

METHOD FOR TRANSIENTLY WETTING LENS MOLDS IN
PRODUCTION OF CONTACT LENS BLANKS TO REDUCE LENS HOLE
DEFECTS

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This invention relates to methods for reduction of defects in, and an improvement in yield, in the production of contact lens blanks. More particularly, it provides measures to control and minimize lens blank defects known as lens holes.

Contact lens prepared from hydrophilic hydrogel polymeric materials are now well known, and are prepared commercially in great volume in highly automated manufacturing facilities. As these products are intended for intimate contact with the eye, great care is taken to assure that they meet stringent quality control standards. This can result in a relatively high reject rate, adversely affecting economies in their production.

Accordingly, it is an object of the invention to control and minimize lens blank defects, specifically lens holes. Additionally, it is an object to afford a method operable in high speed automated manufacturing operations to improve yields adversely affected by rejects due to lens holes. Further, it is an object to provide means for reducing lens hole defects originating in the filling operation and attributable to uneven distribution of the reactive monomer mixture forming the lens blank. It is also an object to provide a method for effecting even distribution of reactive monomer mix about and upon the convex or back curve mold. Finally, it is an object to modify and render relatively uniform the surface energy of a mold surface on a temporary or

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transient manner i.e. without a permanent change to the mold surface.

Processes for preparing hydrogel contact lens blanks have been well documented. Briefly, reactive monomer mix (RMM) for the formation of hydrophilic contact lenses is dispensed into a concave or front curve mold, formed from a hydrophobic polymer such as polystyrene, at a filling station. A convex or back curve mold is then brought into proximate engagement with the front curve mold to form and shape the lens blank therebetween. Next a mechanically associated assembly formed from the front curve mold/RMM/back curve mold is traversed through a UV curing tunnel under conditions to cure the RMM. The cured lens blank products associated with the forming molds are then dissociated by removing the back curve mold. The cured lens/front curve assembly is then traversed through leaching and hydration tanks, and a contact lens is thereby produced.

The continuous process implementing the complete manufacturing process utilizes a lens mold manufacturing zone, comprising first and second injection molding stations for the formation of concave and convex lens molds, respectively, and includes a transport line upon which concave and convex lens parts may be conveyed from zone to zone; an enclosed zone ('nitrogen tunnel') maintained under nitrogen for degassing mold halves or sections; a filling zone for filling concave mold sections with reactive monomer composition, registering concave and convex mold sections in aligned relation, and engaging same in

mating molding relation optionally under vacuum conditions, and procuring said reactive monomer composition with ultraviolet light to a gel-like state, and a curing zone in which the cure is completed and the finished lens blank readied for demolding. It will be appreciated that the entire process is integrated via transport means, generally one or more conveyors upon or in relation to which lens molds are assembled, arranged or interleaved in the course of conveyance through the said zones or stations in operational sequence. The lens molds may for convenience be situated in or upon mini-pallets (for example, fabricated of cast aluminum, stainless steel or the like) containing a number of lens molds (for example eight) arranged regularly thereon in spatial relation correlated with the treatment stations and the automated material transfer equipment where employed. All of the conveyance belts or tunnels are under nitrogen or inert gaseous blankets.

In greater pertinent detail, the concave or front curve mold incorporating an optical molding surface together with a peripheral zone or flange for interactive engagement with the convex or back curve mold is traversed through a stamping station in which the peripheral flange portion of the mold is treated with a surfactant material without contact with the optical surface of the mold; the mold is thereafter filled, sometimes to overflowing with reactive monomer mix whereupon the front curve mold is engaged in mating relation with the convex or back curve mold, (the optical surface of which is typically untreated); the paired, juxtaposed mold assembly including the RMM

molded therebetween, is passed to a curing zone and thence to a first demolding station at which the mold sections are disengaged. Facilitated by the presence of the surfactant upon the peripheral flange of the front curve mold, the excess material is separated from the remainder of the cured lens blank and retained with the convex or back curve mold; the optical portion of the lens then is retained by the front curve mold, whereupon the excess waste material may be removed from the back curve mold by any suitable mechanical means, wherefore the front curve mold associated with the retained lens blank free of excess peripheral material is passed to leaching and hydration stations, ultimately to be demolded, the contact lenses to be collected, and prepared for shipment.

As illustrated in Figures 1 and 2 injection molds #1 and #2, shown at steps 101 and 102 in the flow diagram of Figure 1, mold respectively front curve and back curve lens mold parts or sections; they may be located in tandem as shown in Figure 2 or to shorten exposure to the atmosphere still further, they may be located in a common plane intersecting a bifurcated transport line, even perpendicularly oriented thereto in the same plane.

Robotic means 103, 104 are provided adjacent the mold registry and engagement station for receiving concave and convex lens molds, respectively and transferring said mold part to a low oxygen environment at a high production cycle rate, as noted at step 105.

In the course of or following complete degassing of the lens mold sections as indicated at 106

in Figure 1, the pallets containing concave and convex lens mold sections are ordered into interleaved relation and degassed when enclosed in feed conveyor such that automated equipment may effect their operative interengagement into molding relation.

The sequencing conveyor 32 including the interleaving station 40 is enclosed and pressurized over its entire length with an inert gas, conveniently nitrogen. The amount of nitrogen is not critical, it being suitable to use just enough nitrogen pressure to effectively exclude the atmosphere under the operating conditions experienced. In the nitrogen tunnel surrounding sequencing conveyor 32 the freshly prepared lens mold blanks are degassed as indicated at step 106 in Figure 1.

The concave lens molds are filled with the reactive monomer composition at step 107 and the concave and convex lens molds are placed into registry and urged into complementary molding relation. The filling and assembly zone 50 surrounds a portion of the conveying or transport means 32, which delivers to the zone pallets concave and convex lens mold sections, respectively, and at the terminus of the zone carries pallets of paired and filled molds to the procure zone. The filling and assembly zone illustrated in Figure 2 at 50 is defined by a geometrically appropriate, transparent enclosure, generally of rectangular cross-section, formed of any suitable thermoplastic or metal and thermoplastic construction.

As illustrated at 107 in Figure 1, the concave lens mold sections are filled with degassed monomer

composition from step 108, and then transported to an
1 assembly module optionally having a vacuum chamber
formed intermittently within the nitrogen tunnel in
which filled concave lens molds are engaged with convex
mold sections in vertical alignment and in mating
5 relation, such that the reactive monomer composition is
trapped between the optical surfaces of the respective
mold sections and at least partially sealed by the
engagement of the parting edge formed peripherally in
each of the lens mold sections. If present, the vacuum
10 is released. Then, the mated mold is passed through
nitrogen to the precure station, an integral part of the
nitrogen tunnel.

Following assembly of the mold parts, the
incipient lens monomer is precured at step 109 in the
15 precure module 60 of the present invention. The process
of the precure involves clamping the mold halves in
registration and then precuring the monomer or monomer
mixture to a gel like state.

Following precure, the polymerization of the
20 monomer or monomer mixture is completed in curing tunnel
75 as indicated at step 110 with irradiation.

In the cure zone (75), the monomer/diluent
mixture is then cured in a UV oven whereby
polymerization is completed in the monomer(s). This
25 irradiation with actinic visible or ultraviolet
radiation produces a polymer/solvent mixture in the
shape of the final desired hydrogel. In addition, the
cure zone also has a source of heat which is effective
to raise the temperature of the polymerizable
30 composition to a temperature sufficient to assist the

propagation of the polymerization and to counteract the
1 tendency of the polymerizable composition to shrink
during the period that it is exposed to the ultraviolet
radiation.

After the polymerization process is completed,
5 the two halves of the mold are separated during a
demolding step leaving the contact lens in the first or
front curve mold half 10, from which it is subsequently
removed. It should be mentioned that the front and back
curve mold halves are used for a single molding and then
10 discarded or disposed of.

Heating the back curve lens mold creates
differential expansion of the heated mold polymer
relative to the cooler lens polymer which shifts one
surface with respect to the other. The resultant shear
15 force breaks the polymerized lens/polymer mold adhesion
and assists in the separation of mold portions. The
greater the temperature gradient between the surfaces of
the mold portions, the greater the shearing force and
the easier the mold portions separate. This effect is
20 greatest when there is maximum thermal gradient. As
time continues, heat is lost through conduction from the
back mold portion into the lens polymer and the front
mold portion, and then collectively into the surrounding
environment. The heated back mold portion is,
25 therefore, promptly removed so that very little energy
is transferred to the polymer lens, avoiding the
possibility of thermal decomposition of the lens. The
heating may be accomplished by techniques known to one
skilled in the art such as by steam, laser and the like.

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If the heating step is hot air or steam, after the heating step, the back curve is pried from the front curve and mold in the mold assembly, as indicated at Step 111. If on the other hand, the heating is by laser or infrared, no prying is used and the back curve separates spontaneously from the front curve.

The demolding assemblies of the mold separation apparatus 90 each physically pry the back curve mold half 30 from the front curve half 10 of each contact lens mold to physically expose each contact lens situated in the lens mold for conveyance to a hydration station for hydration of the lenses. The prying process occurs under carefully controlled conditions, so that the back curve half 30 will be separated from the front curve half 10 without destroying the integrity of the lens formed in the lens mold.

After the mold assemblies have been separated in the demold apparatus 90, each pallet containing the front curve mold halves with an exposed polymerized contact lens therein, is subsequently transported to a hydration station for hydration and demolding from the front curve lens mold, inspection and packaging, as indicated at Step 112.

In the course of commercial operations including high speed production of lenses in volume, a small member of defects can seriously affect yield, and resultant economics of the process. This is particularly the case where, in consequence of the use of automated manufacturing equipment a defect in a single lens can result in the loss of a larger number of lenses with which it is associated for example in the

course of being transferred via integral pallets or
1 frames from one manufacturing station to another.

Lens defects occur for many reasons, including
simple misalignment of manufacturing equipment, but as
the latter is readily correctable through engineering
5 adjustment, interest is focussed principally on lens
holes and puddles formed in the course of filling and
curing steps, employing the reactive monomer mix (RMM).

Lens holes include voids i.e. areas which
contain no monomer, pits i.e. areas of nonuniform
10 thickness, and other similar regularities such as uneven
edges, being a function of the efficiency of spreading
of the reactive monomer mix on the surface of the convex
back curve mold when the two mold halves are joined.

Puddles, another lens defect, in random or
15 tree branch shapes generally found along the lens edge,
are generated during the curing step, and are associated
with the concave or front curve mold.

High speed photography has demonstrated the
formation of lens holes in the filling operation during
20 the spreading of the advancing meniscus of the RMM upon
the convex or back curve mold. However, the occurrence
of the defect is apparently indiscriminate, especially
considering the number of sound lenses produced in the
same manner on the same equipment. It had already been
25 established that on a macro scale, RMM wets the
polystyrene mold surface well.

However, fundamental studies (based upon work
reported by R. H. Dettre and R. E. Johnson Jr. J. Phys.
Chem. 68, 1507 (1964) and in Surface and Colloid
30 Science, E. Matijevic, Ed., Wiley-Interscience, NY 1969,

161.2 pp. 85 and S.P. Wesson, TRI Progress Report # 49,
1 Textile Research Institute, Princeton N.J. August 23,
1992) showed that the mold surface, formed of a
hydrophobic polymer such as polystyrene, was a low
energy heterogeneous surface having a small portion of
5 high energy surface domains. This was consistent with
knowledge that the molding resins were typically
fabricated for injection molding purposes to contain
certain additives including mold release agents, which
could provide the high energy domains on the mold
10 surface.

There was in consequence established the need
for means to modify the surface activity at the
interface between the convex or back curve mold and the
reactive monomer mix, in the context of dynamic lens
15 formation during molding and in particular, during the
original contact with the RMM, and the advancing
meniscus thereof onto and across the convex mold. In
particular, it was desired to establish during molding
an increase in the high energy surface area exhibited by
20 the convex mold.

In order to implement the high-speed and mass-
production molding of such hydrophilic contact lenses,
there have been developed two-part molds incorporating
pallet-supported mold structures; for example, as
25 disclosed in U.S. Patent No. 4,640,489 to Larsen, and
methods of forming shaped polymeric hydrogel articles,
such as hydrophilic contact lenses, elucidated in the
disclosures of U.S. Patent Nos. 4,680,336 and 5,039,459
to Larsen et al.

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The release of hydrophilic contact lenses from
1 adherent mold surfaces subsequent to the completion of
the contact lens molding process can be facilitated or
improved upon, as is set forth in the disclosure of U.S.
Patent 5,264,161 to Druskis et al. In that instance,
5 surfactants are introduced in solution into a hydration
bath employed in the molding cavities for molding the
hydrophilic polymeric structures or contact lenses. The
surfactant which is dispersed in the hydration bath in
concentrations not exceeding 10% by weight aids in
10 facilitating release of the lenses from adherent
contiguous mold surfaces being separated, the function
of such surfactant being to reduce the surface tension
properties of water or liquids, and to thereby reduce
the level of adherence between components consisting, on
15 the one hand, of the contact lenses and, on the other
hand, the mold surfaces which become adherent during
molding. Numerous types of surfactants are disclosed in
this patent publication, such as polymeric surfactants
including polyoxyethylene sorbitan mono-oleates, which
20 are especially suitable for releasing in an undamaged
state any hydrophilic polymer articles from adherent
mold surfaces which are constituted of plastic
materials.

U.S. Patent 4,159,292 describes the use of
25 silicone wax, stearic acid and mineral oil as additives
for plastic mold compositions to improve the contact
lens release from the plastic molds.

The use of surface applied surfactants as
release agents in connection with the manufacturing of
30 hydrogel contact lenses is disclosed in commonly

assigned U.S. Patent No. 5,542,978 to Kindt Larsen et
1 al. In this patent, a thin layer or film of a
surfactant such as Tween 80 is applied via a stamping
head to surface regions extending about, i.e.,
peripherally of the front curve of a mold part for the
5 forming of contact lenses, to facilitate the lens
release upon demolding of all or part of the peripheral
rings of RMM material expressed externally of the mold
by virtue of overrun during filling. In this
application, no surface active material is applied to
10 the portion of the mold defining the optical face of the
lens.

In these circumstances, primary consideration
is directed to the physical difficulty engendered by
adhesion of the contact lens to one or another of the
15 mold surfaces, or to efficient handling of waste
material resulting from overrun of the RMM in filling.
In automated operations it is significant to assure
uniform reliable separation of mold components, waste,
and contact lens product on a consistent basis. In
20 consequence, efforts are centered upon the steps of
demolding following filling, in which the concern is to
assure preferential displacement of the concave and
convex molds relative to the contact lens blank and the
waste portion, if any, at the periphery of the product
25 along the peripheral flange of the mold. In preferred
manufacturing practice, the contact lens is retained by
the front curve or concave mold while the waste portion
at the periphery is disengaged from the peripheral
flange thereof and retained by the convex mold assembly
30 as it is mechanically disengaged from molding relation.

This first demolding is contrasted with the second
1 demolding of the cured, hydrated contact lens from the
front curve mold. Different conditions and
considerations obtain of course, in each of these
demolding operations.

5 An entirely distinct problem is presented by
the need to control the wettability of the convex mold
surface to the RMM in an endeavor to reduce lens hole
defects. The release characteristics of the mold
surface for demolding do not straightforwardly correlate
10 to the wettability phenomenon especially under varying
ambient conditions and potential compositional
variations in the RMM formula. Moreover, molds having a
modified surface, as by internal loading with an agent
such as zinc stearate, while useful in affording
15 wettability to the RMM interface, on the one hand can
offer only a singular level of surface energy domains at
any one time, and if reused, may offer degradation in
that characteristic with use over time as an internal
lubricant source is exhausted by exudation.
20 Furthermore, the phenomena of wettability and demolding
involve fundamentally different considerations, such
that a semi-permanent change in the mold surface may
favorably affect wettability but unfavorably affect
demolding.

25 In consequence it is desired to meet the
requirements for enhanced wettability at the mold/RMM
interface in a more flexible and responsive manner,
taking into account ambient conditions and other dynamic
aspects of the manufacturing process such as speed of

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the operating line, hence time for mold wetting and
1 demolding.

It has now been found that one may
conveniently control characteristics of the mold
surfaces critical to the minimization of lens hole
5 defects by providing a transiently modified mold surface
having an enhanced, more homogeneous population of
surface domains of high energy thusly facilitating the
wettability and spreadability of RMM across the mold
surface under conditions of high speed automated
10 operations.

The present invention is directed to an
improved process for molding hydrophilic hydrogel
contact lenses from a reactive monomer mixture in which
cooperating concave and convex mold faces are interposed
15 in molding relation about a cavity formed therebetween
to form a contact lens blank, containing reactive
monomer mixture the improvement which comprises treating
at least one of said mold faces with a transient coating
of an agent to facilitate wetting of said mold face with
20 the reactive monomer mixture whereby lens hole defects
and or puddle defects in said contact lens blanks are
reduced.

More specifically, the hydrophobic optical
surface of the mold may be treated with a removable
25 surface agent forming a transient uniform coating
thereon whereby the transfer efficiency at the RMM/mold
interface is improved for the wettability and coating of
that mold surface as the advancing meniscus of the RMM
is engaged during the molding sequence. It is important
30 to appreciate that the surfaces are engaged in mating

relation about the RMM for microseconds during each
1 molding cycle. Naturally, given the somewhat viscous
nature of the RMM material, any domain of the mold seen
to lack receptivity to, i.e. wetting by the RMM will be
bypassed in the dynamic spreading of the RMM upon and
5 around the defining surface of the mold, leading to
defects.

Given that the mold where reused may cycle
thousands of times per hour an internal lubricant such
as zinc stearate, while effective in most cases, may not
10 over longer runs at high speeds and under different
ambient conditions be capable of controlling surface
characteristics consistently; the periodic modulation of
surface characteristics provided by a surface coating of
transient nature offers operating advantages and greater
15 certainties of yield with improved quality performance,
together with flexibility and responsiveness to ambient
conditions, as aforesaid.

More specifically it has been recognized that
ambient operating conditions, in particular relative
20 humidity, can impact the wettability of the mold contact
surface for the hydrophilic RMM - and when employed
along or in conjunction with the use of surface applied
surfactants or internal lubricants can establish
satisfactory conditions for minimization of lens hole
25 defects. Control of this variable alone under proper
conditions can also be effective.

As is well known, relative humidity commonly
refers to an ambient moisture condition in the
surrounding air, which will of course vary seasonally as
30 in response to heating or air-conditioning conditions

obtaining in the manufacturing environment. That
1 environment itself may be controlled or a microclimate
may be created by at least partial closure of any
operating zone, in this case the filling zone of the
manufacturing zone. The latter constitutes a
5 particularly convenient application where a surfactant
is used, conjunctively, as either or both of a reduced
humidity and reduced level of surfactant may be
employed, and recovery of excess chemical agents from
the enclosed zone may be more readily achieved for
10 better environmental control and recycling.

In general it has been found that maintenance
of a relative humidity of 60 to 80% in the area of the
filling zone is sufficient to maintain a surface
condition on the optical surface of the mold of
15 satisfactory receptivity to efficient spreading of the
RMM on the mold surface to achieve minimization in lens
hole defects. Such a condition may be effected as
necessary by spray jets or other vaporization source
inducing a higher level relative humidity than that
20 obtained under ambient conditions; or those conditions
themselves, specifically ambient temperature, may be
manipulated to induce the desired relative humidity in a
manner well known in the art. Thus the temperature in
the zone may be increased, as by the use of electric
25 strip heaters to permit the ambient air to accommodate a
higher relative humidity. The temporal or transient
nature of the condition is appreciated when one
recognizes that the moisture coating is readily absorbed
upon contact with the reactive monomer mix.

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In an alternate process for reducing lens hole defects in production of contact lens blanks, the convex mold is pretreated by application of a surface active agent to at least the contact face of the mold by applying, as by spraying, dipping or any other suitable means, a surfactant such as Tween 80, appropriately in a solvent vehicle therefor such as water, to provide a concentration of 0.05 to 5.0% w/w of surfactant. The pretreatment may be applied in conjunction with i.e. to precede each mold cycle or may be effected intermittently, to maintain the required surface energy requirements for reduction of lens hold defects. The amount of surfactant to be employed will also be gauged by a certain balance between measures taken to ensure desired lens release preferentially from the convex molding surface at this stage; and lens demolding from the concave or front curve mold following cure. In addition the mold materials may be made with additives in which the concave or front curve mold may be formed from a composition incorporating a compatible agent such as zinc stearate whereas the surface of the convex or back curve mold is treated periodically with a surfactant in accordance with this invention as aforesaid.

In this manner, it has been shown that lens hole defects can be reduced by as much as several percent in a high speed automated pilot production line thereby effecting substantial economic savings while increasing efficiency of the manufacturing operation.

Figure 1 is a flow diagram of the continuous process for contact lens production, including molding,

treatment and handling of the molds and contact lenses
1 in a low oxygen environment.

Figure 2 is a top elevational planar view of
the production line system.

Figure 3 is a graph of the % lens holes
5 (visual) vs. water wetting force (mg) of lens holes
reduction with increasing water wetting force and
illustrating the preference herein for the use of
wetting agents exhibiting a water wetting force
generally in excess of 70 mg.

10 In accordance with the invention, the
interfacial tension between the reactive monomer mix,
more specifically the advancing meniscus thereof, and
the optical surface of the convex or back curve mold is
controlled and minimized by normalizing and extending
15 the surface areas representing high surface energy
domains in the convex mold contact surface. This is
accomplished by the temporal or transient application of
a surface modifying agent to the optical surface of the
convex mold in amount and characteristics effective to
20 increase the population of the high surface energy areas
on the convex mold surface to afford improved
wettability by the RMM and effecting a differential in
surface energy as between the respective mold halves, to
overcome the energy required to separate the two mold
25 halves so to preferentially effect the retention of the
optical lens portion on the front curve mold.

Thus, it will be appropriate to consider the
surface characteristic expressed in and upon the front
curve mold in applying the precepts of this invention,
30 as it is desired to assure that the lens blank be

demolded preferentially from one mold surface
1 consistently throughout the manufacturing process,
usually (and as described herein) from the convex mold,
thereby permitting the retention of the lens blank in
the concave front curve mold in its procured,
5 prepolymerized state for traverse to and through the
remaining manufacturing stages. In consequence, it is
necessary to take into account, relative to the type and
amount of surface modifying agent to be applied to the
convex mold surface, whether the front curve or concave
10 mold has itself been pretreated, usually by an internal
additive such as zinc stearate to modify the surface
characteristics of the mold. More specifically, one
implements the practice of the present invention in such
manner as to assure that, relative to the surface energy
15 retentive characteristics of one mold surface, that a
certain effective differential be induced in the second
mold surface, to effect preferential displacement on a
consistent basis throughout the manufacturing process.
As aforesaid, it is understood that it is preferred that
20 the differential referred to favors release from the
convex surface, especially because the benefits of
reduced lens defects arising from poor wetting of the
convex surface with RMM can thereby also be realized.

The selection of surface modifying means is
25 directly related to the wettability of the mold surface
by the RMM as aforementioned. The theoretical
estimation of wetting, which is the thermodynamic
parameter called the spreading coefficient, is defined
as:

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$$S = \gamma_s - \gamma_l - \gamma_{sl}$$

where S is the spreading coefficient, γ_s is the surface energy of the mold material, γ_l is the surface tension of the reactive monomer mix ("RMM") and the γ_{sl} is the interfacial tension between reaction monomer mix and the mold material. A positive " S " indicates spreading (or wetting). Therefore, in order to spread or to wet, γ_l and γ_{sl} should be made as small as possible or should be made as large as possible. Practically, this means that the surface energy of the mold is increased or the surface tension of the reactive monomer mix is reduced or both is performed in order to obtain the appropriate wetting between reactive monomer mix and the mold. With respect to increasing the mold surface energy, this requires consideration of increasing not only the total surface energy, but also increasing the portion of high energy surface.

Thus, one method of affording improved wettability is to reduce surface tension of the RMM by incorporating therein a surfactant. Another method with similar effect is to heat the RMM, which can reduce surface tension from 38 dynes/cm at 20°C to 34 dynes/cm at 60°C which a concomitant decrease is viscosity.

The mold surface when composed of polystyrene is highly non-polar, and has a surface free energy of 42 dynes/cm. Wetting between the RMM and the mold surface is alternatively improved by the presence of a surface modifying agent such as moisture at the interface in the form of a thin layer. The surface energy of a water thin film is 72 dynes/cm hence a significant increase of surface energy is readily achieved by coating a thin water layer on the polystyrene mold surface. A uniform

thin moisture layer on the polystyrene mold surface
1 represents a homogenous high energy, highly wettable
surface. After assembly of the mold surfaces about the
RMM the water layer is absorbed by the RMM, rendering
the mold surface again less wettable and favoring lens
5 demolding, emphasizing the importance of a transiently
modified surface.

To correlate the improvement in lens hole
defect performance to water wettability, a modified
Wilhelmy wetting method was developed to measure the
10 wettability of polystyrene back curve molds. Water was
used as the probe liquid because of its high surface
tension and its high polarity. The experimental detail
is set forth in working Example 1.

Figure 3, a plot of water wetting force vs
15 lens hole defects, is illustrative. The plot shows that
a mold surface with a water wetting force greater than
70 mg produces little or no lens holes. A larger value
represents a large wetting force and indicates the mold
surface is more wettable. Among the findings was the
20 observation that untreated mold surfaces evidenced a
large variation in wetting properties consistently with
the practical appreciation that lens hole defects occur
on an apparently random, sporadic basis in production.

To determine the feasibility of surface
25 treating mold material for use in the back curve mold to
reduce the tendency to form lens holes in the contact
lenses, the inventors developed a modified wetting
method to measure the wettability of the back curve
mold. This method measures the wetting forces between

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the probe wetting liquid (D.I. water) and the back curve
1 mold surface defined by the relationship:

$$F = 2\gamma \cos \theta$$

wherein

F is the wetting force (mg) of the mold half
5 being measured;

γ is the surface tension of the probe liquid,
i.e., the water;

p is the perimeter of the mold half at the
meniscus (cm) when the mold half is partially immersed
10 in the water; and

θ is the dynamic contact angle in degrees θ .

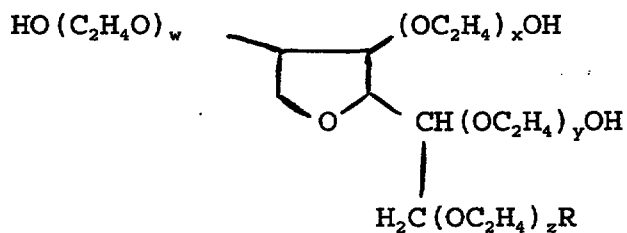
In accordance with the invention, it has been
determined that a back curve with a water dynamic
contact angle less than or equal to 100° produces
15 contact lenses with significantly less lens holes. It
is more preferred that the contact angle be less than or
equal to 90° ; and particularly preferred that such angle
be less than or equal to 75°

The surface modifying or wetting agent may be
20 a surfactant; where consistent with the foregoing
criteria, its selection is not critical, insofar as it
is capable in wetting characteristics relative to RMM
and in differential release characteristics relative to
the companion mold surface to which it is not applied to
25 achieve the benefits of the invention as outlined
herein. Naturally, to the extent that the surfactant is
absorbed into the RMM, or remains to a certain extent on
the surface of the lens after hydration, it will be
selected with regard to its physiological or
30 pharmaceutical acceptability for human use in eye

contact. The surface tension modifying characteristics
1 of the surfactant material in the circumstances
obtaining will be assessed relative to the desired
differential release property; and the surface energy
modifying characteristics will be assessed relative to
5 the enhanced wettability for the RMM in relation to the
mold surface (in particular, the convex mold surface, as
aforesaid) in a manner well known to the artisan. The
surfactant material is also selected for compatibility
with the mold materials and the reactive monomer mix.
10 While, as a consequence, amounts to be applied may
differ in response to these characteristics, it has been
found that in most cases, a selected application in the
range of 0.05 to 5.0 weight % of a solution of the
surfactant material is sufficient, usually 0.05 to 2.0
15 weight %.

Among otherwise suitable surfactants, anti-
static agents, ionic surfactants, non-ionic surfactants
or lubricant formulations may be employed in the present
invention. Suitably, the surfactant constitutes a
20 solution or dispersion of the surface active agents in
an essentially inert vehicle to facilitate application
to the mold surface by spraying, wiping, vapor
deposition, sponging, dipping or the like. Thus, water,
an alkanol or mixtures thereof may be satisfactorily and
25 economically used to constitute a solution or dispersion
of the surface active agent.

Among the materials found to not only aid in
wettability of the mold surface but also to retain
effective release characteristics for lens demolding
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Generally, water soluble or water dispersible
20 materials are preferred for ease of application. As the
mold materials are typically manufactured from
hydrophobic materials such as polypropylene or
polystyrene, the wettability efficiency for these
materials is significant .

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methyl sulfate sold by Cytec) and Atmer 163 (N,N-bis (2-
1 hydroxyethyl) alkylamine)). Other quaternary compounds
include the diamidoamines, the imidazoliniums, the
dialkyl dimethyl quaternaries, the dialkoxo alkyl
quaternaries, and the monoalkyl trimethyl quaternaries.
5 Certain of these materials offer the further advantage
of being soluble in RMM and hence are conveniently
reabsorbed into the lens material, leaving the mold
surface unaffected upon release and therefore more
readily recycled for further use, without cleansing to a
10 base, or neutral condition.

The surface active or wetting agent may be
applied to the mold surface by spraying or swabbing or
dipping, as aforesaid, such that the surface is evenly
coated therewith. The mold is merely drip-dried with or
15 without the aid of heat and stockpiled for use in the
manufacturing process. The amount of surfactant so
applied is adapted to provide a uniform coating of 0.05
to 0.5 weight % solution of surfactant on the surface of
the mold, as aforesaid.

20 The application of the surface modifying or
wetting agent may alternately be suitably integrated
with the manufacturing process such that the molds may
be treated immediately prior to their interpolation with
the transport mechanism, or just prior to the filling
25 operation, such that the surface thereof is fully
wetted, i.e., undried at the point of contact with the
reactive monomer mixture.

The molds can be made from any thermoplastic
material which is suitable for mass production and can
30 be molded to an optical quality surface and with

mechanical properties which will allow the mold to
1 maintain its critical dimensions under the process
conditions employed in the process discussed in detail
below, and which will allow polymerization with the
initiator and radiant energy source contemplated. The
5 concave and convex mold members can thus be made from
thermoplastic resins. Examples of suitable materials
include polyolefins such as low, medium, and high
density polyethylene, polypropylene, including
copolymers thereof; poly-4-methylpentene; and
10 polystyrene. Other suitable materials are polyacetal
resins, polyacrylethers, polyarylether sulfones, nylon
6, nylon 66 and nylon 11. Thermoplastic polyesters and
various fluorinated materials such as the fluorinated
ethylene propylene copolymers and ethylene
15 fluoroethylene copolymers may also be utilized.

It has been found that with the need for a
high quality, stable mold and especially for the use of
a plurality of molds in high volume operations the
choice of material for the molds is significant. In the
20 present invention the quality of production is not
assured by individual inspecting and sorting each lens
for power and curvature. Instead the quality is assured
by keeping the dimensions of each individual mold member
within very tight tolerances and processing molds in
25 particular sequential steps to give all lenses equal
treatment. Since polyethylene and polypropylene partly
crystallize during cooling from the melt there is a
relatively large shrinkage giving dimensional changes
difficult to control. Thus, it further has been found
30 that the most preferred material for the molds used in

the present process is polystyrene which does not
1 crystallize, has low shrinkage, and can be injection
molded at relatively low temperature/to surfaces of
optical quality. It will be understood that other
thermoplastics, including those mentioned above, may be
5 used provided they have these same properties. Certain
copolymers or blend of polyolefins that exhibit these
desirable characteristics are also suitable for the
present purposes as are polystyrene copolymers and
blends having such characteristics, as described more
10 fully in U.S. Patent No. 4,565,348.

The soft contact lens blanks are formed from a
reactive monomer composition which typically
incorporates in addition to the reactive monomer a water
displaceable diluent in the case of the preparation of a
15 hydrophilic lens, a polymerization catalyst to assist in
curing the reactive monomer, a cross-linking agent and
often a surfactant to aid in mold release.

The curable compositions preferably include
copolymers based on 2-hydroxyethyl methacrylate ("HEMA")
20 and one or more comonomers such as 2-hydroxyethyl
acrylate, methyl acrylate, methyl methacrylate, vinyl
pyrrolidone, N-vinyl acrylamide, hydroxypropyl
methacrylate, isobutyl methacrylate, styrene,
ethoxyethyl methacrylate, methoxy triethyleneglycol
25 methacrylate, glycidyl methacrylate, diacetone
acrylamide, vinyl acetate, acrylamide,
hydroxytrimethylene acrylate, methoxyethyl methacrylate,
acrylic acid, methacryl acid, glyceryl methacrylate, and
dimethylamino ethyl acrylate.

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Preferred polymerizable compositions are
1 disclosed in U.S. Patent No. 4,495,313 to Larsen, U.S.
Patent No. 5,039,459 to Larsen et al. and U.S. Patent
No. 4,680,336 to Larsen et al. Such compositions
comprise anhydrous mixtures of a polymerizable
5 hydrophilic hydroxy ester of acrylic acid, a
displaceable ester of boric acid and a polyhydroxyl
compound having preferably at least 3 hydroxyl groups.
Polymerization of such compositions, followed by
displacement of the boric acid ester with water, yields
10 a hydrophilic contact lens. The mold assembly utilized
in the present invention may be employed to make
hydrophobic or rigid contact lenses, but the manufacture
of hydrophilic lenses is preferred.

The polymerizable compositions preferably
15 contain a small amount of a cross-linking agent, usually
from 0.05 to 2% and most frequently from 0.05 to 1.0%,
of a diester or triester. Examples of representative
cross linking agents include: ethylene glycol
diacrylate, ethylene glycol dimethacrylate, 1,2-butylene
20 dimethacrylate, 1,3-butylene dimethacrylate, 1,4-
butylene dimethacrylate, propylene glycol diacrylate,
propylene glycol dimethacrylate, diethylglycol
dimethacrylate, glycol dimethacrylate, diethylglycol
dimethacrylate, dipropylene glycol dimethacrylate,
25 diethylene glycol diacrylate, dipropylene glycol
diacrylate, glycerine trimethacrylate, trimethylol
propane triacrylate, trimethylol propane
trimethacrylate, and the like. Typical cross-linking
agents usually, but not necessarily have at least two
30 ethylenically unsaturated double bonds.

The polymerizable compositions generally also
1 include a catalyst, usually from about 0.05 to 1% of a
free radical catalyst. Typical examples of such
catalysts include lauroyl peroxide, benzoyl peroxide,
isopropyl percarbonate, azobisisobutyronitrile and known
5 redox systems such as the ammonium persulfate-sodium
metabisulfite combination and the like. Irradiation by
ultraviolet light, electron beam or a radioactive source
may also be employed to catalyze the polymerization
reaction, optionally with the addition of a
10 polymerization initiator. Representative initiators
include camphorquinone, ethyl-4-(N,N-dimethyl-
amino)benzoate, and 4-(2-hydroxyethoxy)phenyl-2-
hydroxyl-2-propyl ketone.

Polymerization of the polymerizable
15 composition in the mold assembly is preferably carried
out by exposing the composition to polymerization
initiating conditions. The preferred technique is to
include in the composition initiators which work upon
expose to ultraviolet radiation; and exposing the
20 composition to ultraviolet radiation of an intensity and
duration effective to initiate polymerization and to
allow it to proceed. For this reason, the mold halves
are preferably transparent to ultraviolet radiation.
After the procure step, the monomer is again exposed to
25 ultraviolet radiation to a cure step in which the
polymerization is permitted to proceed to completion.
The required duration of the remainder of the reaction
can readily be ascertained experimentally for any
polymerizable composition.

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The mold assembly comprises at least two
1 pieces, a female concave piece (front curve) and a male
convex piece (back curve), forming a cavity
therebetween, and when said pieces are mated, at least
one piece having a flange thereabout. More
5 particularly, the mold assembly comprises a front mold
half and a back mold half in contact therewith, thereby
defining and enclosing a cavity therebetween, and a
polymerizable composition in said cavity in contact with
said mold halves, the front mold of which has a central
10 curved section with a concave section with a concave
surface, a convex surface and circular circumferential
edge, wherein the portion of said concave surface in
contact with said polymerizable composition has the
curvature of the front curve of a contact lens to be
15 produced in said mold assembly and is sufficiently
smooth that the surface of a contact lens formed by
polymerization of said polymerizable composition in
contact with said surface is optically acceptable, said
front mold also having an annular flange integral with
20 and surrounding said circular circumferential edge and
extending therefrom in a plane normal to the axis and
extending from said flange, while the back mold has a
central curved section with a concave surface, convex
surface and circular circumferential edge, wherein the
25 portion of said convex surface in contact with said
polymerizable composition has the curvature of the back
curve of a contact lens to be produced in said mold
assembly and is sufficiently smooth that the surface of
a contact lens formed by polymerization of the
30 polymerizable composition in contact with said surface

is optically acceptable, said back curve also having an
1 annular flange integral with and surrounding said
circular circumferential edge and extending therefrom in
a plane normal to the axis of said convex structure, and
a generally triangular tab situated in a plane normal to
5 said axis and extending from said flange, wherein the
convex structure of said back mold half contacts the
circumferential edge of the front mold half.

The inner concave surface of the front mold
half defines the outer surface of the contact lens,
10 while the outer convex surface of the base mold half
defines the inner surface of the contact lens which
rests upon the edge. Specifics of such constructions
are known and taught in U.S. Patent 4,640,489 to Larsen.

In applying the surface active material to the
15 surface of the mold several considerations should be
borne in mind: a sufficient level of surfactant is
employed to uniformly cover the mold surface to effect
the desired enhancement of wettability in the
circumstances obtaining, the agent is retained on the
20 surface in effective amounts for use in the filling
operation, and where absorption into the RMM occurs, the
amount of material employed is not in excess of that
which can be diffused into and absorbed by the RMM prior
to the solidification of the lens.

25 As is self evident, the wetting agent is
pharmaceutically acceptable at the levels employed, and
does not affect the surface or the efficacy of the
finished lens.

In accordance with the invention, a convex
30 mold surface which has been pretreated with the surface

modifying agent, as aforesaid is brought into mating
1 engagement with a front curve mold and the reactive
monomer mix filling the molding cavity therebetween,
during which process the optical surface of the convex
mold contacts and by reason of its modified surface is
5 efficiently wetted by the RMM such that the advancing
meniscus uniformly coats the mold surface without the
formation of lens hole defects. The convex mold, when
mechanically separated from the concave mold by reason
of its modified surface, efficiently (and consistently
10 throughout the process, involving an interaction of
similarly treated molds) releases the lens blank (which
remains with the concave mold for curing) without
tearing or otherwise damaging the lens blank.

In a preferred embodiment, the front curve
15 mold is formed from a composition which comprises an
added mold release agent such as zinc stearate, which
aids in demolding of the lens blank after hydration. In
consequence, its surface energy characteristics have
been modified and an additional level of surface
20 modifying agent (in this case a combination of water
vapor and surfactant application) may be required in
application to the convex mold surface to balance the
release characteristics in such manner as to assure
release of the lens blank for retention by the concave
25 or front curve mold surface.

It will be understood in connection with the
foregoing description that the concepts as well as
theoretical considerations affecting demolding are
entirely distinct from the problem of adequately wetting
30 the surface of the forming mold with the monomer

composition although each consideration is interrelated
1 to the other in practice, i.e., one may successfully
demold a lens blank which, however, is defective due to
one or more lens holes. The contact portion of the
convex lens mold in particular must be receptive to the
5 monomer composition at the point and time of application
under the conditions then obtaining, in the sense that
it requires a critical wettability controlling efficient
spreadability across the contact surface of the mold to
be established, by increasing the surface area
10 comprising high surface energy domains in the convex
mold contact surface.

While the invention has been described with
particular reference to application of the surface
modifying agent to the optical surface of the convex
15 mold in a particular manufacturing operation, including
a generally vertical disposition of the mating mold
elements with the concave member generally supporting
the incipient lens blank in a supine or lower position,
it will be understood that to effect preferential
20 displacement of the lens blank as, for example, in other
geometric arrangements the surface modifying agent may
be applied to the optical surface of either lens mold
surface.

Also, while the present invention has been
25 primarily illustrated by reference to the control of a
wetable surface on the convex mold optical surface to
control lens hold defects, it is also effective in
minimizing puddling on the concave lens surface
facilitating the initial spreading and coating of the
30 surface by the RMM in a uniform, homogenous manner.

EXAMPLE 1

1 A number of treated, back curve molds were
tested for water wetting force as follows: The treated
mold is suspended vertically on a microbalance above a
body of water functioning as a probe liquid. The water
5 level is raised incrementally to immerse the back curve.
The wetting force between the probe liquid and the back
curve as the probe liquid is being raised is measured by
the microbalance and recorded. A trace of the wetting
forces as a function of distance traveled by the water
10 meniscus over the back curve is obtained from which the
value p (the perimeter of the mold half at the meniscus
(cm) when the mold half is partially immersed in the
water) can be calculated which when taken together with
the wetting force (mg) F can be employed to determine
15 the dynamic contact angle in degrees according to the
formula:

$$F = 2 \gamma \cos \theta$$

where γ is the surface tension of water (72.75 dynes/cm
at 20°C). As described hereinabove, it is preferred
20 that the water dynamic contact angle afforded by the
treated surface is less than or equal to 100°,
preferably less than or equal to 90°.

The apparent water wetting force for various
treated and untreated back curves is set forth as
25 follows in Table 1.

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TABLE 1

MOLD SURFACE	WETTING FORCE
Untreated Polystyrene A	56.4
Untreated Polystyrene B	56.9
Untreated Polystyrene C	50.9
0.25% CYASTAT LS*/Polystyrene B	67.1
0.5% CYASTAT LS/Polystyrene B	113.0
0.05% CYASTAT LS/Polystyrene C	105.0
0.25% CYASTAT LS/Polystyrene C	81.0
0.5% CYASTAT LS/Polystyrene C	115.0

* (3-lauramidopropyltrimethylammonium methyl sulfactate,
sold by Cytec Industries)

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EXAMPLE 2

Convex molds were immersed in 2% aqueous solutions of Larostat 264 A (PPG), Armostat 410 (Akzo) and Cystat SN (Cytec), respectively, and then dried
5 under ambient conditions for 48 hours. The thus formed coating rendered the surface more wettable by the RMM, a HEMA based composition.

When the treated molds were employed in an automated pilot manufacturing facility, lens mold
10 defects were reduced by about 34.6%.

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EXAMPLE 3

1 Polystyrene contact lens molds were swabbed
with Glucam P-10, Tween 80 and an aqueous dispersion of
Glucam DOE 120, respectively, and the molds were
utilized in molding contact lenses employing a reactive
5 monomer mix comprising 96.8% HEMA, 1.97% methacrylic
acid, 0.78% ethylene glycol dimethacrylate, and 0.1% of
trimethylolpropane trimethacrylate and 0.34% of Darvocur
1173 dispersed (48% RMM) in glycerin boric acid ester as
an inert water displaceable diluent. The mold halves
10 were readily separated without defects.

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WHAT IS CLAIMED IS:

- 1 1. In a process for molding hydrophilic
hydrogel contact lenses from a reactive monomer mixture
in which cooperating concave and convex mold faces are
interposed in molding relation about a cavity formed
5 therebetween to form a contact lens blank, containing
reactive monomer mixture the improvement which comprises
treating at least one of said mold faces with a
transient coating of an agent to facilitate wetting of
said mold face with the reactive monomer mixture whereby
10 lens hole defects and or puddle defects in said contact
lens blanks are reduced.
2. The process of Claim 1 wherein said agent
comprises a surfactant effective to render more
homogeneous the high surface energy domains present on
15 the mold surface.
3. The process of Claim 1 wherein said agent
comprises condensed water vapor.
4. The process of Claim 2 wherein said agent
is absorbable by said reactive monomer mixture.
- 20 5. The process of Claim 1 wherein the convex
back curve is preferentially pretreated with the wetting
agent.
6. The process of Claim 1 wherein the mold is
constructed of a hydrophobic material.
- 25 7. The process of Claim 6 wherein said
hydrophobic material in polystyrene.
8. In a process for molding contact lens
blanks including filling a concave lens mold with a
reactive monomer mixture, juxtaposing therewith in
30 mating molding relation a convex lens mold, the

improvement which comprises pretreating at least one of
1 the optical surfaces of said molds with water vapor to
condense an even coating of moisture thereon to enhance
wettability of the optical surface to the reactive
monomer mix.

5 9. The method of Claim 1 wherein the wetting
agent as applied to the optical mold surface exhibits a
water wetting force of at least 70 mg.

10 10. The method of Claim 1 wherein the treated
optical surface of the convex mold exhibits a water
dynamic contact angle of less than or equal to 100°.

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