 is connected to the rest of the actuation circuit 600.

[0034] A timer 640 is connected and thereby powered from the ON/OFF power switch 630. The timer 640 is also connected to the ground side of the 18VDC power source 610 (which as discussed above also passes through the connector 620). Various inputs/outputs of the timer 640 are connected to resistors and capacitors RA, RB, R5, and C1. The timer 640 outputs a cyclic square wave with a programmable duty cycle. In one embodiment, a 555 timer is utilized to generate 4 seconds long duty cycle determined by the resistors RA, RB and capacitor C1. A light emitting Diode (LED) 642 is connected to the output of the timer 640 and to ground side of the 18VDC power source 610 via a resistor R4. The LED 642 turns on when the output waveform is on (i.e., when the power is supplied to the actuation wires 140 and 150 which causes them contract). The same output of the timer 640 is also used to activate a transistor Q1 (a bipolar transistor is shown, however, other types of switches, e.g.,

a MOSFET switch can also be used). The transistor Q1 is used as an electronic switch to the connector 630 (i.e., the positive side of 18VDC power source 610) to the actuation wires 140 and 150 through a resistor R6, a potentiometer (identified as Pot) and through a connector 660 (identified as Out). In one embodiment, Biometal Helix actuators are used for actuation wires 140 and 150. The potentiometer can be adjusted to set a voltage value that is applied to the actuation wires 140 and 150, which in turn adjusts the level of contraction.

[0035] While the circuit in FIG. 6 is shown with the 18VDC power source 610, in another embodiment a current source can be used. Since the actuation wires 140 and 150 are connected to the circuit in series, using a current source may result in higher accuracy. Using voltage sources may result in varying current levels as the actuation wires 140 and 150 heat up as they are activated (i.e., as current passes through). As the temperature rises, the resistance changes, thereby changing the applied voltage, resulting in unwanted variations. Using a current source ensures that a predetermined amplitude of current is passing through the actuation wires 140 and 150. Referring to FIG. 7, a printed circuit board layout of the circuit in FIG. 6 is shown.

[0036] Referring to FIG. 8, in accordance with one embodiment, a waveform is shown for exciting the actuation wires 140 and 150. Variables such as duty cycle, frequency and amplitude of the excitation waveform affect the behavior of the actuation wires 140 and 150. For example, larger amplitudes (voltage) result in higher currents passing through the actuation wires 140 and 150 which can result in larger contractions. Similarly, duty cycle of the waveform can also affect the contraction of the actuation wires 140 and 150.

[0037] In one embodiment, a feedback signal can be used to monitor the temperature of the actuation wires 140 and 150. For example, using a thermocouple and monitoring the temperature in the vicinity of the actuation wires 140 and 150 or the temperature on the skin can provide the feedback signal to achieve higher accuracies and efficiencies and a safer

practice. In one embodiment, monitoring current through the actuation wires 140 and 150 and cross referencing the current to a predetermined current vs. temperature relationship can also be used to provide a feedback signal without actually measuring the temperature. In either embodiment, the current passing through the actuation wires 140 and 150 can be applied using hysteresis. That is, if the temperature passes a certain threshold, the current would be stopped and a cooling period would start. When the temperature goes below a certain level, the current can be applied again.

[0038] In one embodiment, besides contacting the edges of a wound or other injuries, e.g., an ulcer, the device according to these teachings can be applied at a healthy location to generate new skin. The new skin thus generated would then be excised and used to repair a secondary site. While this approach may initially be viewed similar to autografts, in the traditional autograft approach gaping wounds resulting from removal of strips of skin are experienced leaving the donor site with a major trauma. In the approach according to this embodiment, skin is extended in the donor site prior to harvest so that the donor site provides tissue without leaving any gaping wounds.

[0039] In one embodiment, incorporating drugs in a patch equipped with the actuation wires according to the teachings to treat a skin irregularity can assist in faster recovery of the skin. For example, the patch can be accompanied with skin moisturizers, to facilitate the extension of skin. In addition, the patch can be accompanied with other medications for delivering growth factors and/or antibiotics directly to the skin irregularity.

[0040] Those skilled in the art will recognize that numerous modifications can be made to the specific implementations described above. Therefore, the following claims are not to be limited to the specific embodiments illustrated and described above. The claims, as originally presented and as they may be amended, encompass variations, alternatives, modifications, improvements, equivalents, and substantial equivalents of the embodiments

and teachings disclosed herein, including those that are presently unforeseen or unappreciated, and that, for example, may arise from applicants/patentees and others.

Claims:

1. A system for prevention of hypertrophic scars, comprising:
 - a first patch configured to be affixed to a first portion of skin proximate to a first side of a skin irregularity;
 - a second patch configured to be affixed to a second portion of skin proximate to a second side of the skin irregularity; and
 - a first actuation wire disposed between the first patch and the second patch and selectively placed in (i) a contracted state when an electrical current passes through the first actuation wire and (ii) a relaxed state when the electrical current ceases to pass through the first actuation wire.
2. The system of claim 1, further comprising:
 - a switching circuit configured to selectively provide an electrical current to the first actuation wire.
3. The system of claim 2, further comprising:
 - a power source coupled to the switching circuit for providing the electrical current.
4. The system of claim 3, further comprising:
 - a timing circuit coupled to the power source and the switching circuit, the timing circuit configured to provide activation pulses to the switching circuit, wherein (i) during an on state of the activation pulse the switching circuit couples the power source to the first actuation wire, and (ii) during an off state of the activation pulse the switching circuit isolates the power source from the first actuation wire.

5. The system of claim 3, further comprising:
- a first excitation wire configured to couple a positive terminal of the power source to the first actuation wire; and
 - a first electrical conduction path configured to couple the first excitation wire to the first actuation wire.
6. The system of claim 5, further comprising:
- a second actuation wire disposed between the first patch and the second patch and selectively placed in (i) a contracted state when an electrical current passes through the second actuation wire and (ii) a relaxed state when the electrical current ceases to pass through the second actuation wire, the second actuation wire being electrically connected to the first actuation wire in a series manner;
 - a second excitation wire configured to couple a negative terminal of the power source to the second actuation wire;
 - a second electrical conduction path configured to couple the second excitation wire to the second actuation wire; and
 - a third electrical conduction path configured to couple the first actuation wire to the second actuation wire.
7. The system of claim 5, further comprising:
- a second actuation wire disposed between the first patch and the second patch and selectively placed in (i) a contracted state when an electrical current passes through the second actuation wire and (ii) a relaxed state when the electrical current ceases to pass

through the second actuation wire, the second actuation wire being electrically connected to the first actuation wire in a series manner;

a third actuation wire disposed between the first patch and the second patch and selectively placed in (i) a contracted state when an electrical current passes through the third actuation wire and (ii) a relaxed state when the electrical current ceases to pass through the third actuation wire, the third actuation wire being electrically connected to the second actuation wire in a series manner;

a second electrical conduction path configured to couple the first actuation wire to the second actuation wire;

a third electrical conduction path configured to couple the second actuation wire to the third actuation wire; and

a fourth excitation wire configured to couple a negative terminal of the power source to the third actuation wire.

8. The system of claim 3, further comprising:

a feedback circuit configured to measure the temperature of the first actuation wire and to deactivate the switching circuit when the temperature of the first actuation wire has passed a predetermined threshold.

9. The system of claim 8, wherein the feedback circuit activates and deactivates the switching circuit according to a hysteresis.

10. The system of claim 9, wherein the feedback circuit comprises a thermocouple.

11. The system of claim 3, further comprising:

a feedback circuit configured to (i) measure current passing through the first actuation wire; (ii) associate the current to a temperature; and (iii) deactivate the switching circuit when the temperature of the first actuation wire has passed a predetermined threshold.

12. The system of claim 11, wherein the feedback circuit activates and deactivates the switching circuit according to a hysteresis.

13. The system of claim 12, wherein the feedback circuit comprises a sense resistor.

14. The system of claim 3, wherein the power source is a DC voltage source.

15. The system of claim 3, wherein the power source is a DC current source.

16. The system of claim 1, wherein the at least one section of the actuator wire is composed of a nitinol.

17. The system of claim 1, wherein the first actuation wire is positioned on a plane that is substantially perpendicular to planes associated with the position of the first and the second patches .

18. The system of claim 1, further comprising:

a first deformation limiter disposed between the first patch and the second patch and configured to limit separation between first patch and the second patch to a maximum separation.

19. The system of claim 18, further comprising:

a second deformation limiter disposed between the first patch and the second patch and configured to limit separation between first patch and the second patch to the maximum separation.

20. A method of prevention of hypertrophic scars, comprising:

affixing a first patch to a first portion of skin proximate to a first side of a skin irregularity;

affixing a second patch to a second portion of skin proximate to a second side of the skin irregularity;

fixedly coupling a first actuation wire to the first patch; and

fixedly coupling the first actuation wire to the second patch,

wherein the first actuation wire is configured to be selectively placed in (i) a contracted state when an electrical current passes through the first actuation wire and (ii) a relaxed state when the electrical current ceases to pass through the first actuation wire.

21. The method of claim 20, further comprising:

limiting the separation between the first patch and the second patch to a maximum separation.

22. The method of claim 20, further comprising:

selectively applying an electrical current to the first actuation wire.

23. The method of claim 22, wherein the electrical current is in form of pulses.

24. The method of claim 22, further comprising:

measuring temperature of the first actuation wire;

ceasing the electrical current passing through the first actuation wire when the temperature of the first actuation wire has increased above a first threshold; and

reapplying the electrical current when the temperature of the first actuation wire has decreased below a second threshold.

25. The method of claim 24, wherein the temperature of the first actuation wire is measured by a thermocouple.

26. The method of claim 24, wherein the temperature of the first actuation wire is measure by measuring current passing through the first actuation wire and associating the current to the temperature of the first actuation wire.

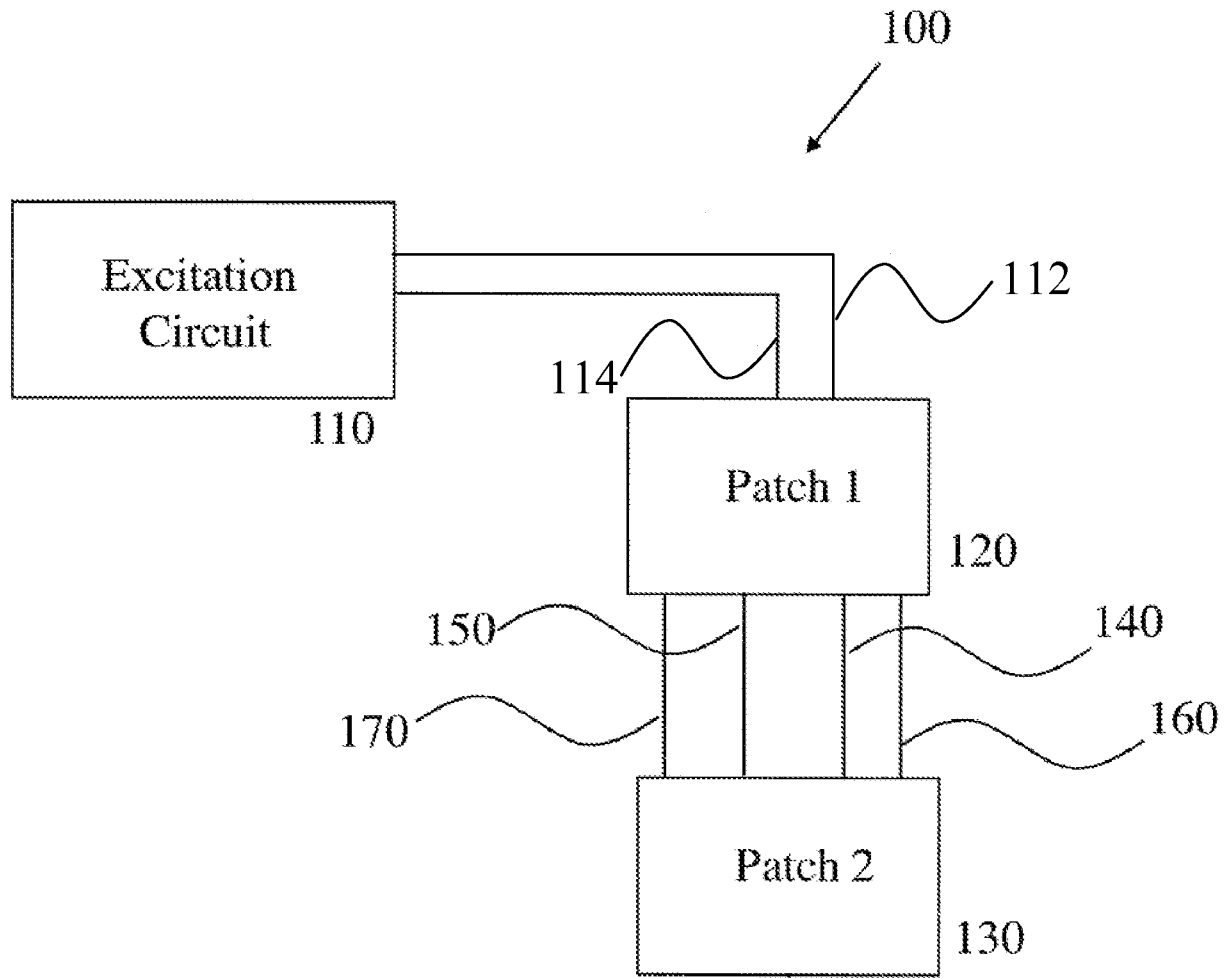


FIG. 1

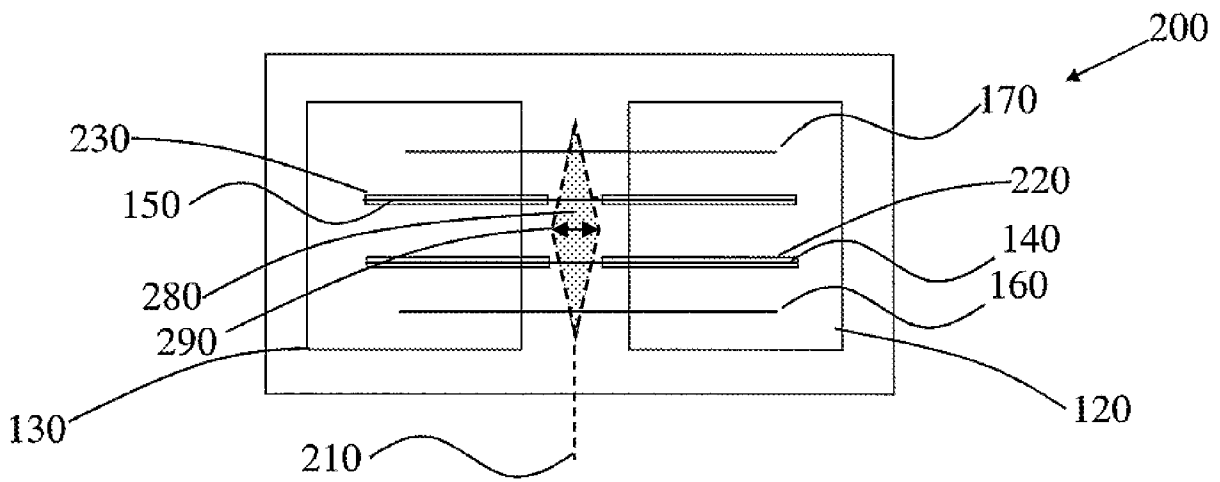


FIG. 2

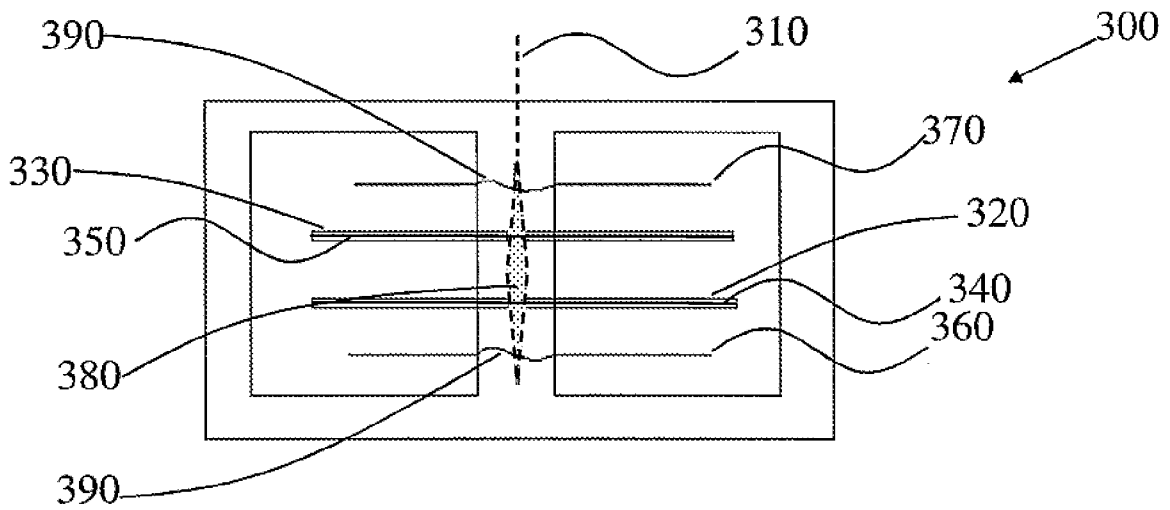
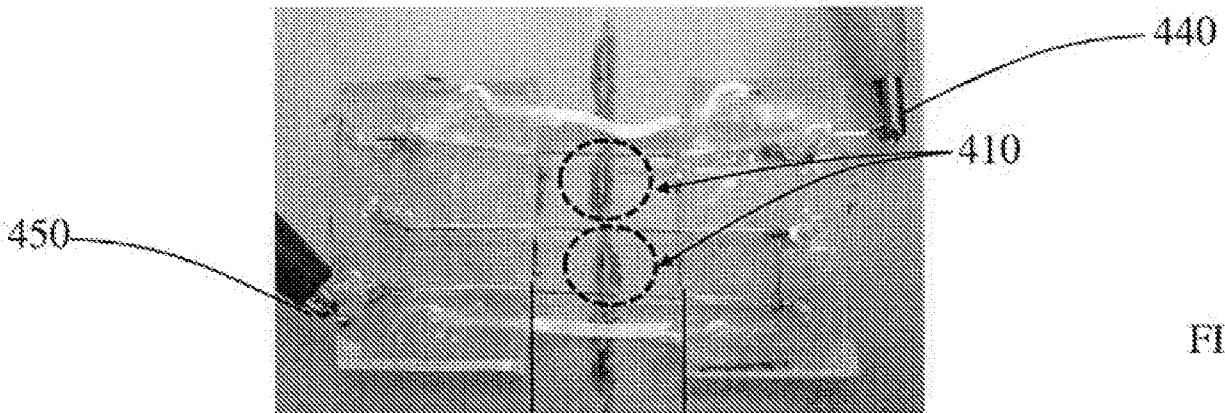


FIG. 3

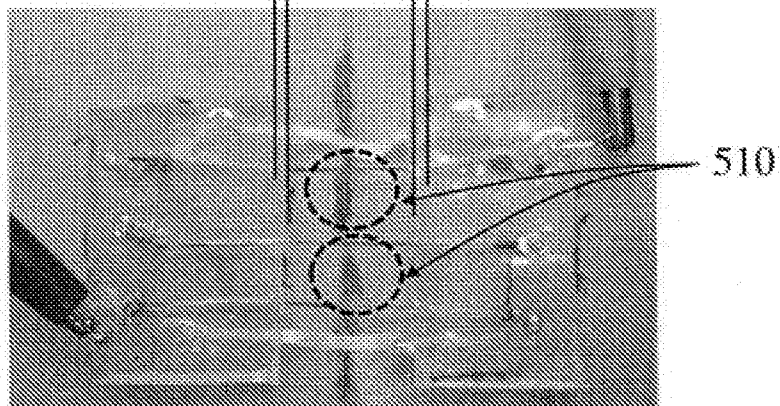
400



520

530

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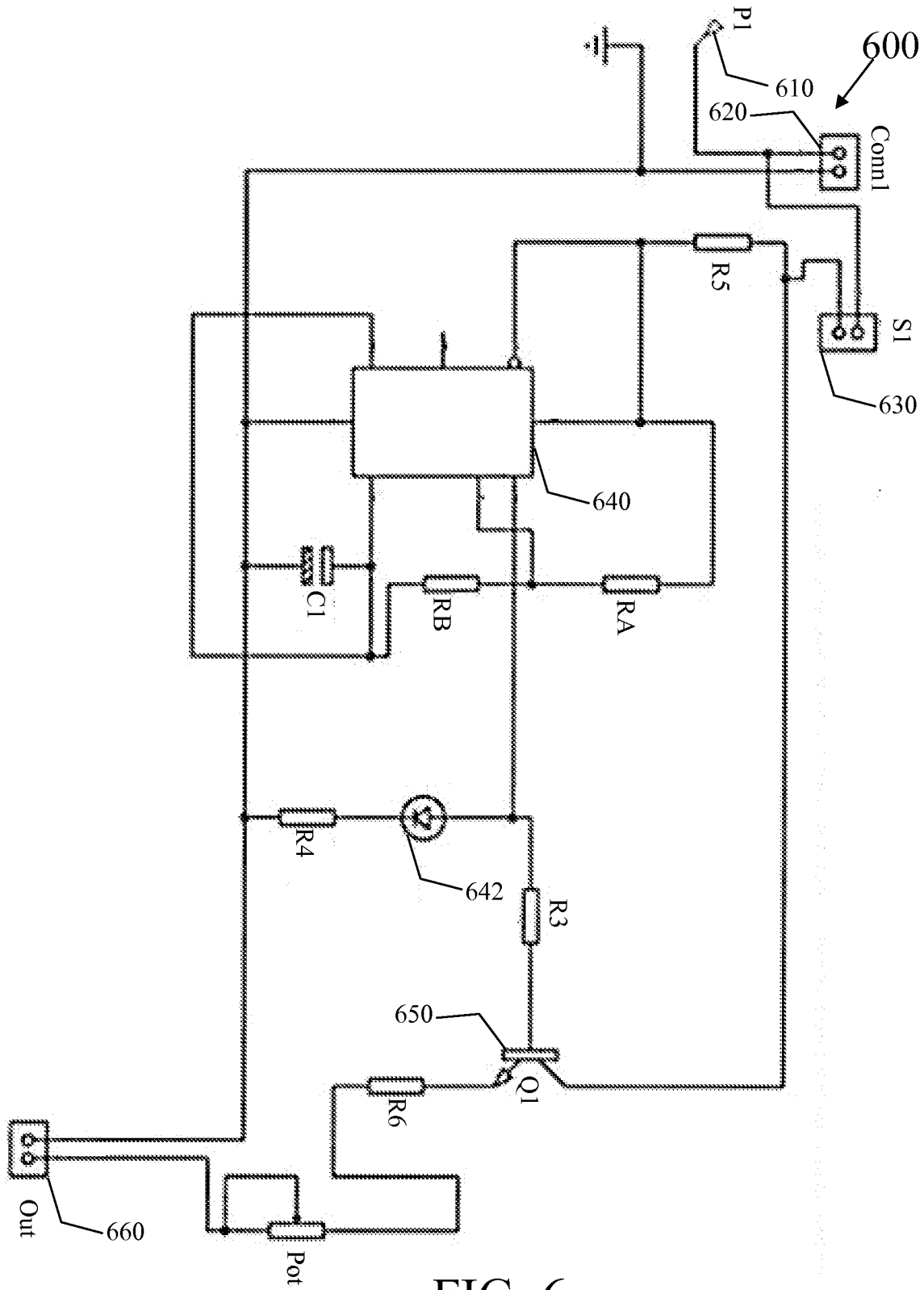


FIG. 6

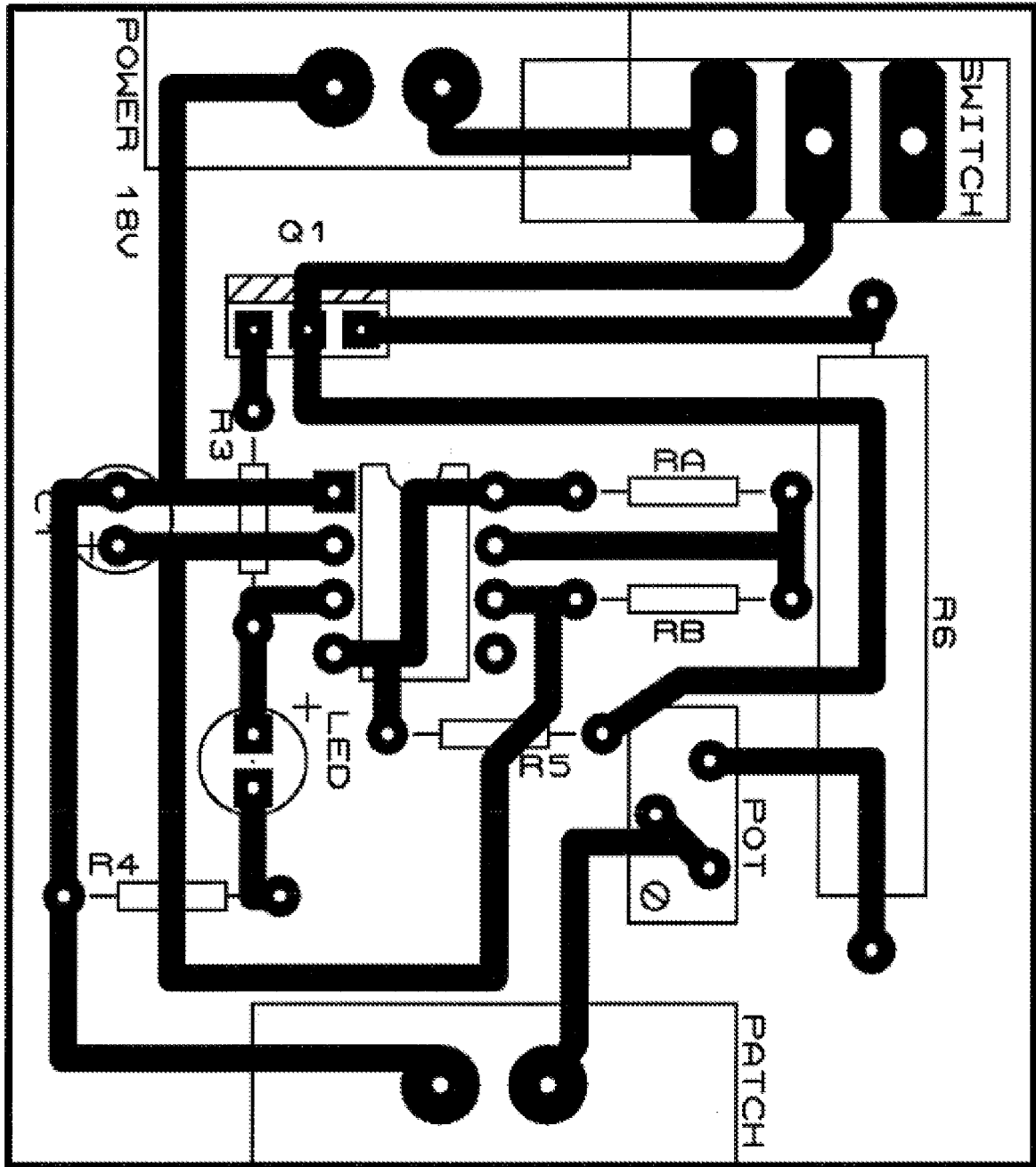


FIG. 7

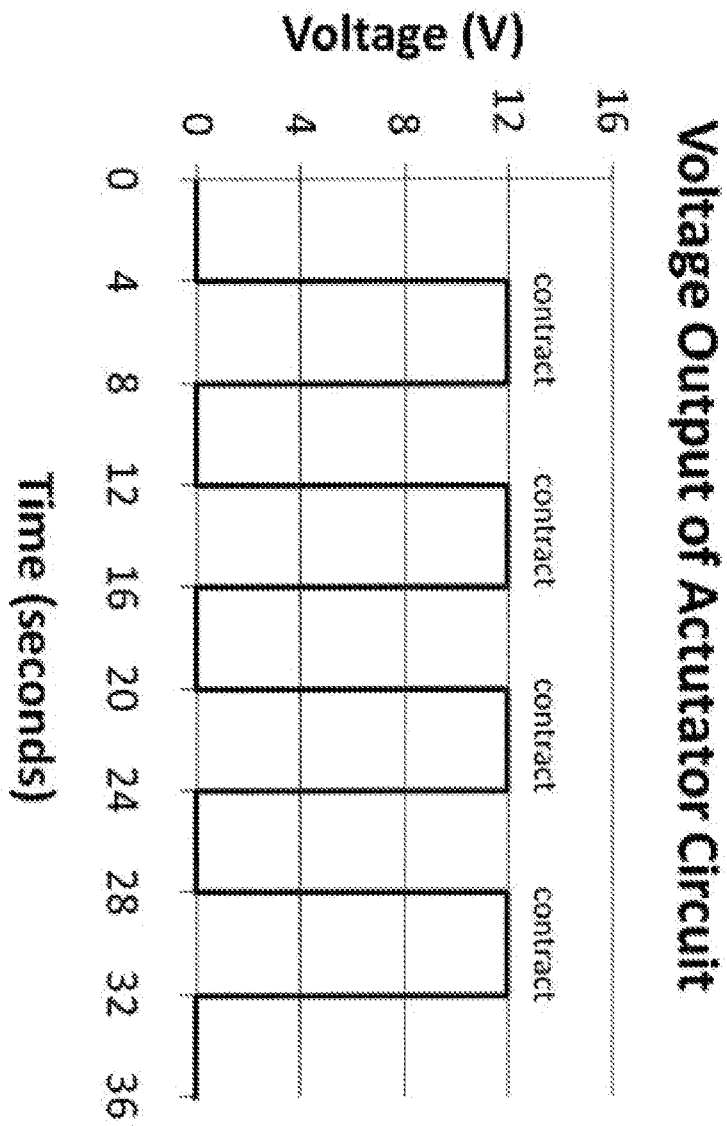


FIG. 8