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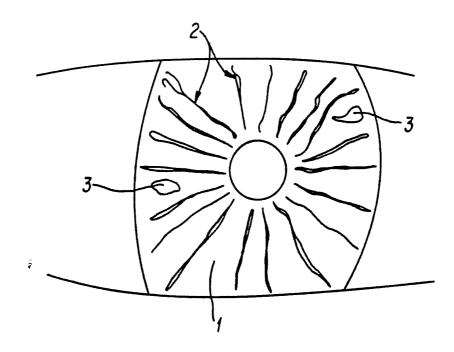
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US

(54) Title: TINTING CONTACT LENSES



(57) Abstract

Contact lenses and other lenses are tinted in any predetermined pattern without masking any portions of the lens by forming the pattern before applying it to the lens. Preferably the colorant is formed into the pattern on a printing pad or equivalent means.

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TINTING CONTACT LENSES BACKGROUND OF THE INVENTION

The present invention relates to coloring lenses, such as ophthalmic lenses and particularly hard and soft contact lenses. Past known attempts have included painting or printing a colored central portion onto a soft contact lens, fabricating the lens from two distinct pieces, the central one of which is colored (U.S. Patent No. 4,252,421) or masking selected areas of the lens and dipping it in its entirety into the coloring agent.

It is desirable to color a lens so that its central portion is clear, thereby providing the wearer with vision that is not impeded by coloring over the pupillary opening. Providing colorant around, but not in, the pupillary opening requires for aesthetic reasons a precise line between the colored and uncolored areas, without bleeding of the colorant into the uncolored area. Achieving this precision has up to now been difficult and time-consuming, which has worked against the widespread availability of low-cost, rapidly produced colored lenses.

SUMMARY OF THE INVENTION

In its broadest aspect, the present invention is a method for applying a dye to an ophthalmic, corneal contact, or intraocular lens, in a predetermined pattern, which comprises forming a colorant containing said dye into said pattern before applying it to the lens, then contacting the colorant with the lens while it is in said pattern, and then fixing the dye to said lens. No masking of portions of the lens, or equivalent expedients, are necessary.

In a preferred embodiment, the present invention provides colored lenses in a process which includes the steps of

- (a) applying the colorant in a predetermined pattern onto a pad means;
- (b) pressing the pad means against a surface of the lens to transfer the colorant to the lens in said pattern;
- (c) heating the colored lens under conditions effective to fix the dye into the lens; and then, if necessary,
- (d) washing the lens to remove residual colorant material from the surface of the lens.

DESCRIPTION OF THE DRAWINGS

The Figure depicts a normal human eye, to show the non-uniformity of the color pattern formed by the iris.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A. Application methods

The preferred method for applying the colorant to the lens is indirect gravure. In this method, the desired pattern is etched into a preferably horizontal metal plate, to one to two thousandths of an inch in depth. Colorant is filled into the etched pattern, for instance, by washing the plate with the colorant and wiping off the plate with a doctor blade, thereby leaving colorant only in the etched area. A printing pad is then pressed temporarily against the pattern, so that all the colorant is transferred to the pad. The pad is then temporarily pressed against the surface of the lens sufficiently so that all the colorant in the desired pattern comes in contact with the lens and thereby transfers to the lens.

Preferred pads are elastomeric, more preferably silicone rubber, or neoprene (polychlorobutadiene), polybutadiene, polyisoprene, styrene-butadiene rubber, butyl rubber, nitrile rubber, ethylene-propylene

copolymer, or polyurethanes. The elastomer should be chemically inert to the colorant. The pad should be soft enough so that it can deform in shape as it is pressed against the metal plate, and against the entire curved surface being colored without fracturing the lens, but hard enough to retain its shape when at rest. Shore hardness values of about 1 to about 18 are satisfactory. The end portion of the pad which transfers the colorant should approximate the shape of the lens being marked; thus, for a contact lens the end of the pad should be a hemisphere or a paraboloid having a circular cross-section. The pad is preferably a solid elastomeric body, but can be hollow.

Alternatively, the pad can be a cylinder which is rolled across the colorant on the etched plate, and then rolled across the lens to transfer the colorant to the lens. The pad can also be made of harder material, such as hard rubber, provided that the printing surface matches the contour of the lens surface being colored so that when the pad is pressed against the lens surface all of the colorant contacts the lens. Likewise, the plate in which the pattern of colorant is initially formed is contoured to match the surface of the pad, so that all the colorant can be picked up by the pad when it is pressed against the plate.

Each lens can be mounted individually on a chuck or spindle, or a series of lenses on a conveyor can be passed through the printing station where they are colored.

A satisfactory machine is available through Tampoprint America, Inc., Schaumburg, Illinois. This machine quickly repeats the steps of filling colorant in the desired pattern into an etched portion of a flat plate while a silicone rubber pad alternates between one station at which it is pressed against the plate to pick up the pattern, and a second station at which it presses against

an object (such as a lens) fixed to a spindle to transfer the pattern to the object.

Another satisfactory coloring method is flexography. A "negative" of the desired pattern is formed on the raised areas of a printing pad (in much the same manner as a conventional "rubber stamp", date stamp, and the like) by cutting away those portions of the pad which are not to form part of the pattern. Colorant is then applied to the pattern only, for instance by rolling a colorant-loaded roller across the pad or by dipping the pad into a pan of colorant. The pad is then pressed against the lens surface.

The pad can be made of the same range of elastomeric materials as disclosed above for the indirect gravure method. Alternatively, the flexographic pad can be made of stiffer material (e.g. hard rubber) if the pad is given a curve which closely approximates the surface of the lens being colored.

Another satisfactory, though less preferred, method is silk-screening, using conventional screen materials. The desired pattern is formed on the screen, by combining numerous very small openings in the screen. The colorant is forced through this pattern onto the lens using a wiper blade.

Jet-printing of the lens surface is also considered within the scope of this invention. The colorant is sprayed through a number of closely spaced small-diameter orifices which are arrayed in the desired pattern and which are spaced just far enough from the lens surface so that after the colorant has been sprayed and is moving toward the lens surface, the individual sprays of colorant merge to form a continuous band defining the desired pattern (which then hits the lens surface). Another technique employs as the pad means a strip of paper or an equivalent carrier on which the pattern is formed, preferably by a thermosetting dye.

B. Lens materials

The present invention is applicable to a wide range of lens materials. Particularly preferred are polymers which possess free hydroxyl groups, such as HEMA (2-hydroxyethyl- methacrylate),

2,3-dihydroxypropylmethacrylate, and other hydroxylated monomers, and copolymers of HEMA or such other monomers with one, two, or more other monomers such as:
HEMA/N-vinyl pyrrolidone

2,3-dihydroxypropylmethacrylate/methyl methacrylate
HEMA/N-(1,1-dimethyl-3-oxobutyl)acrylamide/methacrylic acid
HEMA/N-vinylpyrrolidone/methyl methacrylate
HEMA/methacrylic acid

HEMA/2-ethoxyethylmethacrylate

HEMA/methacrylic acid/N-vinylpyrrolidone
HEMA/methacrylic acid/isobutyl methacrylate

Other preferred lens materials are cellulosics, such as cellulose acetate butyrate, which like the hydroxyl-containing polymers, has a reactive bond or site with which a "reactive" dye (discussed below) can react.

Other lens materials which can be treated by this invention include poly(methylmethacrylate), which many hard contact lenses are made from, and copolymers thereof, and allyl diglycol carbonate (known under its trade name "CR-39"), silicones, silicone acrylates, and polycarbonates.

The hydroxyl-bearing polymers and copolymers are generally hydrophilic, that is, they absorb water and are worn as "soft" contact lenses in the hydrated state, though they are manufactured in the hard, unhydrated state. Lenses made of these materials can be tinted by the present invention in either the hard or hydrated state, although if they are hydrated they should be blotted lightly so that the aqueous solution in which they have been hydrated is not dripping or running off the surface of the lens.

Soft contact lenses are commercially available in the above polymers and copolymers. The copolymers are generally cross-linked with a minor amount less than 1 wt. % of a cross-linking agent such as divinyl benzene, 1,1,1-trimethylolpropane trimethacrylate, ethylene glycol dimethacrylate, ethylene bis (oxyethylene)dimethacrylate, ethylene dimethacrylate, or 2-ethyl-2-hydroxymethyl-1,3-propanediol trimethacrylate.

C. Colorants

As used herein the term "colorant" is intended to mean a dye or pigment, that is, the agent which actually imparts color to the lens or combinations of dyes or pigments, plus the one or more solvents, vehicles, carriers, thickeners, and other auxiliary agents with which the dye or pigment is blended. The following discussion begins with a description of dyes.

The most preferred dyes are those known as "reactive" dyes. A reactive dye is defined as one which reacts chemically with the substrate to which it is applied. Such dyes generally include an easily displaced halogen atom, sulfone group, or sulfonyl group. In the present invention, such dyes are the preferred ones to use with lens materials which contain hydroxyl groups (such as hydroxyethylmethacrylate and copolymers thereof, and cellulosics such as cellulose acetate butyrate).

Particularly preferred reactive dyes include these:

Reactive Black 5: 4-amino-5-hydroxy-3,6-bis((4-

((sulfooxy)ethyl)-sulfonyl)-phenyl)azo)-

2,7-naphthalenedisulfonic acid,

tetrasodium salt.

Reactive Blue 21: copper-(29H,31H-phthalocyaninato(2-)-

N(29),N(30),N(31),N(32))-,sulfo((4-((2-sulfooxy)ethyl)sulfonyl)phenyl)-

amino)-sulfonyl(CAS registry

Number 73049-92-0).

Reactive Orange 78: 7-acetylamino-4-hydroxy-3-((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)2-naphthalene-sulfonic acid

Reactive Yellow 15: 4-(4,5-dihydro-4-((2-methoxy-5-methyl-4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)-azo)-3-methyl-5-oxo-lH-pyrazol-1-yl)-benzene-sulfonic acid

These dyes are available in the U.S. from BASF Wyandotte Corp., Parsippany, New Jersey, and American Hoechst Corp., Charlotte, North Carolina. Other reactive dyes having the above characteristics will readily occur to the practitioner; a source which identifies such dyes is the Color Index, which is the standard reference in this field. The ability of these dyes to bond chemically to the lens polymer greatly reduces the risk that the dye would be removed from the lens by washing or by normal wear in the eye.

Another class of dyes which are highly suitable for use in this invention are the vat dyes. These dyes do not react with the lens but nonetheless penetrate into the lens and are retained therein, when the dye is dissolved in water under alkaline conditions. Examples of satisfactory vat dyes include:

- N,N'-(9,10-dihydro-9,10-dioxo-1,5-anthracenediyl)bisbenzamide (Vat Yellow No. 3)
- 7,16-dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone (Vat Blue No. 6)
- 16,17-dimethoxydinaphtho(1,2,3-cd:3',2',1'-lm)perylene-5,10-dione (Vat Green No. 1)
- Dibromodibenzo(b,def)chrysene-7,14-dione
 (Vat Orange No. 1)
- 6,6'-diethoxy-2,2'-(3H,3'H)bibenzo(b) thiophene-3,3'-dione (Vat Orange No. 5)

These are available from dye suppliers.

Another class of dyes is the thermosetting dyes. These become fixed in the lens material by the application of heat. Examples include (numbers are references to the dye's entry in the Color Index): Yellow 54; Yellow 230; Red 60; Orange 25; Blue 95; and Blue 352. These are available from dye suppliers.

As mentioned above, the dye is blended with other components to make up the colorant that is applied to the lens.

The reactive dye is mixed with water, an alkaline agent, and a thickener. The alkaline agent can be sodium carbonate, sodium bicarbonate, or soda ash. The amount must be effective to raise the pH ehough so that the dye and lens react together. A satisfactory amount is about 15-30 grams of soda ash per kilogram of colorant, preferably 20-25 g/kg. A highly satisfactory thickener is an alginate, such as sodium alginate, or a finely divided montmorillonite clay. The amount should be effective to adjust the viscosity of the colorant to about 1000-3000 centipoise so that the colorant does not drip or run when it is on the printing pad or on the lens. Preferably, the viscosity should be high enough so that if a layer of the colorant is deposited on a smooth plate which is inclined at a 45° angle, the colorant does not flow down the plate. Generally, the alginate can comprise 10-40 wt. % of the colorant. Optional preferred additives to the colorant include a color-penetration improving agent such as thiodiethylene glycol; and a hygroscopic agent such as urea.

Colorants containing vat dyes or thermosetting dyes are formulated from water, thickener such as alginate, and an alkaline agent, with urea as an optional hygroscopic agent following the same criteria discussed above for reactive dyes. Sodium hydroxide and sodium hydroxulfite are preferred vat dye alkaline reagents.

In the colorants described herein, the amount of dye is not critical and can be adjusted in accordance with the intensity desired in the finished lens. As a general guide, though, the dye can comprise about 1-15 wt. % of the colorant, and usually about 5-10 wt. %.

If a hydrated hydrophilic contact lens is being colored, the lens is preferably hydrated with a solution which contains up to 1-2 wt. % of sodium bicarbonate or equivalent alkaline agent to promote the reaction of the dye and polymer.

Another class of dyes is oil-soluble dyes, which are formulated into the colorant by dissolving them in an organic or silicone oil. No alkaline agent is necessary; the colorant is otherwise thickened as taught above. Examples of such dyes are D&C Yellow No. 11, D&C Red No. 17, D&C Green No. 6, and 2-((2,5-diethoxy-4-((methylphenyl)thio)phenyl)azo)-1,3,5-benzenetrione.

D. Fixing the colorant

When the colorant has been applied to the lens, the pattern which the colorant has assumed on the lens can be inspected. An advantage of this invention is that if the pattern has a defect or is otherwise unsatisfactory for any reason, it can simply be washed off and the lens returned to be recolored.

After the colorant has been placed onto the lens in the desired pattern, the lens-colorant combination is treated to fix the dye into the lens. In each type of dye the fixing is preferably accomplished by applying heat. With a reactive dye, the object is to cause the dye to react with the polymer's -OH groups. The combination is heated in a current of hot air at 150°C for 3 to 5 minutes, or at 190°C for about 1 minute; alternatively, the combination is heated in saturated or supersaturated steam for about 20-60 seconds at 100-110°C. With a vat dye, the colorant is left on the lens for about 5 to about 30 minutes, at a temperature of 20°C to 100°C. The

colorant with a thermosetting dye or oil-soluble dye is heated to 125-150°C for about 2 to about 6 minutes.

The lens is then washed with water or a weak acid such as acetic or citric, and with solvents for the dye, thickener, and other agents (if any) of the colorant. The object is to remove all material which remains on the surface of the lens. The dyes discussed and applied as taught hereinabove actually penetrate into the lens, so the washing step will not remove the desired color.

If the dye is a thermosetting dye which has been applied onto a paper strip or equivalent pad means, the dye can be transferred from the strip to the lens by pressing the strip against the lens and heating this combination to $100-250^{\circ}$ C for 5 to 30 minutes, whereby the dye sublimes into the lens material.

E. Patterns

The preferred pattern on the contact lens is a ring of color, leaving the central region of the lens uncolored. For instance, the uncolored central area can be about 3.85 to about 4.20 millimeters in diameter, to equal the size of the wearer's pupillary opening. The colored area can have an outside diameter of about 9.60 to about 10.40 millimeters, to cover the wearer's iris. The portion of the lens outside the colored area remains clear.

It will be appreciated, though, that patterns more complex than a simple band of uniform intensity can be applied using this invention. By varying the contours of the etched portion of the gravure plate, for instance, an uneven appearance can be given to the pattern on the lens, and if a series of colors are printed one on top of the other on the same lens, using varied printing plates or pads, an uneven and multi-colored effect can be created. By combining features such as these, the practitioner can approximate the appearance of the natural human iris, which of course, can have minute streaks or

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spots of unevenness in shade and intensity.

The figure depicts a normal human eye and indicates the non-uniformity of the pattern of color in the iris. The color of the general background areas 1 frequently differ slightly from the color that appears to be concentrated in filament-like areas 2 which radiate approximately radially from the pupil. In addition, flecks or highlights 3 can appear randomly in the iris as well. A pattern of this type can be readily reproduced by the process of this invention, by photographing a human eye and transforming the photographed image via conventional photoresist techniques into a detailed pattern in the etched plate of an indirect gravure, or onto the pad of a flexographic printer or a silk screen. Then, by successive applications of colorants containing dyes which have been selected and/or blended to match the desired colors for the various portions of the iris, the lens can be printed with a pattern which matches the actual patterns of the human iris.

It will also be recognized that the present invention can be employed to apply colorants which are coatings or films, and in which there is a pigment instead of a dye. In the case of coatings, conventional film-forming agents such as nitrocellulose can be used in admixture with a desired dye or pigment. The pigment must be reduced to an extremely fine sub-micron particle size, to avoid eye irritation. Pigments include (phthalocyaninato(2-))copper, red iron oxide, and ultramarine blue. The above embodiments, in which the dye is permitted to penetrate into the lens and nothing remains on the lens surface, are preferred, especially for contact lenses.

Examples of colorants which can be employed in this invention are (all amounts in grams):

With reactive dyes:	_A_	В	<u> </u>	_ <u>D</u> _
Stock thickener (4 wt. % alginate:	785	785	785	785
96 wt. % deionized water)				
Sodium bicarbonate	25	25	25	25
Thiodiethylene glycol ("Glyezine")	45	45	45	45
Urea	150	150	150	150
Reactive Blue 21	10	_	-	-
Reactive Black 5		10	_	-
Reactive Yellow 15	-	-	10	_
Reactive Orange 78	-	_	-	10
With vat dyes	_E_	F	G	_H_
Stock thickener (4 wt. % alginate:	955	955	955	955
96 wt. % deionized water)				
Sodium bicarbonate	25	25	25	25
Vat Blue 6	10		_	_
Vat Brown 1	_	10	-	-
Vat Yellow 3	-	-	10	_
Vat Green 1	_	-	-	10

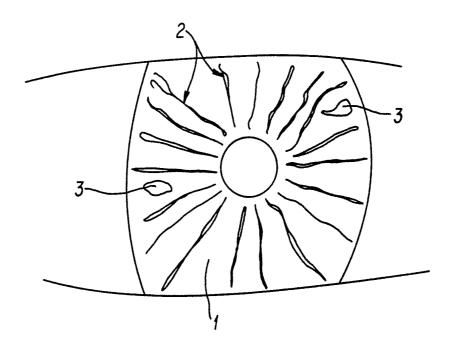
This invention can also be utilized to tint the entire surface of a contact or ophthalmic lens. In addition, functional coatings can be applied in the same manner such as photochromic and scratch-resistant compounds and ultraviolet absorbers.

WHAT IS CLAIMED IS:

- l. The method of applying a dye in a predetermined pattern to an artificial lens, which comprises forming a colorant containing said dye into said pattern before applying it to the lens, then contacting the colorant with the lens while it is in said pattern, and then fixing the dye in the colorant to said lens.
- 2. The method of claim 1 comprising the steps of
- (a) applying the colorant in said predetermined pattern onto a pad means;
- (b) pressing the pad means against the lens to transfer the colorant to the lens in said pattern;
- (c) heating the colored lens under conditions effective to fix the dye into the lens; and then, if necessary,
- (d) washing the lens to remove residual colorant material from the surface of the lens.
- 3. The method of claim 2 wherein the pad means is an elastomeric body, having a smooth surface, and the colorant is applied to said body by forming the colorant into said pattern on a plate means and pressing the elastomeric body against said colorant in said pattern.
- 4. The method of claim 2 wherein a surface of said pad means has raised portions defining said pattern and portions which are not raised, and colorant is applied to said raised portions.
- 5. The method of claim 1 wherein said lens is a contact lens.
- 6. The method of claim 5 wherein said pattern comprises a circular uncolored area surrounded by a concentric, circular colored area.
- 7. The method of claim 6 wherein said colored area is of one color of uniform intensity.
- 8. The method of claim 6 wherein said colored area contains a plurality of colors.

- 9. The method of claim 2 wherein steps (a),(b), (c) and (d) are carried out a second time using a different pattern or a dye of a different color.
- 10. The method of claim 1 wherein the dye is selected from the group consisting of reactive dyes, vat dyes, and thermoset dyes, oil-soluble dyes, and pigments.
- 11. The method of claim 1 wherein the dye is a reactive dye and the lens is made of a polymer or copolymer having free hydroxyl groups.
- 12. The method of claim 11 wherein the lens is a polymer or copolymer of hydroxyethylmethacrylate.
- 13. The method of claim 11 wherein the dye is selected from the group consisting of Reactive Black 5, Reactive Blue 21, Reactive Yellow 15, Reactive Orange 78, and mixtures thereof.
- 14. The method of claim 10 wherein the dye is a dye selected from the group consisting of D&C Yellow No. 11, D&C Red No. 17, Vat Brown No. 1, Vat Yellow No. 3, Vat Blue No. 6, Vat Green No. 1, Vat Orange No. 1, Vat Orange No. 5, D&C Green No. 6, 2-((2,5-diethoxy-4-((4-methylphenyl)thio)phenyl)azo)-1,3,5-benzenetrione, and mixtures thereof.
- 15. The method of claim 10 wherein the dye is a thermosetting dye selected from the group consisting of Yellow 54, Yellow 230, Red 60, Orange 25, Blue 95, and Blue 352.
- 16. A colored artificial lens containing within the lens material one or more dyes which have been applied in accordance with the method of claim 1.
- 17. An artificial lens containing a coating or film which has been applied in accordance with the method of claim 1.
- 18. A lens according to claim 17 wherein the coating or film contains a dye or pigment.

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INTERNATIONAL SEARCH REPORT

International Application No PCT /IIS85/00584

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) 3										
According to Integrational Patent Classification (IPC) or to both National Classification and IPC INT . CL. DO6P 5/00										
U.S. CL. 8/507, 471										
II. FIELDS										
			Minimum Document							
Classification	n System	1		Classific	ation Symbols	44				
U.S. 8/507, 471										
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched 5										
III. DOCUMENTS CONSIDERED TO BE RELEVANT 14										
Category *	Cita	ation of Document, 16 with i	ndication, where appr	opriate,	of the relevant passages 17	Relevant to Claim No. 18				
Y		A, 4,447,474				1-18				
Y	ŲS,	A, 4,238,524	PUBLISHED Laliberte	09	DECEMBER 1980	1-18				
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* Special categories of cited documents: 15 "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 or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention filing date "C" document but published on or after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step document of particular relevance; the claimed invention cannot be considered to involve an inventive step document of particular relevance; the claimed invention cannot be considered to involve an inventive step document of particular relevance; the claimed invention cannot be considered to involve an inventive step document of particular relevance; the claimed invention cannot be considered to involve an inventive step document is combined with one or more other such document; such combination being obvious to a person skilled in the art.										
"P" document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family										
IV. CERTIFICATION										
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International Searching Authority 1					ature of Authorised Officer 20	juan				