

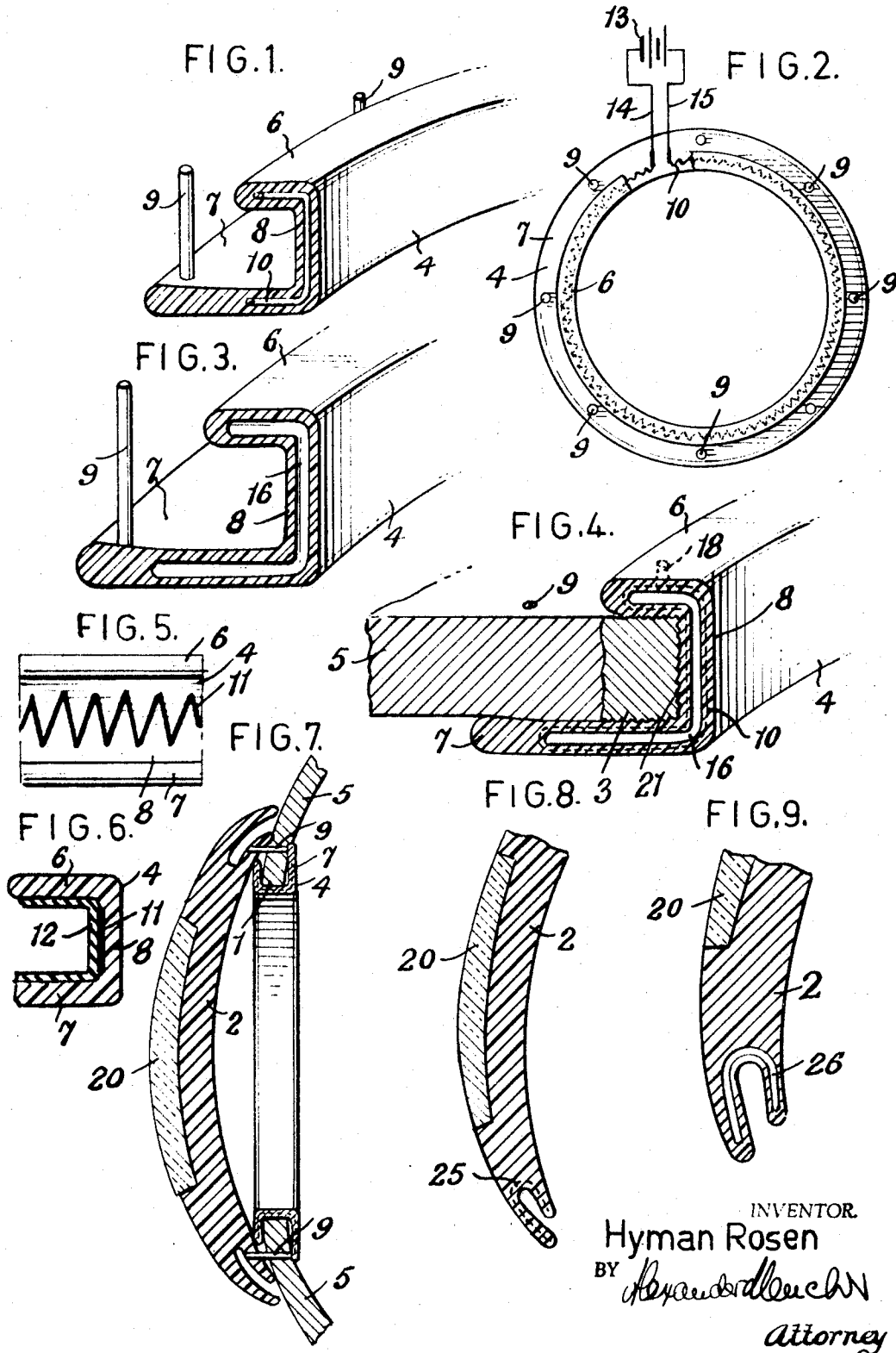
July 15, 1969

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3,454,966

PROSTHETIC CORNEAL FABRICATION WITH HEATING AND COOLING
MEANS TO FACILITATE ATTACHMENT TO CORNEAL TISSUE

Filed Feb. 11, 1965



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PROSTHETIC CORNEAL FABRICATION WITH HEATING AND COOLING MEANS TO FACILITATE ATTACHMENT TO CORNEAL TISSUE

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Filed Feb. 11, 1965, Ser. No. 431,868

Int. Cl. A61f 1/16; A61b 17/04; G02c 7/04

U.S. Cl. 3-13

11 Claims

ABSTRACT OF THE DISCLOSURE

The invention has application to a corneal transplant structure of synthetic material compatible with body tissue wherein said structure either per se or in conjunction with a mounting ring has built-in means for affording and transmitting temperature variations to the corneal rim tissue to facilitate permanent attachment thereof to said structure or ring.

This invention relates generally to corneal corrections of the human eye, but more particularly to means involving the substitution of a synthetic transparent body for a removed nonfunctioning corneal portion, and especially when the latter is the basic or contributing cause of blindness. A device and arrangement of the type to which the present invention has reference is shown for example, in my Patent No. 2,952,023, dated Sept. 13, 1960.

In the arrangement shown in the above mentioned patent, there is employed a retention ring or annulus which underlies the corneal rim area and is attached thereto by sutures which pass through the corneal rim area adjacent to the produced corneal opening, said sutures thus serving to attach the ring to the cornea and also to attach a corneal substitute to the ring, the corneal substitute being provided with means for the retention of a corrective lens.

The present invention involves the provision of means by which the marginal edge area of the cornea around the produced corneal opening can be attached to the retention ring, thereby insuring an intimate attachment of the corneal rim area to the ring. As an alternative, the ring may be attached directly to the edge area of a corneal substitute to avoid the possibility of producing gaps or openings between the corneal rim and the ring or corneal substitute.

More particularly, the invention contemplates the provision of a retaining ring provided with means by which it can be subjected to the effects of either high or low temperatures of such a degree as to effectively facilitate the securement between the rim area of the cornea and the ring and to promote the healing of the cornea. The effective and positive attachment of the rim portion of the cornea to the ring as stated avoids the production of openings or gaps between the cornea and the ring. As an alternative, the heating or cooling means may be applied directly to the corneal substitute as distinguished from the application of such means to a retention ring.

These objects and other incidental ends and advantages of the invention will hereinafter appear in the progress of the disclosure and as pointed out in the appended claims. In the accompanying drawing showing illustrative embodiments of the invention:

FIG. 1 is a sectional view taken across a retaining ring containing a heating coil and constructed in accordance with one embodiment of the invention;

FIG. 2 is a face view of the ring, with a portion thereof fragmentarily shown to disclose the heating coil and the

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current supply means such as a battery, for heating the coil;

FIG. 3 is a cross sectional view of another retaining ring in which a passage is provided for the reception of either a heating medium or a cooling fluid such as a refrigerant;

FIG. 4 is another cross sectional view of a ring provided with a fluid passage and with a heating coil arranged around the passage for the selective or alternative use, the ring being shown attached to the corneal rim and to which substitute material as conjunctive or compatible tissue has been applied to reinforce the corneal rim area;

FIG. 5 is a view looking at the inner side of a portion of the retaining ring and showing a printed heating element applied to it;

FIG. 6 is a transverse sectional view through the ring of FIG. 5 and showing insulating material applied over the printed heating element;

FIG. 7 is a sectional view through parts of the cornea with the retaining ring in position, and with the corneal substitute and corrective lens in place;

FIG. 8 is a sectional view of a part of a corneal substitute provided with a heating coil, and

FIG. 9 is a sectional view of a part of another corneal substitute having a fluid passage extending around it adjacent to its outer edge for receiving a heating or cooling passage.

As is stated in my Patent No. 2,952,023, to practice the present invention it is essential that the central deficient portion of the cornea of the eye be removed and that the concentric corneal portion around the cut out edge 1 of the cornea be sufficiently healthy to permit attachment thereto of the corneal synthetic substitute generally indicated by the numeral 2. As is well known, the cornea of the human eye is capable of receiving grafts very easily when the problem of transparency is not involved. Therefore, before practicing the herein described invention, the cornea may, if necessary, be strengthened by the addition of any type of compatible reinforcing material including and especially bone, tooth, cartilage, vascular elements and conjunctival tissue, as indicated at 3 in FIG. 4 to thereby render the cornea strong and healthy for compatibility with a synthetic object.

As shown in one form of the invention, such as that disclosed in FIGS. 1 and 7, a retention ring 4 is attached around the marginal edge 1 of the cornea 5 for the reinforcement of said edge and for facilitating the mounting of the corneal substitute 2. The ring 4 may be made in various cross sectional shapes other than that disclosed, and it may be composed of a suitable plastic material such as "Teflon" or of any other satisfactory material compatible for interlocking attachment or other type of securement to the rim portion 1 of the cornea.

In the form disclosed, the ring 4 is of annular channel shape thus having spaced flange portions indicated respectively at 6 and 7 and integrally joined by the web 8. The flange 7, which extends radially beyond the peripheral edge of the flange 6, has pins or sutures 9 located at spaced intervals and which in the installation of the ring as shown in FIG. 7 serve to attach the corneal substitute 2 to the ring, an arrangement somewhat similar to that shown in Patent No. 2,952,023.

Securement between ring 4 and the rim portion 1 of cornea 5 and the resultant healing of the cornea is materially facilitated by means of the application of heat or cold and possibly both heat and cold to said rim portion of the cornea. Heat may be thus applied by the use of a heating coil 10 which can be enclosed or embedded in the ring 4 or otherwise applied to the ring. For example, a printed heating element 11 might, as shown in FIGS. 5 and 6, be applied to a face portion or other part of the ring 4. Such printed element 11 can be covered by

insulation as shown at 12 in FIG. 6. Current may be supplied to the heating coil from a battery 13 or other suitable current source connected by the wires 14 and 15 to the coil as shown in FIG. 2. The described arrangement is such that when current is supplied to the heating coil 10 or 11, the cornea by receiving an application of the heat from the coil will have its attachment power enhanced to cause it to become more securely connected to the ring 4.

As an alternative, greatly reduced or lowered temperature or extreme cold can be applied to the marginal rim of the corneal opening by means of lowered temperature produced in the ring 4 by the use of a suitable coolant fluid such as liquid nitrogen or some other refrigerant. For this purpose, the ring 4 can be provided with an internal channel or passage 16 extending around it as shown in FIG. 3. The refrigerant can be forced into the channel 16 by suitable pressure means such as a pump or syringe reaching the interior of the channel 16 through an aperture 18 or by other means of access to the channel.

It is also possible to provide the ring 4 with both a refrigerant channel and a heating coil. One way in which this can be done is disclosed in FIG. 4, wherein the refrigerant channel is shown at 16 and the same is surrounded by a heating coil 10. The heating coil and the refrigerant channel can thus be used selectively for the respective applications of heat and cold to the ring and thus to the portions of the cornea that contact therewith.

From the foregoing, the uses of the described means will be apparent. When the marginal rim portion 1 of the cornea, produced by the removal of the central deficient portion of the cornea, is introduced into the peripheral groove or channel of the ring, either heat or cold is applied to the ring to thereby facilitate better connection of the cornea to the ring and resultant healing of the cornea, whereupon the corneal substitute 2 can be affixed to the ring by the sutures 9 as disclosed in my Patent No. 2,952,023. The application of heat or cold to the cornea is discontinued when the securement is obtained.

The retaining ring 4 may, if desired, be serrated or roughened as shown at 21 in FIG. 4 to facilitate the securement or firm attachment of the marginal edge of the corneal opening, or the edge portion of the compatible tissue 3 to the ring.

While it has herein been suggested that the heat or cold be applied to a retaining ring disposed around the corneal opening, the ring may be eliminated and the edge of the corneal opening be attached directly to the corneal substitute 4. In such case in order to obtain good securement of the cornea to the peripheral edge area of the corneal substitute 4, the latter may have its peripheral area encircled by an embedded or otherwise applied heating element or coil 25 as shown in FIG. 8. As an alternative, the corneal substitute might have its peripheral edge area provided with an encircling fluid passage 26 as shown in FIG. 9 for receiving a refrigerant. The edge area of the corneal substitute might also be provided with both a refrigerant passage and a heating coil as was suggested in FIG. 4.

Numerous modifications of the suggested constructions are possible. For example, the ring 4 need not necessarily be of channel shape; the heating or cooling of the same or of the corneal substitute may be otherwise than herein disclosed; the shape and form of the heating or cooling means may be varied, and various other possibilities for the transmission of heat and/or cold to the corneal tissue to secure fusion of the same either directly or indirectly to a corneal substitute, are possible and are believed to be within the scope of the invention.

I claim:

1. In a synthetic and functional corneal fabrication for a corneal opening resulting from a sectional corneal removal, a transparent plastic member, a retaining ring adapted to be permanently attached to the marginal edge

area of the cornea around the opening produced by the sectional removal, said retaining ring having means for attaching said plastic member thereto, and said retaining ring having built-in means for application of controlled temperatures to the marginal edge area of the cornea.

2. In a synthetic and functional corneal fabrication according to claim 1, wherein said built-in means comprises a heating element adapted to transmit higher temperatures to corneal areas in contact with said retaining ring.

3. In a synthetic and functional corneal fabrication according to claim 1 wherein said built-in means comprises a passage for introduction of a refrigerant adapted to withdraw heat from the corneal areas in contact with said retaining ring.

4. In a synthetic and functional corneal fabrication according to claim 1 wherein said built-in means comprises a refrigerant passage and a heating element adapted to withdraw and convey heat respectively with respect to the corneal areas in contact with said retaining ring.

5. In a corneal fabrication, a transparent corneal substitute of synthetic material compatible with body tissues and adapted to be applied to the rim of a corneal opening created by the removal of a portion of the cornea, said corneal substitute having a size and shape substantially complementary to said corneal opening whereby said substitute is adapted to lie in intimate contact with the rim of the corneal opening, said substitute having a heating element therein adapted to transmit higher temperatures to the contacting corneal rim to facilitate permanent attachment therebetween.

6. In a corneal fabrication, a transparent corneal substitute of synthetic material compatible with body tissues and adapted to be applied to the rim of a corneal opening created by the removal of a portion of the cornea, said corneal substitute having a size and shape substantially complementary to said corneal opening whereby said substitute is adapted to lie in intimate contact with the rim of the corneal opening, said substitute having a passage therein for a refrigerant adapted to withdraw heat from the contacting corneal rim to facilitate permanent attachment therebetween.

7. The method of attaching a transparent corneal substitute of synthetic material compatible with body tissues as a replacement for a removed section of the cornea of an eye comprising positioning said corneal substitute about the opening created by the removed section of the cornea so that the outer marginal portion of said substitute is in intimate contact with the marginal rim of the cornea surrounding the opening, and applying a controlled temperature of sufficient quantum to said substitute around the area of its contact with parts of the cornea to facilitate permanent attachment therebetween.

8. In a corneal fabrication for the marginal rim of a corneal opening resulting from the sectional removal of a portion of the cornea, a transparent plastic member of synthetic material compatible with body tissues, a retaining ring engaging said member and adapted to be permanently attached to the marginal rim of the corneal opening defined by the removed portion thereof, the ring having a channel in which the rim of the corneal opening is adapted to be fitted, the ring having a heating element in said channel adapted to transmit heat to the corneal rim to facilitate permanent attachment between said corneal rim and said ring channel.

9. In a corneal fabrication according to claim 8 and in which the heating element consists of an element printed on the ring.

10. In a corneal fabrication according to claim 8 in which the heating element consists of a coil extending around the interior of the ring.

11. In a corneal fabrication resulting from a sectional removal of a portion of the cornea, a transparent plastic member of synthetic material compatible with body tissues and adapted for attachment at its outer marginal

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portion to the cornea around the opening created by the removal of the portion of the cornea, said transparent plastic member having a size and shape substantially complementary to said opening defined by the marginal corneal portion surrounding said opening whereby said outer marginal portion of the plastic member is adapted to lie in intimate contact with the marginal corneal portion, and temperature regulating means within said plastic member by which either raised or lowered temperature can be applied to the plastic member whereby the temperature thereof is adapted to be conveyed to the corneal marginal portion to facilitate attachment therebetween.

References Cited

UNITED STATES PATENTS

2,224,793 12/1940 Malcom ----- 351—62
2,033,397 3/1936 Richman ----- 128—303.17

5

10

15

6

2,754,520 7/1956 Crawford ----- 3—13
2,952,023 9/1960 Rosen ----- 3—13
3,022,783 2/1962 Tucker ----- 128—1
3,096,767 7/1963 Gresser et al. ----- 128—395
3,228,400 1/1966 Armao ----- 128—303.1

FOREIGN PATENTS

647,638 7/1937 Germany.
20,735 4/1906 Sweden.

OTHER REFERENCES

"Medical Synthetics," by William D. Hartley, Wall Street Journal, Nov. 4, 1964, vol. CLXIV, No. 90, pages 1 and 22.

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