**Automated Inspection of Colored Contact Lenses**

The present invention relates to a method for manufacturing colored contact lenses, and in particular to automated inspection of colored images printed either on molds or on contact lenses.

For cosmetic purposes, colored contact lenses having one or more colorants dispersed in the lens or printed on the lens are in high demand. In general, there are two types of colored contact lenses. The first are contact lenses which use essentially transparent or semi-transparent enhancement colors that allow the color of the natural iris to show through but combine with that natural color to produce a new appearance. Such tinted lenses are typically used to turn a light eye (e.g., green) to a slightly different hue (e.g., aqua). This class of colored lenses may not be able to change an underlying dark colored, brown iris to blue. The second category is the class of opaque colored lenses having a continuous opaque pattern that fully covers the iris or having an intermittent opaque pattern that does not fully cover the iris. Opaque colored contact lenses can effectively and substantially modify the wearer's eye color. Colored contact lenses enhance the natural beauty of the eye, or provide unique patterns on the iris of the wearer, or provide non cosmetic patterns.

Colored contact lenses can be produced in a high volume manufacturing process involving cast-molding and printing on molded lenses or printing on molds for cast-molding contact lenses (e.g. described in US 5034166). The large number of lenses which can be produced per minute necessitates the use of an automated inspection system to ensure not only the quality of a lens but also the quality of a colored print (or image) applied onto a lens.

In the contact lens manufacturing industry, it is well known that automated inspection of contact lenses offers the opportunity to reduce production costs while increasing product consistency. A number of automated inspection systems and methods have been developed for automatically inspecting non-colored contact lenses. Automated inspection of colored images (e.g., iris patterns, inversion marks, orientation marks, etc.) printed on lenses has been described in US 6047082 and US 6471891.

Each of these techniques for automated inspection of colored contact lenses is effective for reducing production costs and increasing product consistency. However, these techniques require that the center of a lens with a colored print applied thereon must be found in a digital image by algorithms prior to analyzing the quality of the pattern on the lens. The need to find the center of the lens in the digital image can be complicated and demand extensive computing if the digital image has a high resolution and/or three colors (red, green,

and blue) are captured therein. In addition, finding the center of the lens in the digital image may be complicated by the alternation in the configuration of the lens due to handling between removal from the mold and placement in a container suitable for inspection. Moreover, determination of the center of the lens in the digital image could be difficult if the print is non-symmetrical.

Therefore, there still exists a need for automated inspection of colored contact lenses.

In one aspect, the invention provides a method for automatically inspecting a colored print applied on a mold half. The method of the invention comprises: obtaining a mold half including a molding surface, wherein the molding surface includes a colored print; automatically aligning in a precisely predetermined manner, by using centering and adjusting means, a camera with the mold half having the colored print on its molding surface; taking a picture with the camera, wherein the picture comprises an image of the mold half having the colored print on its molding surface, wherein the predetermined alignment of the camera with the mold half ensures that the center of the mold half image is located substantially at a predetermined pixel in the picture; analyzing by computing at least a pixel area corresponding to the colored print in the mold half image to determine if the colored print applied onto the mold half has any defects.

In another aspect, the invention provides a method for automatically inspecting a colored print applied on a contact lens which is cast-molded in a mold having a male half and female mold half, each mold half having a molding surface. The method of the invention comprises: (1) curing a lens-forming material in a mold for making a contact lens to form a colored contact lens, wherein the mold comprises a male mold half with a first molding surface and a female mold half having a second molding surface, wherein the male and female mold halves are configured to receive each other such that a mold cavity is formed between the first and second molding surfaces when the mold is closed, wherein at least one of the first and second molding surface has a colored print applied thereon prior to dispensing the lens-forming material in the cavity, wherein at least one of the first and second molding surfaces is optically transparent or translucent, wherein the colored print detaches from the molding surface and becomes integral with the body of the colored contact lens; and (2) prior to opening the mold, automatically inspecting colored print quality, wherein this step includes (a) automatically aligning in a precisely predetermined manner, by using centering and adjusting means, a camera with the mold with the colored contact lens therein, wherein the camera is facing one of the mold halves having the optically-transparent or translucent molding surface, (b) taking a picture with the camera, wherein the picture

comprises an image of the mold with the colored contact lens therein, wherein predetermined alignment of the camera with the mold ensures that the center of the mold image is located substantially at a predetermined pixel in the picture; (c) analyzing at least a pixel area corresponding to the colored print in the mold image to determine if the colored print applied onto the colored contact lens has any defects.

In a further aspect, the invention provides a method for making colored contact lenses. The method of the invention comprises the steps of: (1) providing a mold including a male mold half having a first molding surface and a female mold half having a second molding surface, wherein the male and female mold halves are configured to receive each other such that a mold cavity is formed between the first and second molding surfaces when the mold is closed, wherein at least one of the first and second molding surfaces is optically-transparent or translucent; (2) applying a colored print onto an area of a to-be-printed molding surface which is the first or second molding surface; (3) automatically inspecting quality of the colored print applied on the to-be-printed mold half by (a) taking a first picture, wherein the first picture comprises a first image of the mold half with the colored print applied thereon with a camera, (b) analyzing the first image to determine if there are any defects in the colored print, and (c) rejecting the mold half having defects in the colored print thereon; (4) dispensing a specific amount of a lens-forming material into one of the male and female mold halves after successfully passing automatic inspection of the step (3); (5) mating the male and female mold halves to close the mold; (6) curing the lens-forming material located between the two mold halves, thereby forming a molded colored contact lens, wherein the colored print detaches from the molding surface and becomes integral with the body of the colored contact lens; (7) separating the mold into the male and female mold halves, with the colored contact lens adhered on a lens-adhering mold half which is one of the male and female mold halves; (8) automatically inspecting the colored contact lens adhering on the lens-adhering mold half, wherein the step (8) includes taking a second picture which comprises a second image of the lens-adhering mold half with the colored contact lens thereon and comparing at least each pixel of a pixel area corresponding to the colored print in the second image with each pixel of the first image to determine if the quality of the colored print is substantially preserved during transferring of the colored print from the to-be-printed molding surface to the colored contact lens; (9) removing the colored contact lens from the lens-adhering mold half.

The method may further comprise the step (10) comprising automatically inspecting the colored contact lens removed from the lens-adhering mold half, wherein the step (10) includes taking a third picture which comprises a third image of the colored contact lens

removed from the lens-adhering mold half and comparing at least each pixel of a pixel area corresponding to the colored print in the third image with each pixel of the first image and/or the second image to determine if the colored print applied onto the colored contact lens has any defects.

In a still further aspect, the invention provides a method for making colored contact lenses. The method of the invention comprises the steps of: (1) providing a mold including a male mold half having a first molding surface and a female mold half having a second molding surface, wherein the male and female mold halves are configured to receive each other such that a mold cavity is formed between the first and second molding surfaces when the mold is closed, wherein at least one of the first and second molding surfaces is optically-transparent or translucent; (2) applying a colored print onto an area of a to-be-printed molding surface which is the first or second molding surface; (3) dispensing a specific amount of a lens-forming material into one of the male and female mold halves; (4) mating the male and female mold halves to close the mold; (5) automatically inspect quality of the colored print, wherein the inspection is carried out by (a) taking a first picture, wherein the first picture comprises a first image of the mold with the colored print and with the lens-forming material therein with a camera, (b) analyzing the first image to determine if there are any defects in the colored print; (6) curing the lens-forming material located between the two mold halves, thereby forming a molded colored contact lens, wherein the colored print detaches from the molding surface and becomes integral with the body of the colored contact lens; (7) prior to opening the mold, automatically inspect quality of the colored print, wherein the inspection is carried out by (d) taking a second picture, wherein the second picture comprises a second image of the mold with the colored contact lens therein, (b) analyzing the second image to determine if there are any defects in the colored print, and (c) rejecting the mold containing the colored contact lens having defects in the colored print; (8) separating the mold into the male and female mold halves, with the colored contact lens adhered on a lens-adhering mold half which is one of the male and female mold halves; (9) removing the colored contact lens from the lens-adhering mold half.

The method may further comprise the step (10) comprising automatically inspecting the colored contact lens from the lens-adhering mold half, wherein the step (10) includes taking a third picture comprising a third image of the colored contact lens removed from the lens-adhering mold half and comparing at least each pixel of a pixel area corresponding to the colored print in the third image with each pixel of the first and/or second image or a combination thereof to determine if the colored print applied onto the colored contact lens has any defects.

A "contact lens" refers to an object that can be placed on or within a wearer's eye. A contact lens can correct, improve, or alter a user's eyesight, but that need not be the case. A contact lens can be of any appropriate material known in the art or later developed, and can be a soft lens, a hard lens, or a hybrid lens. A contact lens can be tinted before printing any color patterns. A contact lens can be in a dry state or a wet state. "Dry State" refers to a soft lens in a state prior to hydration or the state of a hard lens under storage or use conditions. "Wet State" refers to a soft lens in a hydrated state.

A "colored contact lens" refers to a contact lens (hard or soft) having a colored print applied thereon. A colored print can be any colored image which can be one or more cosmetic patterns, for example, iris-like patterns, Wild Eye® patterns, made-to-order (MTO) patterns, and the like; an inversion mark that allows a user to handle and insert easily a contact lens; a toric rotation mark, or contact lenses stock keeping units (SKUs), for example, either in forms of numbers or as bar codes. A colored print can be a single color image or a multi-color image.

The term "eye color" refers to the color of the iris.

The term "non-opaque" as used herein is intended to describe transparent or translucent color or a part of the lens that is colored with transparent or translucent coloring.

A "colorant" means either one or more dyes or one or more pigments or a mixture thereof that is used to print a pattern of colored elements on a contact lens.

"Dye" means a substance that is soluble in a solvent and that is used to impart color. Dyes are typically transparent or translucent and absorb but do not scatter light. Dyes can cover both optical regions of contact lenses and non-optical regions of contact lenses. A "pigment" means a powdered substance that is suspended in a liquid in which it is insoluble. Pigments are used to impart color. Pigments, in general, are more opaque than dyes.

A "lens-forming material" refers to a polymerizable composition which can be cured (i.e., polymerized and/or crosslinked) thermally or actinically (i.e., by actinic radiation) to obtain a crosslinked polymer. Examples of actinic radiation are UV irradiation, ionized radiation (e.g. gamma ray or X-ray irradiation), microwave irradiation, and the like. Thermal curing or actinic curing methods are well-known to a person skilled in the art. Lens-forming materials are well known to a person skilled in the art. Any known suitable lens-forming materials can be used in the invention. Examples of lens-forming materials include lens formulations for making non-silicone hydrogel contact lenses and silicone hydrogel contact lenses.

"Hydrogel" means a polymeric material which has having an equilibrium content between about 10 and 90 percent water.

A "print-on-mold process for producing colored contact lenses" refers to a process for molding a colored contact lens as described in US 5034166.

The term "align in a precisely predetermined manner" or "predetermined alignment", in reference to a camera, a mold, or a mold half, is intended to describe an alignment process in which the camera and the mold or the mold half is physically aligned by physical means in a way so that, in a picture taken by the camera and comprising an image of the mold or mold half, the center of the mold or mold half image is located substantially at a predetermined pixel in the picture. In accordance with the invention, the predetermined pixel can be anywhere in the picture, but preferably is within a radial distance of 20 pixels or less, preferably of 10 pixels or less, more preferably 5 pixels or less, even more preferably 2 pixels or less from the central pixel (i.e., the center of the picture). Most preferably, the center of mold or mold half image is located at the central pixel (i.e., the center of the picture). The term "precisely" is intended to describe that the location of the center of the mold or mold half image can be known at a position of a picture with a precision of 2.0 mm or less, preferably 1.0 mm or less, more preferably 0.5 mm or less (in the picture).

In general, the invention is directed to improved and efficient methods for automatic inspection of one or more colored prints applied onto a mold for making a colored contact lens or a colored contact lens produced according to a print-on-mold process for producing colored contact lenses and also to manufacturing processes of colored contact lenses involving automated inspection of colored prints.

It is discovered that there is no need for locating, through analysis by algorithms, the center of an image of either a colored print applied on a molding surface of a mold half or a colored print on a cast-molded contact lens, which is still within a mold prior to mold opening or is still adhered on one of mold halves of a mold after mold separation. The center of a mold surface of a mold or mold half is well defined mechanically, the center of a colored contact lens in the mold or on the mold half is known precisely and fixed, and any picture has a predefined central pixel. Likewise, the position of camera placed to view the lens in a mold or on a mold half can also be known exactly. Now, it is a matter of coordinating the movement of the mold and the camera. By using centering and adjusting means which is associated with each mold or mold half and/or camera, one can accurately align a camera with a mold or a mold half in a precisely determined way so that, in any picture taken by the camera and comprising an image of the mold or mold half, location of the center of the mold

or mold half image is predetermined and well known in the picture. For example, the center of the mold or mold half image is located at the central pixel of the picture (i.e., the center of the picture). Furthermore, for any mold having at least one optically-transparent molding surface, a colored print on a mold can be inspected through the optically-transparent molding surface. Without a step of finding the center of a colored lens in a digital image through a complicated and extensive computing based on one or more algorithms, one can therefore enhance the efficiency in automated inspection of a colored print on a mold half or a colored contact lens.

In accordance with the invention, a colored print can be non-opaque or opaque. A colored print can comprise non-opaque patterns that can enhance the color of the natural iris, opaque patterns that effectively and substantially modify the wearer's eye color or provide unique patterns on the iris of the wearer, an inversion mark that allows a user to handle and insert easily a contact lens, a toric rotation mark, or contact lenses stock keeping units (SKUs), or combinations thereof. A colored print can be a single color image or a multi-color image. Examples of colored prints includes without limitation those shown in commercial products, for example, Freshlook® color contact lenses, Focus® Softcolors®, Cibasoft® Softcolors®, Wild Eye® (all available from CIBA Vision Corporation, Atlanta, USA). Examples of non-opaque patterns and opaque patterns includes without limitation a transparent or translucent solid color disk, a transparent or translucent annular solid color ring, a color disk with a radial gradient of color intensity in which the color intensity changes from light or transparent to dark in a radial direction from the center to the edge of the central zone.

A colored print can be formed by applying one or more layers of non-opaque and/or opaque patterns onto a molding surface of a mold. A transparent or translucent colorant can be applied to a circular area of the contact lens covering the iris and pupil of the contact lens wearer's eye or to an annular area of the contact lens covering only the iris of the contact lens wearer's eye. An opaque colorant generally is applied to an annular area of the contact lens covering only the iris of the contact lens wearer's eye to form a colored, opaque, intermittent patterns. The pattern leaves a substantial portion of the iris section within the interstices of the pattern non-opaque or lightly tinted. The opaque pattern or patterns can be made up of dots having regular or irregular, uniform or non-uniform shapes, for example, round, square, hexagonal, elongated, or other dot shapes. Further, the elements of the pattern may have a shape other than dots, so long as the elements are indiscernible to the ordinary viewer, cover between 10 and 30 percent, preferably about 20 percent of the iris, and leave a substantial portion of the iris section within the interstices of the pattern non-

opaque. The patterns that make up the portions of the iris can be islands of color or worms, corkscrews, starbursts, spokes, spikes, striations, radial stripes, zig-zags and streaks. In certain cases, a single transparent or translucent color background is used to complement the multi-pattern design. These patterns blend with each other to provide a colored contact lens that enhances the structure of the iris of a person wearing the lens.

In a preferred embodiment, an inversion mark and/or other marks (e.g., rotation mark, toric marks (cylindrical axis, ballast axis), SKU, UPC codes, etc.) can be embedded in a colored pattern so that the those marks are noticeable to a wearer before wearing the colored lens whereas unnoticeable to an ordinary viewer when worn by a wearer.

A preferred method for applying an ink including at least one colorant onto a contact lens in accordance with this invention is through printing, such as for example, pad transferring printing and/or inkjet printing using an ink, preferably a water-based ink. An ink typically comprises at least one colorant, a binder polymer, a solvent, and one or more other components selected from the group consisting of a crosslinker, a humectant, a surfactant, a monomer, a polymerization initiator, an antimicrobial agent, an antioxidant agent, an anti-kogating agent, and other additives, as well known to a person skilled.

Lens molds for making contact lenses are well known to a person skilled in the art and, for example, are employed in cast molding or spin casting. For example, a mold (for cast molding) generally comprises at least two mold sections (or portions) or mold halves, i.e. first and second mold halves. The first mold half defines a first molding (or optical) surface and the second mold half defines a second molding (or optical) surface. The first and second mold halves are configured to receive each other such that a lens forming cavity is formed between the first molding surface and the second molding surface. The molding surface of a mold half is the cavity-forming surface of the mold and in direct contact with lens-forming material. Alternatively, a single sided molding method could be used, where one side is cast molded, and the other side is lathed.

Any known suitable centering and adjusting means can be used in the invention. Examples of centering and adjusting means include without limitation guiding surface associated with a mold or mold half and with a camera and guiding rods associated with a mold or mold half and with a camera. A person skilled in the art will know well to design centering and adjusting means for precisely aligning a camera with a mold or mold half at a predetermined manner.

A person skilled in the art will know how to calibrate predetermined alignment of a camera with a mold or mold half. For example, one can use a mold half, the center of its molding surface of which is marked clearly with a print (e.g., a cross), as a calibration tool for

adjusting centering and adjusting means so that the center of the mold half image is precisely located at a predetermined pixel in a taken picture.

In accordance with the invention, any cameras can be used in the invention so long as they can generate digital pictures composed of pixels. A camera can be a gray-scale or color camera. Where a camera is a gray-scale camera, in an image captured by the camera, the light intensity of each pixel is assigned a value of, e.g., 0 to 255, and is then registered in a coordinate system, such as Cartesian or polar coordinate system.

In accordance with a preferred embodiment, the light intensity of pixels of the image is registered in polar coordinates. This light intensity information in polar coordinate form is stored in a matrix wherein light intensity values at incremented angles are listed in rows of the matrix and the light intensity values for incremental radii are listed in columns. This matrix presentation of the light intensity data facilitates the analysis of defects. The matrix shall be referred to hereafter as the S-matrix. Preferably, a 1024 by 1024 pixel array is used to capture the image for the single gray-scale image, although less or more resolution can be used if desired. Where a color camera is used, a picture (or image) can be divided into the red, green and blue layers on 3 chips in the color camera and three color images (red, green and blue color images) can be created by the camera. The light intensity of pixels in each color image can be registered as described above. For color images, preferably fewer pixels are used, e.g., 768 by 494 pixel arrays for each color image, because more calculations have to be performed when three colors are captured within an individual images.

"Taking a picture" or "capturing an image" can be accomplished according to any known suitable methods. A person skilled in the art will understand well how to select a light source for taking a picture. An Illumination light can be a continuous or pulse light.

Considering that the level of ambient light may cause variations in an image of a print under inspection, it is desirable that the output of a camera is normalized for variations in ambient light across the field of the image. This normalization process ensures that the image of the lens under inspection is not affected by variations in ambient light. Alternately, collimated light could be used to minimize the variations in ambient light. It is preferably that the illumination is normalized. Uneven illumination can arise because of variations in either the illumination system or in the optical elements of the imaging system. The illumination variations typically have a slow variation across the image. The effect of these variations can be greatly reduced by using a normalization algorithm which is for example described in US 6047082.

In accordance with the invention, defects in a colored print applied onto a mold half or a contact lens can include imperfections in a printed iris pattern, imperfections in printing a logo, an inversion mark, a toric rotation mark, or stock keeping units (SKUs), the unwanted presence of colorant in a particular area (e.g., the optical zone or the peripheral zone of a colored contact lens). Examples of imperfections in a printed iris pattern includes without limitation decentralization of the printed iris pattern (i.e., being not correctly centered), a variety of misprints (e.g., the absence of colorant in a particular area, a fairly large blank area in an iris pattern, the presence of too much colorant (an excess) in a particular area) which can reduce the attractiveness and functionality of a contact lens. Examples of imperfections in printing a logo, an inversion mark, a toric rotation mark, or stock keeping units (SKUs) include without limitation a damaged or missing print, a misaligned toric rotation mark or inversion mark, and the likes. The presence of any defects in a colored print will allow one to reject the mold half with the colored print applied thereon. Only those mold halves with colored prints applied thereon which pass inspection of the colored prints can be used for production of colored contact lenses.

Typically, a colored contact lens comprising a circular non-opaque pupil section (i.e., optical zone), an annular iris section surrounding the pupil section, and a non-opaque peripheral section surrounding the iris section. When worn, the pupil section allows for a clear pathway of light to the pupil and can have an uneven or substantially even border with the iris section.

Any known suitable algorithms can be used in analyzing by computing at least a pixel area corresponding to the colored print in the mold half image to determine if the colored print applied onto the mold half has any defects. For example, decentralization of an iris print applied onto a mold half can be determined by the radial distances (from the central pixel or a predetermined pixel) of at least three pixels which are closest to the central pixel (or the predetermined pixel) and are not collinear. These pixels would be separated by, for example, at least 45 degrees (in a polar coordinate system referenced to the central pixel or the predetermined pixel). Where the pupil section of a colored contact lens has an even border with the iris section, one can determine if the even border is concentric with the central pixel (or the predetermined pixel). Alternatively, one can use pixels located along the boundary of the iris section with the peripheral section to determine if there is any decentralization of an iris pattern. It is understood that any other algorithms can be used in the invention to determine if there is any decentralization of an iris pattern.

If the decentralization of an iris pattern is above a threshold, e.g., greater than 1 mm, preferably greater than 0.75 mm, more preferably greater than 0.50 mm, even more

preferably greater than 0.20 mm, the mold half with the iris print applied thereon is rejected. The above-described decentralization values are actual values in the actual scale of a mold half without any enlargement or reduction.

Where three color images (red, green and blue color images) are created by a camera, one or more algorithms can be used to determine decentralization of each color image based on any processes as described previously.

The pupil section and the peripheral section are inspected to see if there is any stray colorant, especially opaque colorant, present in those areas. Colorant can mistakenly drip, or splash in the pupil section or the peripheral section during printing (e.g., pad printing or inkjet printing), or be present within these sections by the application of a improperly located colorant layer. The pupil section (optical zone) is a circular zone having a diameter of from 3 mm to 5 mm. For analysis, values for the sensitivity threshold, which is an allowable contrast in light intensity between neighboring pixels, minimum defect size, which is an area in which the light intensity values of the pixels are not within an acceptable range of intensities, and the defect size thresholds, which is the minimum allowable sum of the area of all the defects in a zone, are inputted into an algorithm and used by the system during the area inspections. As known to a person skilled in the art, each section can have different sensitivities and defect sizes depending upon how important it is to have an area free of excess colorant, or other defects in the colorant.

Generally, the sensitivity of the pupil section (optical zone) is high and the allowable amount of excess colorant is very low, since excess colorant can adversely affect visual acuity. In contrast, the sensitivity of the iris section can be relatively lower to allow some excess colorant. Excess colorant is a cosmetic consideration in the iris section and does not effect visual acuity. Similarly, the peripheral section surrounding the iris section may also have lower sensitivity and a higher allowable area of excess ink than the pupil section. All of these sensitivity values can be determined by analyzing acceptable and unacceptable colored lenses made from the molds with colored prints applied thereon.

In accordance with the invention, a colored print can be analyzed for clear spots (i.e., substantially free of colorant) of excessive size. Preferably, algorithms described in US 6047082 are used to analyze a colored print for clear spots (i.e., substantially free of colorant) of excessive size. It is understood that the clear spots can also be lightly tinted or has a single transparent or translucent color background.

The colored print can be inspected with a set of data that can easily be gathered since the center of the mold half (or lens) and the colored print has been known, for example, precisely at the central pixel (or any predetermined pixel) of the picture. This data

set is an array of image brightness values along radial lines at regular angle intervals around the compass of the mold half (or lens). The brightness values along each radial line are stored in the S-matrix. As explained previously, the S-matrix columns contain the values along a path of constant angle and the rows contain the values along a path of constant radius. The iris portion of the S-matrix represents a picture of the brightness values within a region bounded by an inner radius ($r_1$) and an outer radius ($r_2$) of the iris print zone and a first angle ($\theta_1$) and a second angle ($\theta_2$), but displayed on a rectangular row and column format. In analysis, the angles $\theta_1$ and $\theta_2$ are selected to cover the entire circle from 0 to 360 degrees. This description of the S-matrix assumes that the radial paths cross a circular path centered on the mold half (or lens) center. A more sophisticated version of the algorithm can use an elliptical or polynomial generated path that models the shape of the mold half (or lens).

The size of the S-matrix is MxN, where M is the number of points taken along a path of constant angle and N is the number of angles. Experimentation can be done with the best size for S. The trade-off is between more detail and more processing time. Since the purpose is to find fairly large blank areas in the colored pattern, it is not necessary to use a large number of points in S. The best size to use can be determined empirically.

It is understood that an iris color pattern can have a number of medium size gaps in the printed area, but this is a part of the pattern design. Such ink pattern is acceptable. In contrast, a large unprinted region running through the printed area should clearly be a defect and be rejected.

The contrast between the bright areas and the colored pattern can be enhanced by a standard contrast enhancement procedure. This procedure consists of applying a point function u=f(s) to each element "s" of the array in such a way that the gray levels are spread more evenly over the total range of brightness values. However, this process takes time, with at least one multiplication per element of the S-matrix, and does not accomplish anything useful toward the goal of detecting bright areas. Such a process is useful to match the image of S with a detector such as the human visual system, but is not useful in an automated detection process where one can tailor the detector to the image. Instead, we use a process of threshold detection as described below.

Threshold detection can be used to differentiate pixels that have bright values from others that do not. Let a threshold (T) function be defined by u = f(s), where

$$f(s) = \begin{matrix} 1, s \geq T \\ 0, s < T \end{matrix}$$

As a matter of implementation, the U-matrix is scaled so that 0 is the minimum (black) and 1 is the maximum (white). Applying the threshold function to S will produce a

new array, say U, in which all of the values are either 0 or 1. A region of S that has a large number of bright areas will appear in U as a cluster of ones.

The choice of the threshold is important, but not particularly sensitive. It should be between the highest gray level of a printed pixel and the brightness value of an unprinted pixel. There is a range of values that can be used for the threshold (T). The value of T can be set automatically in an operational system by measuring the average brightness over the optical zone for several lenses in sequence. If you set the threshold just on the current lens, then a cloudy optical zone may lead to a value that is too low for T. T should be set to be about 20 brightness steps lower than the average. As an example, the average brightness in the center zone of the lens could be 242, which would place a threshold at 222. Using this automated technique will ensure that the printing will be lower than T and will appear black in the U-matrix. Automatic setting of T is recommended for robust operation.

The range of possible threshold values can be verified by examining the brightness histogram. One can conduct a search for bright areas by summing over a rectangular region that is stepped over the array U. One would expect the sum to be large in bright areas and small in other areas. The size of the block should be approximately the size of the smallest bright area in a printed zone that would lead to a rejection. The step size is a trade-off between efficiency and the need to be sure that the window steps within the bright area.

Let A be a matrix in which A(i,j) is the sum of the values of U within the block located at position (i,j). Then A will have a large value when the block is over a bright area and a small value when it is over a dark area. A surface plot of A for a block size of 50x50 and a step size of 10 in each direction has a peak at column 21 and row 6.

To look for larger problems in the print area it is necessary to increase the size of the inspection box, for example, an inspection box of size 100x100 fits within an unprinted area. This provides an indication of the size to be chosen for the inspection box.

The analysis program has the following components:

1. Select the rows of the S-matrix that correspond to the printed area. The selected rows should cover the printed area but not pick up the bright area in the optical zone and outside the printed area.

2. Construct a matrix U that is a thresholded version of S. The threshold should be about 20 brightness steps below the average brightness in the optical zone.

3. Scan the U-matrix with an inspection box that is about the same size as the gaps in the printed zone that you want to detect.

4. Reject the mold half or lens if any of the boxes have a sum that is greater than an acceptable threshold. This threshold should be about 80% of the size of the scanning box.

Inspection of a logo, an inversion mark, a toric rotation mark, or stock keeping units (SKUs) can be preferably carried out according to the procedure described in US 6047082. Those marks can be used in analysis for easy recognition of the rotational position and displacement of each colorant layer. Commercially available pattern recognition software could be adapted to locate those marks and to measure the angle and displacement between each of the marks. This technique would then provide a means to compare the relative position of the different colorant layers that does not rely on finding the center of an individual colorant layer.

Where a single transparent or translucent color background is used to complement the multi-pattern design, the inspection could be performed by an algorithm that would determine based on the relative intensity values. For example, the lowest intensity value would correspond to no color, the next level of intensity values would correspond to the first colorant, e.g. transparent or translucent color background, and the next range of intensity values would correspond to the second colorant, e.g. a layer of opaque colorant. The values assigned to each colorant can also be checked by knowing the pattern for each colorant and comparing the pixel intensity values in the captured image to the expected location of the pixels in the colored print.

In a preferred embodiment, the image of the colored print applied onto a mold half can be compared with a designed image of the colored print stored in a computer as well known to a person skilled in the art. The light intensities and positions in relation to the picture center of pixels in an image of the colored print and in the designed image of the colored print can be compared as a whole, by analyzing all portions of each image in a systematic manner. More preferably, the images can be compared in discrete zones.

In accordance with the invention, when two or more images are compared with each other, they should be in the same scale in size.

In a more preferred embodiment, a colored print (or rotational orientation of a colored print in reference to its center) applied onto a mold half, the image of the colored print on the mold half, and a designed image of the colored print stored in a computer all are aligned at a predetermined angular orientation (with their corresponding centers are predetermined and known). "Predetermined angular orientation" of a colored print (or rotational orientation of a colored print in reference to its center) applied onto a mold half can be achieved by properly aligning a cliché and/or the mold half. Predetermined angular orientation of the image of the colored print on the mold half can be achieved by physical means in the step of automatically aligning a camera with the mold or mold half.

With such predetermined angular orientation, it is easier to compare the two images

to check any print defects and/or determine the rotation of the colorant layers. Rotation of a colorant layer's pattern can be determined relative to its designed image. This is accomplished by comparing the angular position of one or more features in the pattern. The angle between a feature on the outer edge of the designed image and the corresponding feature on the captured image yields the amount of rotation. The algorithm can provide for multiple features or for the ability to repeat the search if an attempt to find a feature is unsuccessful, such as in the case of distortion of the applied colorant or a missing area of pattern on the captured image. The amount of rotation of the pattern is the angular difference between the expected or desired position of the feature in the designed image and the location of the feature in the captured image and can be averaged if multiple individual angle measurements are measured. Where multiple colorant layers must be applied in exact angular positions to achieve a desired cosmetic effect, the rotation of each pattern may be very important.

A colored print can be applied on the molding surface defining the posterior (concave) surface of a contact lens or on the molding surface defining the anterior surface of a contact lens or on both mold portions. Preferably, a colored print is applied on the molding surface defining the anterior surface of a contact lens.

Optionally, a transferable coating can be applied to a molding surface of a mold before applying the ink by pad transfer printing or inkjet printing. A transferable coating is intended to describe a coating which can be detached from a molding surface of a mold and become integral with the body of a contact lens molded in the mold. A transferable coating can be applied to a molding surface of mold by any suitable techniques, such as, for example, spraying, printing, swabbing, or dipping. A transferable coating can be prepared from a solution comprising polymerizable components and free of any colorants. For example, a transferable coating with substantially uniform thickness (less than 200 microns) can be prepared by spraying a molding surface with a solution having the composition (without colorant) of an ink to be used or a solution of prepolymer or a lens-forming material to be used. This transferable coating can optionally be dried or cured to form a transferable clear film (without any pigment but optionally with dyes including reactive dyes). One or more colored patterns can then be printed on this transferable coating or film. By applying a transferable coating before printing, one can make a colored lens in which printed colored patterns are embedded just below a film derived from the transferable coating. Such lens may be more comfortable for wearing and have much less susceptibility to colorant leaching out of the colored lens.

After printing an ink of the invention on a molding surface of a mold, the printed ink

can be partially or completely cured by UV, other actinic radiation, or thermal means to form a colored film. It is desirable that the printed ink is cured actinically to an extent to minimize loss of pattern definition resulting from subsequent filling of a lens-forming material.

Any lens-forming materials can be used in the invention and is not presently considered a critical part of this aspect of the invention. A lens-forming material can comprise one or more prepolymers, optionally one or more vinylic monomers and/or macromers and optionally further include various components, such as photoinitiator, visibility tinting agent, fillers, and the like. It should be understood that any silicone-containing prepolymers or any silicone-free prepolymers can be used in the present invention.

Any lenses having one or more print defects will be rejected. The presence of any defects in a colored print will allow one to reject the resultant colored lens or the mold with the colored lens therein if the mold is a disposable mold. Only those molds with colored lens therein which pass inspection of the colored prints will be subjected to further processes, such as, for example, demolding, extraction, hydration, surface treatment, sterilization (e.g., autoclave), or combinations thereof.

In a preferred embodiment, the image of the colored print, which detaches from the molding surface and becomes integral with the body of the colored contact lens, can be compared with a designed image of the colored print stored in a computer. The light intensities and positions in relation to the picture center of pixels in an image of the colored print and in the designed image of the colored print can be compared as a whole, by analyzing all portions of each image in a systematic manner. More preferably, the images can be compared in discrete zones. Even more preferably, a colored print applied onto a mold half, a designed image of the colored print stored in a computer, and the image of the mold with the colored contact lens therein all are aligned at a predetermined angular orientation (with their corresponding centers are predetermined and known).

In accordance with the invention, the first picture is preferably taken with a camera which is aligned in a precisely predetermined manner with the mold having the colored contact lens therein, wherein predetermined alignment of the camera with the mold ensures that the center of the first image is located substantially at a predetermined pixel in the first picture. At least a pixel area corresponding to the colored print in the first image is analyzed by computing to determine if the colored print has any defects. Preferably, the first image is compared with a designed image of the colored print stored in a computer as described previously. More preferably, the first image and the designed image are aligned at a predetermined angular orientation.

In accordance with the invention, automatic inspection of quality of the colored print on a colored contact lens adhering on the lens-adhering mold half ensures that the quality of the colored print is substantially preserved during transferring of the colored print from the to-be-printed molding surface to the colored contact lens. With such inspection step, one can reject any colored lenses with defected colored prints applied thereon and avoid further processing of those colored lenses with defected colored prints applied thereon. Preferably, the second picture is taken with a camera which is aligned, in a precisely predetermined manner, with the lens-adhering mold half, wherein predetermined alignment of the camera with the lens-adhering mold half ensures that the center of the second image is located substantially at a predetermined pixel in the second picture. More preferably, the first and second images of the colored print are aligned at a predetermined angular orientation, preferably in a concomitant manner. With such predetermined angular orientation, it is more easily to compare the two images to check any print defects and/or to determine the rotation of the colorant layers.

In accordance with the invention, automatic inspection of the colored print of the colored contact lens removed from the lens-adhering mold half can be carried out in a lens holder containing a liquid. Examples of lens holders include without limitation lens inspection cells and lens packages or containers. The liquid can be water, a saline, a buffered saline, or a packaging solution known to a person skilled in the art.

In accordance with the invention, the step (10) can further comprises automatic inspection of the colored contact lenses for mechanical defects in lens materials, for foreign material attached to the lens, and for edge defects (e.g., nicks, cuts, chops and adhering foreign matter on the rim of the lens). Mechanical defects in the lens material include without limitation tears, nicks, cuts, holes, folds, and other problems. Any kind of dirt or "flash" that is attached to the lens can be a functional and safety problem, and must be detected. The edge of lenses must be smooth and continuous. Any edge defects on the rim of the contact lenses must be detected and rejected. A person skilled in the art will know well how to automatically inspect the above-described defects.

The approaches to lens inspection could have different computer algorithms or inspection schemes, depending upon the manufacturing step. For example, the method to inspect the lens immediately after the printer step should focus on the print quality alone, but the method to inspect the lens after lens formation should focus on print quality and lens quality. Different inspection schemes could be done after the printing step, after lens formation, after mold separation, after lens demolding, after lens has been inserted into a package, and after lens autoclave. This could be done either automatically (in-process),

semi-automatically (after process, loaded manually, but inspected with an automatic inspection system), or manually.

Alternatively, the print could be inspected in a step-wise approach. For example, the mold or lens could be imaged between print layers, to ensure that each printing step is printed correctly. This would provide the maximum print control and assurance, and is in particular suitable for identifying problems during development.

The invention also provides various pattern recognition methods to help separate required elements (i.e., print pattern, inversion marks), obscuring elements (i.e., bubbles in solution, scratches on the mold or particulate in solution), and non-desired elements (i.e., nicks, scratches, bubbles in the lens). For example, these elements can be identified by using a combination of bright field and dark field analysis.

Print element structures could be defined by the contact lens designer (i.e., dots, ellipses, or even reproducible irregular shapes), which could be loaded into the pattern recognition description. Any identified patterns on the contact lens that match that scheme would be identified as print, and, if desired at that location, would pass for good print quality.

Basic pattern recognition schemes separate between required, obscuring, and non-desired elements could be based upon geometric specifications, such as the circularity value. This algorithm defines each element as how close it approaches a circle (perfect circle = 1, straight line = 0). The good print could be defined based upon circularity value, particularly if the designer uses circular elements. Alternatively, a range of circularity values could be used to screen print quality. This scheme would be particularly good in sorting spikes, tears, nicks, lines (with low circularity values) and bubbles (with high circularity values). Other geometrical specifications could include aspect ratio, fractal number, or symmetry.

Another alternative pattern recognition scheme would be to recognize colored areas as groups. For example, individual colored elements could be recognized together as individual parts of a large group. This grouping could be done based upon colored elements of the same color, or upon multiple colored elements. This large group could be realized or quantified by a shape, density, or intensity (either black and white or color intensity) function. The sum of the groups would help define the overall colored lens image.

Various lighting schemes could be used to help identify between required, obscuring, and non-desired elements. For example, filters could be used help separate or improve the color contrast between different layers. Polarizing or cross-polarizing filter could be used to help identify anisotropic elements. Polarized, uniform, and non-uniform lighting conditions could be used to help identify the elements of interest.

The combination of bright and dark field analysis could be used to help separate among required, obscuring, and non-desired elements. Summing the light and dark field images could be used to emphasize particulate matter, which is particularly important in the optical zone.

Various photographic schemes could be used to identify required, obscuring, and non-desired elements. For example, a background image of the mold or cuvette could be taken before the lens or print is placed into the field. The subtraction of the first will eliminate any defects in the background, such as mold defects or cuvette scratches. Depending upon the background, these background defects could be used to reject lenses (i.e., mold defects), or are simply eliminated to help emphasize print quality (i.e., in the case of cuvette scratches).

Two pictures of each lens could be taken, with the lens holder rotated between images. Images processing could be used to align the print of the two images. Any difference observed are obscuring elements, such as bubbles in solution or dirt in the solution. This is a good system for inspection after lens has been demolded and is in an inspection cuvette or blister pack.

Use of top-lighting or side lighting could be used to obtain color information from the print. Each pixel element would have an associated RGB value. Each color layer could be compared with a reference value or range, or with an ideal image. This could help identify which image layer is printing poorly. This system could possibly determine if the ink color is within a certain color range as a QA check.

Previous inspection systems have much emphasis on ensuring the print center is aligned with the lens center. Not all print patterns require this scheme; the relationship of each print layer with respect to subsequent layers may be developed with any need for alignment or measurement, as long as they are printed within the lens. Alternatively, one layer only has to fit within a previous layer to achieve good print; the previous print layer would be able to obscure any variance in the subsequent print (i.e., the outer starburst is able to obscure any variance in the iris pattern within about 200 microns). For example, the inspection scheme would only have to identify prints of the first layer outside or inside of the second layer to fail print quality.

Another aspect of the invention is determining the centralization of the print relative to the edge of the lens. Prior art does this by first finding the center of the lens. This has a disadvantage in that the consumer judges the centralization of the print when wearing the lens by judging distance of the print to the outer edge of the lens. The center of the lens is not as easy to be discerned by to the customer. This aspect of the invention is a method to

evaluate centralization of the printed pattern by having the automatic inspection system evaluate the adequacy of pattern centralization by measuring the difference in distance between the edge of the lens and the edge of the pattern. This measurement is compared to the same difference at a point opposite the first measurement. The differences are subtracted and the subtracted value must be less than a specified value. This technique can be used for one or all of the patterns on a lens.

Alternatively, the captured image can be compared with a reference location on the lens which is not central with respect to the contact lens or print center. While this off-center reference mark could be used for spherical lenses, this is preferentially used for toric lenses. Toric lenses would require a reference mark to identify the toric, horizontal angle, and/or rotation mark, and determine if rest of image is oriented to the toric angle mark. Optionally, an off-axes reference mark would be beneficial for ballasted products, such as Wild-Eyes®, or lenses for presbyopia. This reference mark may not necessarily be printed; reference marks for ballasted lenses or lenses for astigmatism could be accomplished by measuring power of lens thickness, either on-line or off-line.

**Claims**

1. A method for making colored contact lenses, comprising the steps of:
   (1) providing a mold including a male mold half having a first molding surface and a female mold half having a second molding surface, wherein the male and female mold halves are configured to receive each other such that a mold cavity is formed between the first and second molding surfaces when the mold is closed, wherein at least one of the first and second molding surfaces is optically-transparent or translucent;
   (2) applying a colored print onto an area of a to-be-printed molding surface which is the first or second molding surface;
   (3) automatically inspecting quality of the colored print applied on the to-be-printed mold half by (a) taking a first picture, wherein the first picture comprises a first image of the mold half with the colored print applied thereon with a camera, (b) analyzing the first image to determine if there are any defects in the colored print, and (c) rejecting the mold half having defects in the colored print thereon;
   (4) dispensing a specific amount of a lens-forming material into one of the male and female mold halves after successfully passing automatic inspection of the step (3);
   (5) mating the male and female mold halves to close the mold;
   (6) curing the lens-forming material located between the two mold halves, thereby forming a molded colored contact lens, wherein the colored print detaches from the molding surface and becomes integral with the body of the colored contact lens;
   (7) separating the mold into the male and female mold halves, with the colored contact lens adhered on a lens-adhering mold half which is one of the male and female mold halves;
   (8) automatically inspecting the colored contact lens adhering on the lens-adhering mold half, wherein the step (8) includes taking a second picture which comprises a second image of the lens-adhering mold half with the colored contact lens thereon and comparing at least each pixel of a pixel area corresponding to the colored print in the second image with each pixel of the first image to determine if the quality of the colored print is substantially preserved during transferring of the colored print from the to-be-printed molding surface to the colored contact lens;
   (9) removing the colored contact lens from the lens-adhering mold half.

2. A method for making colored contact lenses, the method comprising the steps of:

(1) providing a mold including a male mold half having a first molding surface and a female mold half having a second molding surface, wherein the male and female mold halves are configured to receive each other such that a mold cavity is formed between the first and second molding surfaces when the mold is closed, wherein at least one of the first and second molding surfaces is optically-transparent or translucent;

(2) applying a colored print onto an area of a to-be-printed molding surface which is the first or second molding surface;

(3) dispensing a specific amount of a lens-forming material into one of the male and female mold halves;

(4) mating the male and female mold halves to close the mold;

(5) automatically inspecting quality of the colored print, wherein the inspection is carried out by (a) taking a first picture, wherein the first picture comprises a first image of the mold with the colored print and the lens-forming material therein, (b) analyzing the first image to determine if there are any defects in the colored print, and (c) rejecting the mold containing defects in the colored print;

(6) curing the lens-forming material located between the two mold halves, thereby forming a molded colored contact lens, wherein the colored print detaches from the molding surface and becomes integral with the body of the colored contact lens;

(7) prior to opening the mold, automatically inspecting quality of the colored print, wherein the inspection is carried out by (a) taking a second picture, wherein the second picture comprises a second image of the mold with the colored contact lens therein, (b) analyzing the second image to determine if there are any defects in the colored print, and (c) rejecting the mold containing the colored contact lens having defects in the colored print;

(8) separating the mold, which passes the inspection of the step (5) or (7) or both, into the male and female mold halves, with the colored contact lens adhered on a lens-adhering mold half which is one of the male and female mold halves;

(9) removing the colored contact lens from the lens-adhering mold half.

3. The method of claims 1 or 2, further comprising the step

(10) automatically inspecting the colored contact lens removed from the lens-adhering mold half, by taking a third picture which comprises a third image of the colored contact lens removed from the lens-adhering mold half and comparing at least each pixel of a pixel area corresponding to the colored print in the third image with each pixel of the first image and/or the second image to determine if the colored print applied onto the colored contact lens has any defects.

4. The method of claim 3, wherein the step (10) further comprises automatic inspection of the colored contact lenses for mechanical defects in lens materials, for foreign material attached to the lens, and for edge defects.

5. The method of claim 3 or 4, wherein the step (10) is carried out in a lens-inspection cell containing a liquid or in a lens package containing a liquid.