Title: PROCESS FOR REMOVING EXTRACTABLES FROM POLYMERIC CONTACT LENSES

Abstract: In an improved process for treating contact lenses, the improvement comprises contacting a polymeric contact lens containing extractables with substantially pure vapor or substantially pure condensate of the vapor of a volatile solvent that is effective for dissolving and thereby removing the extractables from the contact lens.
PROCESS FOR REMOVING EXTRACTABLES FROM POLYMERIC CONTACT LENSES

Field of the Invention

The present invention relates to contact lens manufacture and, more particularly, to an improved process for removing extractables from polymeric contact lenses.

Background of the Invention

Hydrogels represent a desirable class of materials for the manufacture of contact lenses. A hydrogel is a hydrated cross-linked polymeric system that contains water in an equilibrium state. Hydrogel lenses offer relatively high oxygen permeability as well as desirable biocompatibility and comfort.

In a typical process for the manufacture of hydrogel polymeric contact lenses, a composition containing a diluent and suitable monomers is charged to a mold and cured. The molded lens can be subjected to machining operations such as lathe cutting, buffing, and polishing and further subjected to extraction, hydration, and sterilization procedures.

Generally, in the manufacture of contact lenses, some of the monomer mix components are not fully polymerized. The residual material from the polymerization process may affect optical clarity and/or be harmful to the eye. Residual material, which may be either hydrophilic or hydrophobic, include solvents, unreacted monomers, or low molecular weight oligomers. Residual materials are referred to herein as “extractables”. Hydrophilic residual materials can be extracted by water whereas hydrophobic residual components are typically removed by extraction with water-miscible organic solvents, in particular, alcohols such as isopropyl alcohol. Following the alcohol extraction process, the lens needs to be hydrated by treatment with water before being sterilized by, for example, autoclaving in buffered saline.
Removal of extractable hydrophobic components from contact lenses is typically carried out by immersing the lenses in the extraction solvent for a period of time to ensure removal of the components. A problem arises in that the buildup in the concentration of monomeric and oligomeric materials in the solvent results in decreasing efficiency in the removal of these components with time and requires that the spent solvent be periodically replaced. Manufacturing contact lenses on a commercial scale requires the replacement and disposal of large volumes of spent solvent, which is undesirable both economically and environmentally. Finding a way of reducing the amount of spent extraction solvent needing to be replaced and disposed of would be desirable. The present invention provides such a way.

**Summary of the Invention**

The present invention is directed to an improved process for treating contact lenses. The improvement comprises contacting a polymeric contact lens containing extractables with substantially pure vapor or substantially pure condensate of the vapor of a volatile solvent that is effective for dissolving and thereby removing the extractables from the contact lens.

**Brief Description of the Drawings**

FIG. 1 schematically depicts a lens extraction process of the prior art.

FIG. 2 schematically depicts the improved process of the present invention.

**Detailed Description of the Invention**

Hydrogel lenses are generally formed of a copolymer of at least one hydrophilic monomer and a cross linking monomer. The hydrophilicity is due to the presence of hydrophilic groups such as, for example, hydroxy, carboxylic acid, amide and sulfonic acid. The swollen equilibrated state results from a balance between the osmotic driving forces that cause the water to enter the hydrophilic polymer and the forces exerted by the
polymer chains in resisting expansion. In the case of silicone hydrogel contact lenses, the copolymeric material further includes a silicone-containing monomer. Lenses in this class are generally formed of a copolymer of at least one hydrophilic monomer and a cross-linking monomer. Hydrophilic monomers include those known in the art such as: unsaturated carboxylic acids such as methacrylic acid and acrylic acid; (meth)acrylic substituted alcohols or glycols such as 2-hydroxyethyl methacrylate, 2-hydroxyethyl acrylate, and glyceryl methacrylate; vinyl lactams such as N-vinyl-2-pyrrolidone; and acrylamides such as N-acrylamide and N,N-dimethylacrylamide. Further examples of such hydrophilic monomers can be found in U.S. Patent Nos. 4,153,641; 4,740,533; 5,034,461; and 5,070,215, the disclosures of which are incorporated herein by reference.

The cross-linking monomer may be material having multiple polymerizable functionalities, preferably vinyl functionalities. Representative cross-linking monomers include: divinylbenzene, allyl methacrylate, ethylene glycol dimethacrylate, tetraethyleneglycol dimethacrylate, polyethyleneglycol dimethacrylate, and vinylcarbonate derivatives of the glycol dimethacrylates. In the case of silicone hydrogel contact lenses, the copolymeric material further includes at least one silicone-containing monomer.

An organic diluent is included in the initial monomeric mixture. As used herein, the term “organic diluent” encompasses organic compounds that minimize incompatibility of the components in the initial monomeric mixture and are substantially nonreactive with the components in the initial mixture. Additionally, the organic diluent serves to minimize phase separation of polymerized products produced by polymerization of the monomeric mixture. Also, the organic diluent will generally lower the glass transition temperature of the reacting polymeric mixture, which allows for a more efficient curing process and ultimately results in a more uniformly polymerized product. Uniformity of the initial monomeric mixture and the polymerized product are of particular concern for silicone hydrogels primarily due to the inclusion of silicone-containing monomers.

Contemplated organic diluents include: monohydric alcohols, with C₆-C₁₀ straight-chained aliphatic monohydric alcohols being especially preferred; diols such as ethylene glycol; polyols such as glycerin; ethers such as diethylene glycol monoethyl
ether; ketones such as methyl ethyl ketone; esters such as methyl heptanoate; and hydrocarbons such as toluene. A preferred diluent is nonanol, a C<sub>9</sub> alcohol. Preferably, the organic diluent is sufficiently volatile to facilitate its removal from a cured article by evaporation at or near ambient pressure.

Various processes are known for curing a monomeric mixture in the production of contact lenses, including spincasting and static casting. Spincasting methods are disclosed in U.S. Patent Nos. 3,408,429 and 3,660,545, and static casting methods are disclosed in U.S. Patent Nos. 4,113,224 and 4,197,266, the disclosures of all of which are incorporated herein by reference. Curing of the monomeric mixture is often followed by a machining operation in order to provide a contact lens having a desired final configuration.

According to several known techniques for manufacturing contact lenses, a casting process may yield a shaped article having the desired posterior and anterior lens surfaces. For example, in static casting processes, a monomeric mixture can be charged to a mold comprising a first mold section including a surface for forming a desired anterior lens surface and a second mold section including a surface for forming a desired posterior lens surface. In spincasting processes, the monomeric mixture can be charged to an open mold having a surface for forming a desired anterior lens surface, and a desired posterior lens surface is formed from rotation of the mold. However, machining operations, subsequent to the curing of the article, may still be necessary to provide a contact lens more suitable for placement on the eye. Such machining operations include lathe cutting the lens to obtain a desired lens edge, buffing the lens edge, or polishing the lens edge or surface.

In other known manufacturing techniques, the casting process may yield a shaped article which does not have the desired anterior and/or posterior lens surfaces. Accordingly, the casting process is followed by a machining operation to form a desired lens surface. As an example, U.S. Patent No. 4,555,732, the disclosure of which is incorporated herein by reference, describes a process where an excess of a monomeric mixture is cured by spincasting in a mold to form a shaped article having an anterior lens surface and a relatively large thickness, and the posterior surface of the cured spincast article is subsequently lathe cut to provide a contact lens having the desired thickness and
posterior surface. Further machining operations such as the previously described edge finishing operations may follow the lathe cutting of the lens surface.

Removal of extractable components from contact lenses is typically carried out by contacting the lenses with an extraction solvent for a period of time sufficient to ensure substantially complete removal of the components. For example, a batch of contact lenses is immersed in a bath of isopropyl alcohol and held for several hours to effect removal of extractables such as monomers and oligomers from the lenses. The lenses are removed, and a new batch is immersed in the bath. After several hours holding, this batch is removed, and the process is repeated. Thus, the isopropyl alcohol bath is reused, several thousand contact lenses being extracted with a given quantity of isopropyl alcohol before it is replaced with fresh solvent.

In the bath of isopropyl alcohol, the concentration of extractables builds up as lens extraction proceeds and results in decreased efficiency in the removal of extractable material from the lenses. Thus, even though all the lenses extracted by a bath of isopropyl alcohol may meet finished product specifications, there is a trend of lenses extracted near the end of the solvent bath lifetime containing higher levels of residual extractables than those treated earlier in the lifetime. It would be desirable to maintain uniform extraction efficiency during the lifetime of the bath of solvent. This could be achieved by lowering the number of lenses treated by a given quantity of solvent, but this is undesirable from both an economic and an environmental standpoint.

In FIG. 1 is schematically depicted a lens extraction process of the prior art. One or more contact lenses 10 in a holder 11 is immersed in a solvent 12 in a vessel 13. Solvent 12 acts to dissolve extractable components (not shown) and thereby remove them from lenses 10.

In the improved process of the present invention, the contact lens is contacted with the vapor or vapor condensate of substantially pure solvent for a period of time effective to remove substantially all extractables such as, for example, monomers or oligomers, from the lens. The contact lens preferably is formed from a hydrogel, more preferably, a silicone hydrogel. The extraction solvent preferably has a boiling point of up to about 200°C at atmospheric pressure. More preferably, the boiling point of the solvent is 100°C or less (at atmospheric pressure) to ensure that substantially all the
extractables removed from the lenses remain condensed in the bulk solvent and are not included in the vapor generated therefrom. The extraction solvent is an organic solvent, which can be selected from the group consisting of alcohols, glycols, ketones, ethers, alkanes, and aromatic hydrocarbons, is preferably an alcohol containing up to about 8 carbon atoms. A particularly preferred extraction solvent is isopropyl alcohol. By contacting the contact lens with substantially pure solvent vapor or condensate for a period preferably of about 1 hour to 72 hours, more preferably about 1 hour to 8 hours, substantially all extractables are removed from the lens.

FIG. 2 schematically represents the improved process of the present invention. Contact lenses 10 in holder 11 are suspended above solvent 12 contained in a closed vessel 23. Solvent 12 is heated above its boiling point by a source of heat 24. Included in vessel 23 is a condenser 25. The resulting solvent vapor 26 and its condensate droplets 27 contact lenses 10 and dissolve extractables (not shown) contained in lenses 10 and transport the extractable components to the bulk solvent 12. Because the extractables are much less volatile than solvent 12, vapor 26 and condensate droplets 27 are composed of substantially pure solvent 12. The extractables removed from lenses 10 are thereby concentrated in bulk solvent 12. The process can be run substantially continuously; upon completion of the treatment of a batch of lenses 10, they can be removed and replaced by a new batch.

In the process of the present invention, the tray assembly described in the copending, commonly assigned application MESH TRAY ASSEMBLY FOR CONTACT LENS EXTRACTION PROCESS, Application Serial No. 60/163,208, filed November 2, 1999 by Stafford et al., the disclosure of which is incorporated herein by reference, can be advantageously employed.

Because the improved process of the present invention provides for the extraction of the lenses with substantially pure solvent vapor or condensate, there is no loss in extraction efficiency. Thus, one can, in principle, extract unlimited numbers of contact lenses using a single batch of solvent. Of course, the solvent can be replaced after extraction of a specified number of lenses, but this number can be substantially increased over that of current practice, resulting in large savings in the cost of spent solvent disposal and replacement.
A further advantage of the improved process of the present invention lies in the fact that the solvent-extracted lenses contain less residual solvent to be removed in a subsequent hydration step. Furthermore, the lenses may be obtained dry and unwarped, enabling them to be surface treated immediately following the extraction step.

Having thus described the preferred embodiment of the invention, those skilled in the art will appreciate that various modifications, additions, and changes may be made thereto without departing from the spirit and scope of the invention as set forth in the following claims.
What Is Claimed:

1. An improved process for treating contact lenses, the improvement comprising:
   contacting a polymeric contact lens containing extractables with substantially pure vapor or substantially pure condensate of said vapor of a volatile solvent effective for dissolving and thereby removing said extractables from said contact lens.

2. The process of claim 1, and further comprising:
   contacting said contact lens with said vapor or said condensate of said solvent for a period of time effective to remove substantially all of said extractables from said contact lens.

3. The process of claim 1 wherein said solvent is an organic solvent.

4. The process of claim 3 wherein said solvent is selected from the group consisting of alcohols, glycols, ketones, ethers, alkanes, and aromatic hydrocarbons.

5. The process of claim 4 wherein said solvent comprises an alcohol containing up to about 8 carbon atoms.

6. The process of claim 5 wherein said solvent is isopropyl alcohol.

7. The process of claim 1 wherein said contact lens comprises a hydrogel.

8. The process of claim 7 wherein said hydrogel is a silicone hydrogel.

9. The process of claim 1 wherein said contact lens is disposed above the solvent contained in a closed vessel, said solvent being heated to about its boiling point.
10. The process of claim 9 wherein said solvent has a boiling point of up to about 200°C at atmospheric pressure.

11. The process of claim 10 wherein said solvent has a boiling point of up to about 100°C.

12. The process of claim 2 wherein said period of time is from about 1 hour to about 72 hours.

13. The process of claim 11 wherein said period of time is from about 1 hour to about 8 hours.

14. The process of claim 2, and further comprising:
following contacting of the contact lens with said solvent vapor or condensate, hydrating said lens, thereby removing substantially all of said solvent from said lens.

15. The process of claim 1 wherein said process is substantially continuous.

16. A process for removing extractables from polymeric contact lenses, said process comprising:
placing the contact lenses into a vessel above a quantity of volatile solvent contained in said vessel;
closing the vessel;
heating the vessel to a temperature sufficient to generate substantially pure vapor of said solvent; and
contacting the lenses with said vapor or with substantially pure condensate of said vapor to remove said extractables from said lenses.

17. The process of claim 16 wherein said solvent is an organic solvent.
18. The process of claim 17 wherein said solvent is selected from the group consisting of alcohols, glycols, ketones, ethers, alkanes, and aromatic hydrocarbons.

18. The process of claim 18 wherein said solvent is isopropyl alcohol.

19. The process of claim 16 wherein said contact lenses are formed from a hydrogel polymeric material.

20. The process of claim 16 wherein said contacting is carried out at a temperature of up to about 200°C for a period of about 1 hour to about 72 hours.

21. The process of claim 20 wherein said contacting is carried out at a temperature of up to about 100°C for about 1 hour to about 8 hours.
FIG. 1
(PRIOR ART)

FIG. 2
(SUBSTITUTE SHEET (RULE 26))
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 G02B1/04 C08J7/02 B29C71/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G02B C08J C08F B29D B29C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
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"*" document member of the same patent family

Date of the actual completion of the international search

6 October 2000

Date of mailing of the international search report

16/10/2000

Name and mailing address of the ISA

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