METHOD AND APPARATUS FOR TREATING MEIBOMIAN GLAND DYSFUNCTION EMPLOYING FLUID JET

Inventors: Stephen M. Grenon, Durham, NC (US); Lyle Paul, Russell, KY (US); Steven Roc, San Mateo, CA (US); Donald R. Korb, Boston, MA (US)

Assignee: TearScience, Inc., Morrisville, NC (US)

Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 305 days.

Appl. No.: 12/887,165
Filed: Sep. 21, 2010

Prior Publication Data

Related U.S. Application Data
Continuation of application No. 11/541,291, filed on Sep. 29, 2006, now Pat. No. 7,981,095, and a continuation of application No. 11/931,646, filed on Oct. 31, 2007, now Pat. No. 7,833,205, said application No. 11/541,291 is a continuation-in-part of application No. 11/434,033, filed on May 15, 2006, said application No. 11/931,646 is a continuation of application No. 11/541,291, filed on Sep. 29, 2006, now Pat. No. 7,981,095.

Provisional application No. 60/700,233, filed on Jul. 18, 2005.

Int. Cl. A61M 35/00 (2006.01)

U.S. Cl. USPC .......................... 604/294; 604/295; 604/291

Field of Classification Search
USPC .............................. 604/294; 295

See application file for complete search history.

References Cited
U.S. PATENT DOCUMENTS
1,006,945 A 10/1911 Houston
(Continued)

FOREIGN PATENT DOCUMENTS
AU 2011203832 A1 8/2012
(Continued)

OTHER PUBLICATIONS
(Continued)

Primary Examiner — Susan Su
Attorney, Agent, or Firm — Withrow & Terranova, PLLC

ABSTRACT
According to the present invention, there is provided a method of treating meibomian gland dysfunction in a mammal wherein an occlusion blocks at least a portion of the flow of naturally occurring secretion out of a gland channel orifice. The invention comprises selecting a device capable of delivering a jet of heated medium. The device is positioned such that when the jet is applied to the exterior surface of the eyelid, proximate to the gland channel orifice, a jet of heated medium is applied to the exterior surface of the eyelid proximate to the gland channel orifice at a pressure of from about 2 psi to about 30 psi. Application of the jet of heated medium is maintained for sufficient time to loosen, break up, fracture, soften or liquefy at least a portion of the occlusion such that at least a portion of the occlusion is removed. In an exemplary embodiment, the medium is water heated to a temperature of about 42° C. and about 46° C. Depending on the particular type and composition of the obstruction, the fluid jet operates to melt or soften the obstruction and to milksingly move the corpus of the softened obstruction up the gland channel from the end opposite the meibomian gland orifice and out of the gland orifice. Repeated application of the heated fluid jet may also be necessary to soften and/or express the obstruction.

44 Claims, 6 Drawing Sheets
gland margin. Similarly, the heating and vibrational features
discussed above may also be employed.

Another embodiment of the invention employs the use of
chemical or pharmaceutical agents to open or dilate the
gland and gland orifice wherein the obstruction naturally is
expressed and returns the normal secretions of the gland.
Alternatively, the chemical or pharmaceutical agent would be
used to soften or breakup the obstruction with such obstruc-
tion being expressed with the use of devices as defined above
or combinations thereof. Chemical or pharmaceutical
agents may also be used in connection with the device for post
treatment. Once the glands have been opened then chemical
or pharmaceutical agents may be used to enhance the nor-
mal production or secretion to maintain the glands in its
unblocked state.

Dilation of the meibomian gland channel and orifice may
also be employed to loosen or free the obstruction from the
gland walls. Dilation may be accomplished by chemical,
pharmacological, or mechanical means.

Stimulation of the meibomian gland may also be employed
in conjunction with the other modalities discussed above to
loosen or fracture the obstruction.

As mentioned herein above, the present invention has been
described in detail on conjunction with the figures in conec-
tion with the meibomian glands of the eye. The reader will
note that the principals of this invention may be applied with
equal efficacy to the other glands of the human body and
potentially to valuable domesticated farm animals to treat
various ailments.

That which is claimed is:
1. An apparatus for treating meibomian gland dysfunction
in an eyelid wherein at least one occlusion blocks at least a
portion of a flow of naturally occurring secretion out of at
least one meibomian gland, comprising:
a mask configured to deliver and maintain at a pressure
from about 2 psi to about 30 psi the application of at
least one jet of heated medium to an exterior surface of a
closed eyelid, proximate to at least one meibomian
gland, for sufficient time to loosen, break up, fracture,
soften or liquefy at least a portion of at least one occlu-
sion in the at least one meibomian gland such that at least
a portion of the at least one occlusion is removed; and
a rotary distributor valve comprising a cylindrical manifold
having a bore extending along its length, the rotary dis-
tributor valve being configured to deliver a heated
medium to the at least one jet.

2. The apparatus of claim 1, wherein the mask further
comprises at least one eye-piece configured to cover an orbit
of an eye and eyelid.

3. The apparatus of claim 2, wherein the at least one eye-
piece is configurable to create a seal around the orbit of an eye
and eyelid.

4. The apparatus of claim 3, wherein the seal is comprised
of a water tight seal.

5. The apparatus of claim 2, wherein the at least one eye-
piece further comprises an oval annulus or ring.

6. The apparatus of claim 5, wherein the at least one eye-
piece is composed of a flexible material.

7. The apparatus of claim 6, wherein the flexible material is
selected from the group consisting of rubber, plastic, and
neoprene.

8. The apparatus of claim 5, further comprising a lens
mounted to the oval annulus or ring.

9. The apparatus of claim 5, further comprising a mem-
brane communicating with the oval annulus or ring and con-
figurable to cover and contact an eyelid;

wherein the membrane is further configured to receive the
at least one jet of heated medium from the mask and
thereby transmitting a force of the at least one jet to the
eyelid so as to soften the at least a portion of the at least
one occlusion in the at least one meibomian gland.

10. The apparatus of claim 5, further comprising a nose
bridge connecting the at least one eye-piece to a second eye-
piece.

11. The apparatus of claim 5, further comprising a head-
band configured to connect outer edges of the mask and
further configurable to maintain the mask firmly in place
against orbit and cheek areas surrounding an eye.

12. The apparatus of claim 11, wherein the headband is
composed of a flexible material.

13. The apparatus of claim 12, wherein the flexible material
is selected from the group consisting of rubber, plastic, and
neoprene.

14. The apparatus of claim 1, wherein the heated medium is
composed of the temperature of the meibomian gland from at least 40 degrees Celsius to 47 degrees Celsius.

15. The apparatus of claim 1, wherein the heated medium is
selected from the group consisting of fluids, gases, and
flowable creams.

16. The apparatus of claim 1, wherein the mask is config-
urable to be attached to a mammal so as to position the at least
one jet of heated medium to the exterior surface of the closed
eyed.

17. The apparatus of claim 1, wherein the mask is config-
urable to be positioned by manually holding the apparatus so
as to position the at least one jet of heated medium to the
exterior surface of the closed eyelid.

18. An apparatus for treating meibomian gland dysfunction
in an eyelid wherein at least one occlusion blocks at least a
portion of a flow of naturally occurring secretion out of at
least one meibomian gland, comprising:
at least one jet configured to deliver and maintain at a
pressure from about 2 psi to about 30 psi the application of at
least one jet of heated medium to an exterior surface of a
closed eyelid, proximate to at least one meibomian
gland, for sufficient time to loosen, break up, fracture,
soften or liquefy at least a portion of at least one occlu-
sion in the at least one meibomian gland such that at least
a portion of the at least one occlusion is removed; and
a rotary distributor valve comprising a cylindrical manifold
having a bore extending along its length, the rotary dis-
tributor valve being configured to deliver a heated
medium to the at least one jet.

19. The apparatus of claim 18, wherein the rotary distribu-
tor valve is further comprises at least one jet orifice posi-
tioned along a portion of the cylindrical manifold, wherein the at
least one jet orifice is in fluid communication with the bore.

20. The apparatus of claim 19, wherein the rotary distribu-
tor valve further comprises a housing surrounding the cylin-
drical manifold having the bore extending along its length.

21. The apparatus of claim 20, wherein the housing further
comprises a longitudinal slit configured to allow fluid from the
at least one jet orifice to pass there through such that upon
rotation of the cylindrical manifold, the at least one jet orifice
is sequentially exposed to the longitudinal slit.

22. The apparatus of claim 20, wherein the cylindrical
manifold is mounted for rotation within the housing.

23. The apparatus of claim 19, wherein the rotary distribu-
tor valve further comprises an integrally molded gear com-
municating with the cylindrical manifold and configured to
rotate the cylindrical manifold.
24. The apparatus of claim 23, wherein the rotary distributor valve further comprises a rotor communicating with the manifold through the gear and configured to rotate the manifold.

25. The apparatus of claim 19, wherein the rotary distributor valve further comprises:
   a first nipple communicating with a first end of the cylindrical manifold in fluid communication with the bore; and
   a second nipple communicating with a second end of the cylindrical manifold in fluid communication with the bore.

26. The apparatus of claim 25, wherein the first nipple is configured as a fluid inlet.

27. The apparatus of claim 25, wherein the second nipple is configured as a fluid outlet.

28. The apparatus of claim 25, wherein the cylindrical manifold is mounted for rotation between the first and second nipples.

29. The apparatus of claim 19, wherein the rotary distributor valve further comprises:
   a pump in fluid communication with the cylindrical manifold configured to deliver the heated medium into the cylindrical manifold; and
   a rotor communicating with the cylindrical manifold and configured to rotate the bore so as to rotate the position of the at least one jet orifice.

30. The apparatus of claim 29, wherein the rotary distributor valve is configured to milklingly massage the at least one meibomian gland so as to soften the at least a portion of the at least one occlusion.

31. The apparatus to claim 29, wherein the rotary distributor valve is configured to apply the at least one jet to the at least one meibomian gland in a manner that milkingly moves up the at least one meibomian gland from an end opposite at least one meibomian gland channel orifice towards the at least one meibomian gland channel orifice.

32. The apparatus of claim 29, wherein the pump maintains a pressure of the heated medium into the cylindrical manifold.

33. The apparatus of claim 29, wherein the rotary distributor valve further comprises a heater configured to maintain a temperature of the heated medium.

34. The apparatus of claim 33, wherein the heater is configured to supply heat to the heated medium by a modality selected from the group consisting of conduction, convection, and radiation.

35. The apparatus of claim 33, wherein the heater is configured to maintain the temperature of at least a portion of the heated medium to at least 42 degrees Celsius.

36. The apparatus of claim 35, wherein the heater is configured to maintain the temperature of the at least a portion of the heated medium to at most 46 degrees Celsius.

37. The apparatus of claim 19, wherein the application of the at least one jet of heated medium is intermittent.

38. The apparatus of claim 37, wherein the intermittent application of the at least one jet of heated medium is pulsed.

39. The apparatus of claim 37, wherein the at least one jet of heated medium is applied at a frequency between 1 Hz and 300 Hz.

40. The apparatus of claim 37, wherein the at least one jet of heated medium is applied at a frequency between 5 Hz and 60 Hz.

41. The apparatus of claim 18, wherein the heated medium is selected from the group consisting of fluids, gases, and flowable creams.

42. The apparatus of claim 18, wherein the at least one jet is configured to be repositionable during the application of the at least one jet of heated medium.

43. The apparatus of claim 18, wherein the at least one jet is not configured to be repositionable during the application of the at least one jet of heated medium.

44. An apparatus for treating meibomian gland dysfunction in a mammal wherein at least one occlusion blocks at least a portion of a flow of naturally occurring secretions out of at least one meibomian gland, comprising:

   at least one jet configured to deliver and maintain at a pressure from about 2 psi to about 30 psi the application of at least one jet of heated medium to maintain the internal temperature of at least one meibomian gland between 40 degrees Celsius and 47 degrees Celsius, for sufficient time to loosen, break up, fracture, soften or liquify at least a portion of at least one occlusion in the at least one meibomian gland such that the at least a portion of the at least one occlusion is removed; and

   a rotary distributor valve comprising a cylindrical manifold having a bore extending along its length, the rotary distributor valve being configured to deliver a heated medium to the at least one jet.

* * * * *