CONTACT LENSES AND PROCESSES FOR MANUFACTURING CONTACT LENSES

FIELD OF INVENTION

[0001] The present invention relates to contact lenses and processes of manufacturing contact lenses.

BACKGROUND

[0002] Soft contact lenses are traditionally made by polymerising monomers into hydrophilic polymers which are subsequently hydrated to form hydrogels. Traditionally, contact lenses have been made either by machining or moulding. Soft disposable contact lenses are commonly contained in disposable packages. The traditional packaging for disposable lenses (both two weekly and daily) consists of a polypropylene blister pack or receptacle for the lens.

[0003] One potential problem encountered with soft contact lenses is tackiness of the lens surface. The tackiness of the lens surface has implications both for the manufacturer of the lens and the user of the lens. In manufacture, the tacky surface will be more prone to contamination, which leads to a reduced yield. For the wearer of the lens, the tackiness may result in poor handling characteristics, since the lens may tend to exhibit self-adhesion. The ocular health of the wearer may also be compromised, since the tacky surface may allow environmental contamination of the lens surface to occur, and may also facilitate the colonisation of the lens surface by pathogens.

[0004] Another potential problem associated with contact lenses is sensitisation of the eye to residuals. Polymerised lenses that have not fully reached completion will typically have free monomers and short chain species present in the matrix. These free monomers and short chain species are collectively known as residuals. These residuals can leach out in the eye and cause sensitisation reactions. This is a particular concern with frequent replacement lenses whereby there is a repeated exposure to these potentially sensitising species. This problem is most commonly alleviated by flushing fresh

fluid through the lens to remove the residuals. This process takes time and risks damaging the lens; it therefore leads to increased product costs.

[0005] Further problems related to soft contact lenses concern the form of the lenses. A contact lens may be formed with an uneven edge. A contact lens having an uneven edge may be uncomfortable to wear. Furthermore an uneven edge may induce splits, chips or distortions in the soft contact lens. It is also known for contact lenses to be formed with voids, which leads to reduced yields. Contact lens may also suffer from shrinkage caused as the lens is formed into a hard polymer from a liquid monomer mixture. Shrinkage can cause distortions that may affect the lenses fit or the quality of its optical focus. A further known problem is pitting of the lens surface. Such pitting may destroy the quality of the lens' optical focus.

[0006] As well as overcoming some of the problems identified above, contact lens should have a number of characteristics. Some of the key characteristics of a contact lens material that need to be considered include strength, stiffness, elongation to break, oxygen permeability, ion transmission, on eye comfort/performance, surface characteristics, biocompatibility and dehydration/rehydration properties.

[0007] Packaging of the contact lens product is another area where problems may be encountered. The size and design of the traditional packaging is a disadvantage to the disposable lens concept as the receptacle is many times larger than the lens itself. Furthermore, the use of such a package can be troublesome as the contact lens can roll up, turn inside out (invert) and sometimes get wedged between the pack and the lid. Figure 1 shows a prior art package containing a contact lens that has become rolled up; Figure 2 shows a prior art package containing a contact lens that has become inverted; and Figure 3 shows a prior art package containing a contact lens that has become wedged between the pack and the lid. These inconveniences can lead to damaged and contaminated lenses by way of excessive handling prior to insertion.

[0008] It is well known in the art that one of the most common problems encountered when inserting lenses is the issue of their inversion. This occurs when the lens is turned inside out and must be righted before wearing. The net

effect, if this is not completed, is generally a greater level of discomfort and some visual disturbances. Some companies go so far as to place anti-inversion marks on their lenses in order to assist the patient in this matter, but overall these can be considered as a compromise. Storing a contact lens in a preferential orientation in such a way that the lens cannot move excessively can alleviate this problem. Storing the lens in a container where the clearance is always less than the natural overall sagittal height of the contact lens is especially beneficial to this goal.

[0009] As a result of the polypropylene blister component, the individual component is somewhat deeper than the lens from a sagittal perspective and as such does not lend itself to a disposable look nor convenient stacking due to its bulk. If the consumer travels, the lenses can prove to be quite a bulky item. Many of the materials from which contact lens are traditionally formed have a tendency to break and/or distort permanently if flattened for extended lengths of time, resulting in limited packaging design capability.

[0010] Some of the problems associated with contact lenses have been addressed in the prior art. The prior art solutions have included the development of a variety of contact lens materials and the use of particular processing steps in the production of contact lenses.

[0011] It is believed that the tackiness of the lens surface is one of the results of the deleterious effect of oxygen on the free radical polymerisation reaction.

[0012] Soft contact lenses are traditionally made by polymerising monomers into hydrophilic polymers. During the free radical polymerisation process, the presence of oxygen is generally manifested as an induction period. Although the initiator generates free radicals during this induction period, polymerisation does not occur. This induction period is caused by the presence of oxygen which preferentially reacts with the free radicals produced by the initiator. Once the oxygen has been consumed, polymerisation occurs.

[0013] Generally, any dissolved oxygen present in the monomer mixture is removed prior to initiation to minimise the induction period. The oxygen is typically removed either by bubbling an inert gas, such as nitrogen, through the

monomer, or by applying a vacuum to the monomer. Another commonly practised technique is to add sufficient free-radical initiator to scavenge the oxygen from the monomer mixture.

[0014] Traditionally, contact lenses have been made either by machining or moulding. The adverse effects of oxygen on free radical polymerisation can be particularly serious in the production of contact lenses by moulding.

[0015] Contact lenses may be produced by moulding in the following manner. A small quantity of monomer mixture is dosed into a concave plastic mould, which will form the front surface of the lens. A second, convex mould, (which will form the back surface of the lens) is then placed onto the first mould, and the monomer is then cured, to give a part-finished contact lens.

[0016] Whilst any oxygen may be removed from the monomer mixture prior to dosing and closing the moulds, or by the scavenging effects of an excess of initiator, it has been found that small quantities of oxygen may diffuse into the monomer mixture from out of the mould. Whilst not sufficient to inhibit polymerisation, the oxygen diffusing out of the mould may affect the surface characteristics of the lens, i.e. to cause differential polymerisation at the lens surface relative to the lens bulk. This disruption creates more loose polymer ends at the surface due to (premature) termination of polymerisation by oxygen. These shorter chain polymers at the surface of the lens tend to have lower cross link density, less chain entanglement, and more tackiness than the polymer chains in the bulk of the lens. These factors typically result in reduced mechanical strength and increased water content at the lens surface relative to these properties in the lens bulk.

[0017] The surface tack may be overcome by increasing the cross-linker concentration in the monomer, so as to reduce the amount of free chain ends at the surface of the lens. However, this will also increase the degree of cross-linking in the bulk of the lens, which will typically compromise the mechanical properties of the polymer, resulting in a less extensible, more easily torn lens.

[0018] Another means of addressing the problems caused by the presence of oxygen is to substantially reduce the amount of oxygen in the mould.

[0019] The criticality of oxygen level and the difficulty of implementing effective control protocols may be appreciated by recognising that, according to data presented in U.S. Patent No. 6,511,617, the level of oxygen at the reactive monomer/mould interface must be controlled to approximately 300 times less than the concentration of oxygen in air ($3x10^{-3}$ moles/litre).

[0020] Even brief exposure of the moulds to air after degassing, as in normal manufacturing handling, is detrimental; it is known that even a one minute exposure to air results in sufficient absorption of oxygen to require five hours of degassing to reacquire an acceptable condition. Accordingly, a degassing operation immediately proximate the manufacturing line, particularly for large volume transfers of moulds with different exposure times, may be deemed impractical, and no real improvement over other systems.

[0021] The problem is complicated by the fact that the front and back curves of the juxtaposed mould sections exhibit different thicknesses. This can lead to potentially different exposure of the monomer mixture to oxygen across the surfaces of varying cross-sections, which could result in distortion of the lens and degradation of its optical properties. Thus, the concentration distribution of oxygen in the respective mould sections or halves remains symmetrical for short degas times, but becomes progressively less symmetrical for longer degas times, and the anomaly can cause uneven cure and different properties between the front and rear surface. For example, the convex male mould may be degassed within about two hours, whereas the concave female mould may not be entirely degassed even after ten hours.

[0022] It can be seen that the implementation of these measures may detract from a flow-line manufacturing process, or require capital-intensive equipment, both of which will affect the cost of the lens product.

SPIN CASTING

[0023] Spin casting, sometimes referred to as "free forming", is well known in the art for forming contact lenses. In this process, lenses are manufactured, hydrated and packaged in a single fully automated process. Lenses are produced using a single dose of monomer into a mould. In an improvement to

that process, the mould is used as part of the packaging, and no machining or external modifications are made to the lens after spinning. The present invention provides further improvements to the process, wherein the process has been simplified and streamlined to allow full automation.

[0024] The free-forming method is an alternative lens production method that is intrinsically less prone to the problem of oxygen release by the mould. In this process, a single concave mould is dosed with monomer mixture, and then spun at a controlled rate. The centripetal forces acting on the monomer mixture generate the back surface of the lens. The monomer mixture may then be cured, resulting in the formation of a contact lens.

[0025] By conducting the spinning and curing process under an inert atmosphere, the deleterious effects of oxygen may be minimised. However, whilst the back surface of the lens may be free of the effects of oxygen degradation discussed above, the front surface may be affected by oxygen diffusion from the mould, leading to a tacky surface. Unfortunately for the lens wearer, it is the front surface of the lens that will be most prone to environmental contamination during use.

[0026] Whilst the measures to mitigate oxygen diffusion from the mould described above may be applied to the single mould used in free forming, these would detract from the simplicity of the manufacturing process.

[0027] The free forming process is used to produce a high-quality, low-cost contact lens product. This process relies on several stages to work correctly. These are namely: (a) mould wetting, (b) lens spinning and curing, and (c) lens hydration and release from the mould.

[0028] In (a) mould wetting, the monomer mixture used may advantageously permanently wet the entire surface of the mould. This allows, on spinning, a complete lens to be formed with no surface or edge irregularities.

[0029] In (b) lens spinning and curing, the mould is spun on an axis to form the shape of the lens back surface. Next the monomer mixture is polymerised. This is typically achieved by creating free radicals, either by irradiating the mould and monomer mixture with ultra-violet light or by heating the mould and monomer

mixture. On polymerisation, the monomer mixture hardens to create a dry contact lens ready for hydration.

[0030] In (c) lens hydration and release, the dry lens formed in (b) is immersed in an aqueous solution. The lens matrix is hydrated and this causes it to expand and release from the mould, creating a free soft contact lens.

[0031] Some of the problems associated with soft contact lenses which were identified above may develop during the manufacturing process. The development of these problems is described below with reference to the free-forming process.

Mould Wetting

[0032] During the mould wetting stage, the liquid monomer mixture is forced up to the edge of the mould typically by angling and rotating the mould or by spinning the mould. If the surface tension of the liquid monomer mixture is high, the liquid can ripple at the edge and therefore not follow its form perfectly. This can create an uneven edge which may be uncomfortable to wear or may induce splits in the soft contact lens. The liquid monomer mixture may also run back away from the edge leaving voids in the final contact lens produced. Monomer mixtures with lower surface tension form lenses with good even edges and reliably produce fully-formed soft contact lenses. Ideally, the surface tension of the monomer mixture should be close to, or lower than the surface energy of the mould material. This process can be further enhanced by prior treatment of the moulds by corona discharge to facilitate surface wetting. Corona discharge is known in the art.

Spinning/Curing

[0033] The mould and monomer mixture are spun to create the lens shape and then typically irradiated or heated to polymerise the monomer into a dry contact lens. Several issues exist with this stage of the process. Ideally the polymerisation time is short and the completion of the reaction is very high. In addition, the shrinkage caused by the liquid-solid transition should be preferentially as low as possible.

[0034] A long cure time will reduce the rate at which lenses are created and this will increase the cost of goods and reduce capacity. Many soft contact

lenses are sold in high volumes as frequent replacement lenses and therefore require high capacity processes. If the completion of the reaction is insufficient, there will be a high level of residuals in the contact lens, which will typically lead to sensitisation of the eye as described previously. Shrinkage caused by the liquid-solid transition can cause distortions that may affect the lens' fit or the quality of its optical focus.

Hydration/Release

[0035] Upon hydration, dry free formed lenses swell into soft contact lenses. This causes them to expand and release from the mould surface.

[0036] Free formed lenses have intricate edge forms which are thin compared to other sections of the lens and these therefore hydrate quickly. There is a considerable level of stress on these thin edges and they can split, chip or distort on release. Ideally the lens is strong enough to withstand this stress and no defects are formed. This is dependent on both lens design and material properties.

[0037] The centre of the lens is usually the last area to release; and as such is pulled away sharply as the rest of the lens is released and hydrating and expanding rapidly. This can cause pitting of the lens surface. This pitting can destroy the quality of the lens' optical focus. Ideally the lens material should withstand these release forces and remain intact.

[0038] When the lens being formed is an ionic lens, further challenges are encountered. Typical prior art ionic lens compositions contain methacrylic acid. In order for these lenses to achieve their design water content and parameters, the methacrylic acid requires extraction and neutralisation, which is typically conducted by contacting the lens under heated conditions with a basic solution such as sodium carbonate. Once the lens is fully extracted and has realized its hydration potential, it is necessary to then equilibrate the lens in the saline the lens will be packaged in. This extraction therefore constitutes an additional processing step. In the case of a spun cast lens whereby it may be desirable to hydrate and retain the lens in its own mould for final packing, the need to extract the lens in order to achieve its final hydrated parameters may be impacted by the limited volume of extraction solution afforded by the mould dimensions. If the

extraction solution is of insufficient volume for the lens volume being hydrated, the full hydration potential may never be reached.

PACKAGING

[0039] Soft disposable contact lenses are commonly contained in disposable packages. The traditional packaging for disposable lenses (both two weekly and daily) consists of a polypropylene blister pack or receptacle for the lens.

[0040] The blister pack is typically filled with a suitable storage solution, preferably saline, and receives the lens *in situ*. The blister pack is then covered with a composite aluminium sheet, sealed and autoclaved. These blister packs are presented to the patient in boxes of individual packs or as multiple blister strips.

[0041] The objective is to be able to present the contact lens to a patient in an aesthetically pleasing package that both satisfies the statutory requirements for sterility and stability and allows the patient to remove the lens safely and easily, with the minimum of handling prior to insertion into the eye. The packaging is used only once and is discarded after the lens is removed. This can impact on the costs of the lens/package combination. In order to reduce the overall price of the lens, the cost of the packaging should be kept to an absolute minimum. Disposability of lens packaging places an onus to conformity to ecological requirements. The packaging should present the least ecological threat as is possible. The above packages are known generically as blister packs and generally each blister pack holds a single contact lens.

[0042] The lens should be kept hydrated whilst in the package. In use, the user removes the laminated material from a flange formed on the blister pack by peeling back to expose the lens immersed in a hydration solution. Attempts to remove the lens from the solution can be frustrating to the patient and sometimes results in lens damage.

[0043] A variety of contact lens packages and particularly disposable contact lens packages including pre-formed blister packs are taught in the prior art.

[0044] The size of the traditional packaging is a disadvantage to the disposable lens concept as the receptacle is many times larger than the lens itself. As a result the blister is somewhat deeper than the lens from a sagittal perspective and as such does not lend itself to an appearance of innate disposability nor convenient stacking due to its bulk. As noted above, if the consumer travels, the lenses can prove to be quite a bulky item.

POLYMERS

[0045] In the past a number of different materials have been used to form soft contact lenses. Each of these materials has advantages and disadvantages and satisfies some of the requirements of a contact lens to varying degrees. An example of a material used to form soft contact lenses is a co-polymer of 2-hydroxyethyl methacrylate (HEMA) and glycerol methacrylate (GMA). Whilst exhibiting positive attributes, this material has certain limitations. Inherently the material is insufficiently strong. However, this material has a tendency to break and, in the extreme, to crumble on application of a rotational frictional force, such as during cleaning by a patient. Furthermore, it is essential that the GMA monomer be purified by vacuum distillation. Due to the high boiling point of GMA, and its potential to homopolymerise during the distillation process, this is not a trivial undertaking. Many other examples of contact lenses produced from a combination of the polymerisable monomers HEMA and GMA, either alone or in combination with further polymerisable monomers, are known.

[0046] Other polymers suggested for use in contact lens have other drawbacks. For example, some polymers suggested require the inclusion of fluorine-containing monomers, which involves some difficulties, for instance, the hydrophobic nature of fluorine-containing monomers will tend to raise the wetting angle of the resultant contact lens, thus providing a less-wetting surface.

[0047] Thus, there is a need for contact lenses made of a material that is less susceptible to the problems identified above. There is also a need for a method of manufacturing contact lenses that overcomes the problems identified above. The present invention alleviates the problems of the prior art.

SUMMARY OF THE INVENTION

[0048] In a first aspect the present invention relates to a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA).

[0049] Whilst the prior art may list HPMA as one of many polymerisable monomers and GMA as another of many polymerisable monomers, as well as the need to have additional polymerisable monomers, it is to be noted that none of the prior art specifically describes or suggests a useful and beneficial contact lens that has been prepared from HPMA and GMA as the principal polymerisable components.

[0050] In a second aspect the present invention relates to a contact lens obtainable from a process comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA).

[0051] In a third aspect the present invention relates to an ionic contact lens obtainable from a process comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA), along with a relatively minor amount of an alkali metal salt of (meth)acrylic acid, where the ionic lens requires no formal base treatment to achieve its designed water content.

[0052] In a fourth aspect the present invention relates to an unhydrated contact lens comprising a polymer containing an alkali metal salt of (meth)acrylic acid. Also, the present invention relates to a process of preparing an unhydrated contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture includes an alkali metal salt of (meth)acrylic acid.

[0053] In a fifth aspect the present invention relates to a contact lens obtainable from a process comprising polymerising a polymerisable mixture, wherein said polymerisable mixture includes monomers of hydroxypropyl

methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA) and wherein said contact lens is packaged in a flat package.

[0054] In a sixth aspect the present invention relates to an ionic contact lens obtainable from a process comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA), along with a relatively minor amount of an alkali metal salt of (meth)acrylic acid, where the ionic lens requires no formal base treatment to achieve its designed water content, and wherein said contact lens is packaged in a flat package.

[0055] In a seventh aspect the invention relates to a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture comprises polymerisable monomers of:

i) hydroxypropyl methacrylate (HPMA),

ii) 2,3–dihydroxypropyl methacrylate (GMA) and

iii) an alkali metal salt of (meth)acrylic acid.

[0056] In an eighth aspect the invention relates to a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture comprises polymerisable monomers of hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA) and is substantially free of fluorine containing monomers.

[0057] The term "polymerisable monomers" refers to mono-functional monomers and does not include cross-linking agents.

[0058] The term "principal polymerisable monomers" means the polymerisable monomers that constitute at least 95% by weight of the total polymerisable monomers in the polymerisable mixture. In other words, when HPMA and GMA alone constitute the principal polymerisable monomers, the polymerisable mixture contains less than 5% of any polymerisable monomer other than HPMA and GMA.

[0059] It will be readily appreciated that commercially available HPMA and GMA may contain small amounts of contaminants which may be polymerisable monomers. These small amounts of contaminants in commercially available

HPMA and GMA are considered as not to exist when determining the amount of HPMA and GMA in a monomer mixture to determine whether it satisfies the above definition. Preferably, the polymerisable mixture does not contain any separately added 2-HEMA.

[0060] In a preferred embodiment the present invention comprises preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA); wherein the polymerisable mixture contains less than 5% of any other polymerisable monomer and wherein the polymerisable mixture is free of any separately added 2-HEMA.

[0061] It will be readily appreciated that the polymerisable mixture may contain cross-linking monomers. However, these are typically used in amounts of less than 5 wt %.

[0062] Typical levels of the relatively minor amount of the alkali metal salts of (meth)acrylic acid are in the order of from 0.5% to 5%

[0063] A preferred level of the relatively minor amount of the alkali metal salts of (meth)acrylic acid is about 1% to 3.5%

[0064] The (meth)acrylic acid may be derivatised. However, preferably, the (meth)acrylic acid is either methacrylic acid or acrylic acid, or mixtures thereof. More preferably, the (meth)acrylic acid is methacrylic acid.

[0065] Typical alkali metals include lithium, sodium and potassium.

[0066] Preferably the alkali metal salt of (meth)acrylic acid is an alkali metal salt of methacrylic acid.

[0067] Typical alkali metal salts of methacrylic acid include lithium, sodium and potassium.

[0068] A highly preferred alkali metal salt of methacrylic acid is sodium methacylate.

[0069] The term "formal base treatment" means an initial hydration of the lens in either deionised water or saline to which has been added an alkali such as sodium bicarbonate, sodium carbonate or sodium hydroxide, so as to bring the pH of the solution to 8.0 or higher.

[0070] In a broad aspect, we have found that a contact lens having beneficial properties may be formed from HPMA and GMA. The contact lenses of the present invention have improved properties over the prior art contact lenses.

[0071] In one preferred aspect, HPMA and GMA are used as the sole polymerisable components.

[0072] In a highly preferred aspect, HPMA and GMA are used as the principal polymerisable components, along with sodium methacrylate as a minor polymerisable component.

[0073] The term "flat package" means a package capable of maintaining the contact lens in a substantially flat configuration (i.e. less than the natural overall sagittal height of the contact lens). Examples of flat packages are disclosed in PCT Patent Publication WO 03/016175 and in U.S. Patent application Serial No. 10/789,961. The packages themselves do not necessarily need to be flat to be considered a "flat package". A flat package may be made from a flexible material that is capable of bending. The contact lens within such a flat package may also bend with the walls of the package.

BRIEF DESCRIPTION OF THE FIGURES

[0074] Reference is made to the accompanying figures in which:-

[0075] Figure 1 shows a prior art package containing a contact lens that has become rolled up;

[0076] Figure 2 shows a prior art package containing a contact lens that has become inverted;

[0077] Figure 3 shows a prior art package containing a contact lens that has become wedged between the pack and the lid.

[0078] Figure 4 shows measurement of the wetting angle.

[0079] Figure 5 shows a contact lens packaged in a flat package wherein the lens is in a substantially flat configuration.

[0080] Figure 6 shows a contact lens at its natural sagittal height in an open flat package.

[0081] Figure 7 shows flat packages in a strip wherein each flat package is connected to an adjacent flat package via a frangible connection.

[0082] Figure 8 shows an apparatus for inspecting a contact lens.

DETAILED DESCRIPTION

[0083] The present invention will now be further described. In the following passages, different aspects of the invention are defined in more detail. Each aspect so defined may be combined with any other aspect or aspects unless clearly indicated to the contrary. In particular, any feature indicated as being preferred or advantageous may be combined with any other feature or features indicated as being preferred or advantageous.

[0084] It has surprisingly been found that a contact lens prepared by polymerising a polymerisable mixture which has HPMA and GMA as the principal polymerisable monomers overcomes many of the problems of the prior art and has many desirable characteristics. It has also been found that by using a monomer containing an alkali metal salt of (meth)acrylic acid in a contact lens polymer mix, a lens can be formed that can more easily be manufactured and packaged. Most importantly, it has been found that these two discoveries can be used in a synergistic fashion, and that the inclusion of a monomer of an alkali metal salt of (meth)acrylic acid in with a polymerisable mixture which has HPMA and GMA as the principal polymerisable monomers can not only facilitate the contact lens manufacturing process, but also improve the final lens properties.

[0085] In particular it has been found that a contact lens prepared in accordance with one aspect of the present invention is surprisingly resistant to the effects of surface oxygen degradation. For example, such contact lenses have been found to have significantly less surface tack than contact lenses of the same water content known in the prior art, such as contact lenses produced from HEMA and GMA.

[0086] HPMA is more hydrophobic than some of the other polymerisable monomers known in the art, such as HEMA. Without wishing to be bound to theory, it is likely that there will be some enrichment of the more hydrophobic HPMA at the interface between the mould and the liquid monomer, and also

between the air-monomer interface. This will result in a marginal enrichment of HPMA at the surface of the lens. This enrichment will serve to counterbalance the normal increase in surface water content produced by the increase in chain ends resulting from oxygen diffusion from the mould. It is also likely that the increase in surface HPMA content will also lead to some thermodynamic or hydrophobic cross-linking, thus having the effect of reducing the free chain ends.

[0087] A contact lens prepared in accordance with one aspect of the present invention has been advantageously found to contain very low residuals. This is of key importance when producing a lens for frequent replacement modality as it reduces the dose of potentially sensitising species.

[0088] Without wishing to be bound by theory, it is believed that the reason for very low residuals is as follows. As noted above, HPMA is more hydrophobic than some of the other polymerisable monomers known in the art. Therefore by using the more hydrophobic HPMA, it is possible to increase the quantity of GMA within the polymer at a given water content. GMA has a faster reaction rate than HEMA or HPMA, therefore the greater the level of GMA the faster the copolymer reaches completion. A greater level of GMA also increases the viscosity of the formulation, which decreases the termination rate of the polymerisation reaction. The polymerisation reaction of a polymerisable mixture which has HPMA and GMA as the principal polymerisable monomers therefore typically goes essentially to completion, resulting in a low level of residuals. The polymerisation reaction also typically reaches completion fast. This reduces the cycle time for the process and enables a low cost, high quality lens to be produced.

[0089] Yet another advantage of using HPMA in contact lenses is the lower toxicity of HPMA compared to HEMA as illustrated by the following data.

Monomer	**LD50 (oral. Rat)**	**RTECS**
2-hydroxyethyl methacrylate (HEMA)	5050 mg/kg	OZ4725000
hydroxypropyl methacrylate (HPMA)	11200 mg/kg	UD3442500

[0090] Although both HEMA and HPMA are known to be weak sensitisers, HEMA is reported to exhibit a strong tendency to cross-reactivity with other

methacrylates, whilst HPMA is reported to be only weakly cross-reactive (Rustemeyer T, de Groot J, von Blomberg BM, Frosch PJ, Scheper RJ. "Cross-reactivity patterns of contact-sensitizing methacrylates". Toxicol Appl Pharmacol 1998;148:83 –90).

[0091] This weak cross-reactivity sensitisation pattern for HPMA, plus the lower acute toxicity, will confer an advantage in the use of HPMA in contact lenses intended for use as a daily disposable lens. In this wear modality there is a daily challenge to the wearer from any residual monomer present in the lens. Whilst the bulk of any residual components derived from the monomer should be removed from the lens during wet processing, it is clearly advantageous to use materials which are intrinsically safer.

[0092] It has also surprisingly been found that a contact lens prepared in accordance with preferred aspects of the present invention has a more desirable form than contact lenses of the prior art. For example, a contact lens prepared in accordance with one aspect of the present invention typically has no distortion, which results in a lens having very high quality focus. This is believed to be due to the difference in size between HPMA and other molecules typically used in the prior art, such as HEMA. The HPMA molecule is larger than the more traditionally used HEMA molecule, with the result that the volume change on polymerisation is lower. This reduces the instances of distortion.

[0093] A contact lens prepared in accordance with the preferred process of the present invention has also been found to have many advantageous properties, such as improved tensile strength, elastic modulus and extensibility. This prevents chipping, splitting and distortion at the lens edge and provides a lens surface substantially free of the pit marks traditionally seen on lenses, especially those made by the free-forming method. This produces a lens with excellent visual quality and efficacy, making for consistent comfort. Yields are increased and the need for labour intensive inspection reduced. Lenses are therefore lower cost and higher quality.

[0094] Without wishing to be bound by theory, it is believed that some of these improved properties may be due to the surface tension of a polymerisable mixture which has HPMA and GMA as the principal polymerisable monomer.

The HPMA/GMA polymerisable mixture has a lower surface tension than HEMA, HEMA/MA and HEMA/GMA (traditionally used materials). The lower surface tension leads to improved mould wetting, which is especially important in the free-forming process. The improved wetting produces a contact lens having a smoother, well-defined lens edge.

[0095] A further advantage of contact lenses prepared in accordance with the present invention is increased dehydration resistance as compared with those contact lenses of similar water content known in the prior art. The contact lenses prepared in accordance with the present invention also retain the benefits of easy handling and tear resistance.

[0096] Without wishing to be bound by theory, it is believed that by using the more hydrophobic HPMA, it is possible to increase the quantity of GMA within the polymer. Since GMA polymers are known to confer dehydration resistance, as demonstrated by the use of poly-GMA as an emollient in cosmetic preparations and as a moisturiser for burnt skin, the resultant HPMA-GMA lenses likewise typically exhibit improved dehydration characteristics.

[0097] By way of comparison, U.S. Patent No. 5,532,289 discloses lenses produced from a HEMA-GMA copolymer, which are described as having a high water balance ratio, which is defined as the ratio of the water uptake rate, and the dehydration rate. U.S. Patent No. 6,096,799 discribes lenses with an extremely high water balance made of a homopolymer or copolymer of 2,3-dihydroxypropyl methacrylate.

[0098] The prior art lenses described in U.S. Patent No. 6,096,799, whilst having an improved water balance ratio over the lenses described in U.S. Patent No. 5,532,289, suffer the drawback of being of higher equilibrium water content. Such lenses are likely to be mechanically weaker than those comprised of HPMA-GMA.

[0099] A contact lens prepared in accordance with the preferred embodiments of the present invention has improved properties which make it particularly suitable for packaging in a flat package 2, and particularly in a substantially flat configuration (i.e. less than the natural overall sagittal height of the contact lens) as shown in Figures 5-7. The contact lens 4 may therefore

advantageously be packaged in a flat primary package for a contact lens which is almost flat in profile and preferably contains a minimum amount of saline. HPMA provides a unique ability previously not demonstrated by alternative materials known in the industry in that it is possible to hold the lens in an environment with less height than the natural overall sagittal height of the lens, hence squashing the contact lens, for long periods of time without causing defects related to the restricted conditions the lens is put in. This information was discovered experimentally by storing contact lenses of various materials in such conditions and then regularly inspecting them for damage over a set period of time. Unlike other some materials, the HPMA/GMA was not only not damaged, but also easily re-conformed to its original shape without distortion or negative effects on the lenses optical properties. This inspection was carried out using equipment and techniques well known in the contact lens industry. To be suitable for packaging in a flat primary package and particularly in a substantially flat configuration, a contact lens material should preferably demonstrate no or few defects caused by this storage technique.

[00100] The flat primary packaging 2 may be generally flat and thin in profile and store the lens 4 in an enclosure that is restrictive to the contact lens 4 in situ such that the relaxed sagittal shape of the contact lens 4 cannot be realised. Preferably the lens 4 is stored in a flat or near flat state. The packaging 2 is able to maintain the optimum water content of the soft contact lens with a minimum of saline and presents an optimised profile for storage and handling of the lens. The preferred flat packaging has certain features that ensure the lens presents to the wearer in a specified and repeatable way in order to minimise pre-insertion handling, described in more detail in U.S. Patent application Serial No. 10/789,961.

[00101] Whilst this packaging can accommodate most lenses, it has become apparent during the development that some contact lens materials are better suited to restrictive packaging than are others. This is especially true in the case of daily disposable lenses whereby there is a daily risk of inserting an incompletely extracted contact lens.

[00102] It is well known in the art that one of the challenges to successful daily disposability is the control over the minimisation of contact lens residuals. It is well known that most soft moulded disposable lenses retain a small amount of unreacted monomer within them, or some uncrosslinked polymer chains that are attached to their neighbouring chains by entanglement only. These small impurities can leach out on the eye and pose a sensitisation problem. There are generally few problems with two weekly or monthly lenses as the lens is only inserted fresh from the packaging on a periodic basis, and as such the eyes have a time to recover from the first wearing out of the pack. Daily disposables pose a greater potential for this problem as they must be fitted fresh everyday, and any residuals leaching from the lens can gradually contribute to a sensitisation issue for the patient. This problem is particularly acute when flat packaging, in which the storage solution is kept to a minimum, is used. It is preferable therefore to use a lens material that will polymerise with a minimum of unreacted material left over.

[00103] The flat packaging 2 may also maintain a very flat profile and subjects the contact lens 4 to compression forces. Some lens materials such as HEMA/GMA are very friable in nature and can split quite easily when pressed down flat. These types of lenses tend to form small splits or tears around the edge of the contact lens which can open up and create discomfort problems when worn. A particular polymer was sought that would easily be able to withstand these stresses on a long term basis.

[00104] The preferred flat packaging has also been designed with a mechanism to present the lens in an upward orientation when the pack is opened, in order to facilitate its removal from the pack. It is desirable for such a mechanism to work with a contact lens made from a particular range of modulus. Such lens can assist in the upward presentation and make handling simple. This ultimately reduces pre-insertion handling which is an advantage to the patient.

[00105] Many materials were tested and eventually a contact lens prepared in accordance with preferred aspects of the present invention was proven to be optimal in these packaging conditions. Such contact lenses not only produced

excellent clinical results, but also offered the following advantages in the way of package/lens interaction.

[00106] The contact lens exhibited both strength and elasticity in a particular combination that prevented edge splitting when stored flat.

- The contact lens material polymerised particularly well and demonstrated exceptionally low levels of residuals. This is a major advantage when storage solution is kept to a minimum.
- The resultant lens still exhibited excellent wettability due to the large amount of GMA used; and as such was able to instantly wet the eye when inserted, but did not adhere unduly to the inserting finger. This solves a real problem with conventional lenses taken from typical blister packs.
- The contact lenses exhibited excellent memory retention despite long term storage and sprang back to their natural shape once the flat pack had been opened.

[00107] This packaging 2 satisfies many contact lens related criteria including sterility, minimal space and environmental issues.

[00108] HPMA is known to exist in two isomeric forms: primary HPMA (3-hydroxypropyl methacrylate) and secondary HPMA (hydroxypropyl methacrylate, also known as 2-methyl-2-hydroxyethyl methacrylate). A typical source of HPMA contains 11 to 14% primary HPMA and 86-89% secondary HPMA. As used herein and in the claims, hydroxypropyl methacrylate refers to either isomer or combinations of the isomers.

[00109] Preferably at least 75% of the hydroxypropyl methacrylate (HPMA) used to make the contact lens is the hydroxypropyl methacrylate (2-HPMA) isomer. More preferably at least 80% of the HPMA is the 2-HPMA isomer. In a highly preferred aspect at least 85% of the HPMA is the 2-HPMA isomer.

[00110] Commercial sources of HPMA and GMA are known to contain some impurities. Preferably the HPMA and/or the GMA are at least 95% pure. More preferably the HPMA and the GMA are both at least 95% pure. Preferably, the GMA is prepared following the teachings of GB 2 348 878, and used without distillation.

[00111] In a preferred aspect the HPMA and GMA are in a molar ratio of from 1:20 to 5:1, more preferably in a molar ratio of from 1:10 to 5:1, such as from 1:5 to 5:1, such as from 1:2 to 5:1. In a highly preferred aspect the HPMA and GMA are in a molar ratio of from 1:1.5 to 1.5:1, more preferably in a molar ratio of about 1:1.

[00112] In a preferred aspect the HPMA is present in an amount of from 5 to 80% by weight of the polymerisable monomers, more preferably from 20 to 80%, more preferably from 40 to 80%, more preferably from 40 to 60%.

[00113] In a preferred aspect the GMA is present in an amount of from 20 to 95% by weight of the polymerisable monomers, more preferably from 30 to 95%, more preferably from 40 to 95%, more preferably from 40 to 80%, more preferably from 40 to 60%.

[00114] In a preferred aspect the polymerisable mixture comprises an additional polymerisable monomer in an amount of less than 5% by weight of the polymerisable monomers.

[00115] Preferably the additional polymerisable monomer is selected from the group consisting of methyl acrylate, ethyl acrylate, propyl acrylate, butyl acrylate, amyl acrylate, hexyl acrylate, phenyl acrylate, hydroxyethyl, acrylate, hydroxypropyl acrylate, hydroxybutyl acrylate, glycerol monoacrylate, 2-phenoxyethyl acrylate, 2-N-morpholinoethyl acrylate, 2-(2-ethoxyethoxy)ethyl acrylate, 2-(N,N-dimethylamino)ethyl acrylate, 3-(N,N-dimethylamino)propyl acrylate, methyl methacrylate, ethyl methacrylate, propyl methacrylate, butyl methacrylate, amyl methacrylate, hexyl methacrylate, furfuryl methacrylate, hydroxybutyl methacrylate, 2-phenoxyethyl methacrylate, acrylic acid, sodium acrylate, potassium acrylate, methacrylic acid, sodium methacrylate, potassium acrylate, 2-N-morpholinoethyl methacrylate, 2-(N,N-dimethylamino)ethyl methacrylate, 3-(N,N-dimethylamino)propyl methacrylate, 2-pyrrolidinonylethyl methacrylate, N-methylacrylamide, N-ethylacrylamide, N-propylacrylamide, N-butylacrylamide, N-amylacrylamide, N-hexylacrylamide, N-heptylacrylamide, N-octylacrylamide, N-(n-octadecylacrylamide), 3-N,N-dimethylamino)propylacrylamide, allylacrylamide, hydroxymethyldiacetoneacrylamide, N,N-dimethylacrylamide, N,N-

diethylacrylamide, N-ethyl-N-methylacrylamide, N-methylmethacrylamide, N-methylolmethacrylamide, N-(2-hydroxypropyl)methacrylamide, N-4-(hydroxyphenyl)methacrylamide, N-(3-picolyl)methacrylamide, 3-vinylpyridine, 4-vinylpyridine, N-vinylpyrrolidinone, vinyl pyrzaine, 2-methyl-5-vinylpyrazine, 4-vinylpyrimidine, vinyl pyridazine, N-vinylimidazole, N-vinylcarbazole, N-vinylsuccinimide, 4-methyl-5-vinylthiazole, N-acryloylmorpholine, N-methyl-N-vinylacetamide and hydroxyethyl methacrylate (HEMA) and mixtures thereof.

[00116] Preferably the additional polymerisable monomer is selected from the group consisting of acrylic acid, sodium acrylate, potassium acrylate, methacrylic acid, sodium methacrylate, and potassium methacrylate. Preferably the additional polymerisable monomer comprises acrylic acid and/or methacrylic acid. Preferably the additional polymerisable monomer comprises methacrylic acid or sodium methacrylate.

[00117] In a highly preferred aspect the additional polymerisable monomer is sodium methacrylate.

[00118] In one preferred aspect the polymerisable mixture comprises no polymerisable monomer other than the principal polymerisable monomers HPMA and GMA.

[00119] As noted earlier, the term "polymerisable monomers" refers to mono-functional monomers and does not include cross-linking agents.

[00120] In one aspect the polymerisable mixture comprises a diluent. Preferably the diluent is present in an amount of less than 15% by weight of the polymerisable mixture. More preferably the diluent is present in an amount of less than 10% by weight of the polymerisable mixture, such as less than 9% or less than 8%. In a highly preferred aspect, the diluent is present in an amount of 6% to 8% by weight of the polymerisable mixture, such as in an amount of about 7%. Preferably the diluent is water-soluble, and capable of serving as a plasticizer for the lens polymer.

[00121] In a preferred aspect the diluent is selected from the group consisting of an aqueous solvent (such as water), glycerol, ethanol, isopropanol, ethyl lactate, N-methyl pyrrolidinone, solketal, ethylene glycol, diethylene glycol, triethylene glycol, propylene glycol, ethyl icinol, butyl icinol, diethylene glycol

monomethyl ether, triethylene glycol monomethyl ether, boric acid ester, boric acid ester of glycerol, sorbitol, and mixtures thereof. In a preferred aspect the diluent comprises glycerol. In a highly preferred aspect the diluent is glycerol.

[00122] In one preferred aspect the polymerisable mixture comprises a cross-linking agent. Preferably the cross-linking agent is selected from the group consisting of ethylene glycol dimethacrylate (EGDMA), allyl methacrylate, ethylene glycol dimethacrylate, triethylene glycol dimethacrylate and trimethylol propane trimethacrylate, glycerol diacrylate, glycerol triacrylate, glycerol dimethacrylate, glycerol trimethacrylate,1,3-propanediol diacrylate, 1,4-butanediol diacrylate, 1,6-hexamethylene diacrylate, 1,4-phenylene diacrylate, glycerol tris(acrylopxypropyl)ether, 1,3-propanediol dimethacrylate, 1,6-hexamethylene dimethacrylate, 1,10-decanediol dimethacrylate, 1,12-dodecanediol dimethacrylate, glycerol trimethacrylate, N,N'-octamethylenebisacrylamide, N,N'-dodecanomethylenebisacrylamide, N,N'-(1,2-dihydroxyethylene)bisacrylamide, allyl methacrylamide, divinylpyridine, 4,6-divinylpyrimidine, 2,5-divinylpyrazine, 1,4-divinylimidazole, 1,5-divinylimidazole, divinylbenzene and mixture thereof.

[00123] Preferably the cross-linking agent comprises ethylene glycol dimethacrylate (EGDMA). More preferably the cross-linking agent is a mixture of ethylene glycol dimethacrylate (EGDMA) and divinylbenzene.

[00124] The polymerisable mixture may, in addition to the polymerisable monomers, also comprise conventional additional components such as any one or more of emulsifiers, stabilisers, surface active agents, initiators (such as photoinitiators), inhibitors, lubricants and release agents, dispersants, oxidising agents, reducing agents, viscosity modifiers, catalysts, binders, activators, accelerators, tackifiers, plasticizers, saponification agents, chain transfer agents, cross-linking agents, dyes and metal salts.

[00125] By way of example, the surfactants and dispersants can be salts of fatty rosin and naphthenic acids, condensation products of naphthalene sulphonic acid and formaldehyde of low molecular weight, carboxylic polymers and ethoxylated alcohols of the appropriate hydrophile-lipophile balance, polyoxyethylene oleyl ethers and co-polymers of polyethylene and polypropylene glycol, higher alkyl sulfates, such as sodium lauryl sulfate, alkyl aryl sulfonates, such as dodecylbenzene sulfonate, sodium or potassium isopropylbenzene

sulfonates or isopropylnaphthalene sulfonates; sulfosuccinates, such as sodium dioctylsulfosuccinate, alkali metal higher alkyl sulfosuccinates, *e.g.* sodium octyl sulfosuccinate, sodium N-methyl-N-palmitoyl-taurate, sodium oleyl isethionate, alkali metal salts of alkylarylpolyethoxyethanol sulfates or sulfonates, *e.g.* sodium t-octylphenoxy-polyethoxyethyl sulfate having 1 to 5 oxyethylene units, and ethylene glycol/propylene glycol block copolymers, e.g. the Pluronics®. Typical polymerisation inhibitors that can be used include hydroquinone, monomethyl ether, benzoquinone, phenothiazine and methylene blue.

[00126] In a preferred embodiment the dye is selected from the group listed in Title 21 of the US Code of Federal Regulations (parts 73 and 74) for use with contact lenses, examples of which are [2-anthracenesulfonic acid, 1-amino-4-(3-((4,6-dichloro-s-triazin-2-yl)amino)-4-sulfoanilino)-9,10-dihydro-9,10-dioxo, disodium salt], [triphenodioxazinedisulfonic acid, 6,13-dichloro-3, 10-bis((4-((4.6-dichloro-1,3,5-triazin-2-yl)amino) sulfophenyl)amino)-, tetrasodium salt], [Phthalocyaninato(2-)] copper, FD&C Blue 1, FD&C Blue 2, Vat Blue 6, Vat Blue 4, 1,4-Bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester copolymers, 1,4-Bis[(2-methylphenyl)amino]-9,10-anthracenedione 2-[[2,5-Diethoxy-4-[(4-methylphenyl)thiol]phenyl]azo]-1,3,5-benzenetriol and 6-Ethoxy-2-(6-ethoxy-3-oxobenzo[b]thien-2(3H)-ylidene) benzo[b]thiophen-3 (2H)-one.

[00127] Preferably, the dye is an anthracenesulphonic acid derivative, in particular [2-anthracenesulfonic acid, 1-amino-4-(3-((4,6-dichloro-s-triazin-2-yl)amino)-4-sulfoanilino)-9,10-dihydro-9,10-dioxo, disodium salt].

[00128] In one preferred aspect the polymerisable mixture does not comprise a UV absorbing agent. Preferably the contact lens material is optimised to provide excellent manufacturability and clinical/consumer benefits. Preferably the contact lens manufacturing is integrated with a packaging system.

[00129] The present invention is applicable to all types of lenses that can be worn either on or in the eye. These could include but are not limited by spherical contact lenses, toroidal contact lenses, aberration blocking contact lenses, multifocal contact lenses, adaptive contact lenses, tinted contact lenses, combinations of the aforementioned contact lenses, intra stromal lenses and certain speciality designs of contact lenses.

[00130] In a preferred aspect the contact lens has a free monomer residual of less than 2%, preferably less than 1%, preferably less than 0.5%, more preferably less than 0.25%.

[00131] High performance liquid chromatography can be used to determine the level of free monomer residual available for leaching, following the sample preparation method outlined in BS EN ISO 10993-12 "Biological evaluation of medical devices. Sample preparation and reference materials". The sample preparation method suggested in this standard was chosen for the HPLC analysis of residuals as it gives a good indication of the potential for leaching in a physiological environment, and also since the HPLC results may be closely correlated with the toxicological testing performed to BS EN 10993.

SAMPLE PREPARATION METHOD

[00132] Five lenses were taken, and placed in buffered saline, using a ratio of 1ml saline per 6 cm^2 of total lens surface area. The total surface area of each contact lens was estimated by assuming each lens formed a spherical cap, using the following:

$$\text{Surface area } (cm^2) = 2\pi((d/2)^2 + h^2)/100$$

Where d = the lens diameter and h = the lens sagittal height (measured in mm)

[00133] The volume of saline used to extract 5 lenses is therefore $0.033\pi((d/2)^2 + h^2)$ ml, where d and h are both given in mm.

[00134] The lenses were extracted in the requisite quantity of saline for 24 hours at 35°C, after which time the saline was decanted from the lenses and analysed for residual monomer by HPLC, using standard analytical practices. From the concentration of monomer found in the saline extract, and knowing the weight of monomer used to prepare the contact lenses (and hence the dry weight of the contact lens), it is possible to calculate the amount of residual, or unpolymerised monomer present in the non-hydrated contact lens.

[00135] Certain aspects of the polymerisation reaction of a polymerisable mixture can affect the material properties of the resultant contact lens. Examples of these aspects include rate of reaction, viscosity and level of completion. By

careful selection of the amount and types of components in the polymerisable mixture, these aspects can be tailored to create a soft contact lens with the desired properties. Particularly important is the degree of completion of the polymerisation reaction. A low completion reaction results in high residual monomer levels, poor mechanical properties, poor optical qualities and a tacky surface. High performance liquid chromatography can be used to determine the level of residual monomer materials and therefore provide information about the degree of completion of the polymerisation reaction.

[00136] Low residuals are advantageous as this shows a high degree of completion and therefore improved mechanical and optical properties. Additionally, low residuals result in improved, non-tacky surface characteristics and reduced potential for possible sensitisation reactions of the eye to excess free monomer material.

[00137] Surprisingly low residuals are found in the contact lens prepared in accordance with the preferred embodiment of the present invention. Experimentation has indicated that this is because of a decreased negative effect due to the presence of oxygen.

[00138] In a preferred aspect, the contact lens has an elastic modulus of between 0.1MPa and 1.0MPa, preferably between 0.2MPa and 0.5MPa.

[00139] The elastic modulus data is calculated using a tensile testing machine, using standard methods well documented in industry, with suitable data collection software. This involves taking a section slice of the contact lens and placing it between two sets of jaws. A load is then applied pulling the test piece apart. Data on force, area, time and travel distance is then collected by the data system, which then calculates the information required.

[00140] Elastic modulus of a lens is an important characteristic for two main reasons. It is an indication of the ability of a lens to withstand use by the patient, especially during insertion and removal of the lens, and cleaning in the case of non-daily disposable lenses. It also has implications of the fit of the lens on the patient's eye.

[00141] In a preferred aspect the contact lens has a tensile strength of between 0.1MPa and 1.0MPa, preferably between 0.3MPa and 0.6MPa.

[00142] In a preferred aspect the contact lens has an extensibility between 25% and 300%, preferably between 150% and 250%.

[00143] The tensile strength and elongation to break (extensibility) of the contact lens are important for the same reasons as the elastic modulus. These properties are also both measured using a tensile test machine using industry standard methodologies.

[00144] A fine balance of elastic modulus, tensile strength and extensibility creates the ideal soft contact lens, which exhibits superior physical characteristics, is able to withstand use by the patient and at the same time provide an excellent fit on the patient's eye, both as regards clinical suitability and comfort.

[00145] In a preferred aspect the polymerised contact lens material has a wetting angle of between 2° and 45° (H_2O). A wetting angle measurement is shown in Figure 4.

[00146] An important property of contact lenses is their ability to wet easily, thus making the lens more biocompatible with the eye; especially aspects such as tear film and lipid layer break up time. This can be measured non-clinically by establishing the surface tension of the material. This can be calculated experimentally using a dynamic contact angle analyser using the Wilhelmy technique. This, simply described, involves taking a slice section of the lens, suspending it on jaws connected to a microbalance and then raising a body of purified water until the lens test sample is just immersed and then withdrawn from the liquid. Data generated from this technique can be used to calculate contact lens material wetting angles and there after surface tension and surface energies. Ideally a contact lens should have a wetting angle of between 2° and 45° (H_2O) to provide the correct surface tension.

[00147] In a preferred aspect the contact lens has shrinkage/swell characteristics such that the contact lens will swell from the dry state to the fully equilibrated state with a swell factor of between 1.0 and 1.5, more preferably between 1.2 and 1.5.

[00148] Lens shrinkage/swell is simply a ratio based on the new diameter divided by the original diameter when water is gained or lost from the polymer

matrix, and can be measured by any technique which can determine diameters. Typically a lens will swell from the dry state to a fully equilibrated state with a swell factor of between 1 and 1.5, more preferably between 1.2 and 1.3

[00149] Preferably the contact lens had handling characteristics on a scale of 1 to 10 of greater than 7, more preferably greater than 8.

[00150] The handling of a soft contact lens is directly related to the material characteristics of the hydrogel employed in the manufacture of the lens and additionally the dimension design of the lens itself. Handling is appraised on a 0-10 scale during clinical testing by the patients involved in the test. It is a subjective analysis but rendered more objective by taken a large sub set of testers to generate a more average assessment.

[00151] In a preferred aspect the process is a free forming moulding process. Preferably the present invention provides a contact lens obtainable from the process as herein described, wherein said contact lens is packaged in a flat package 2. At times such a package may be referred to as a "retort package", as it may have the same configuration as packaging commonly referred to as retort packaging used for food products and the like. Figure 5 shows a contact lens 4 packaged in a flat package 2 wherein the lens is in a substantially flat configuration. Figure 6 shows a contact lens 4 at its natural sagittal height in an open flat package 2.

[00152] Preferably the flat package 2 is pliable, more preferably pliable and flexible. Preferably the package 2 is made from one or two pieces of the same material wherein the package is a pliable and flexible flat package 2.

[00153] Preferably the flat packaging 2 comprises at least one barrier layer of flexible/pliable package material forming at least first and second opposing surfaces which define an internal package space in which the contact lens is retained; a medium 10 in the space for maintaining lens hydration; and means for enabling release of said contact lens from said package; wherein the at least one barrier layer 6, 8 of material is capable of assuming a generally planar configuration and may not be preformed.

[00154] More preferably each of said at least first 6 and second opposing surfaces 8 oppose an anterior and/or posterior surface of said lens 4.

[00155] Preferably the means for releasing the contact lens 4 from the package 2 comprises peeling away one of said barrier layers 6 from the other layer 8.

[00156] The barrier layers 6, 8 are capable of mutual deformation responsive to a load applied to the package. Preferably the barrier layers 6, 8 are formed from two pieces which provide the two opposing inner surfaces which define said space in which said lens 4 is held. Opposing edges of the barrier layers 6, 8 are preferably heat sealed.

[00157] Preferably the lens hydration maintenance medium is a suitable storage solution which may be, but is not limited to, a saline based solution.

[00158] In one aspect the flat package 2 is joined to other flat packages 12, 14 in a strip wherein each flat package is connected to an adjacent flat package via a frangible connection, as shown in Figure 7.

Example 1: a non-ionic lens

[00159] In this example the material was formulated from the following ingredients:

Constituent	Level	Purpose
Glycerol Methacrylate	48.34%	Co-Monomer
2 - Hydroxypropyl Methacrylate	43.73%	Co-Monomer
Glycerol	7.00%	Diluent
Benzoin Methyl Ether	0.50%	Initiator
Ethylene Glycol Dimethacrylate	0.40%	Cross-linker
Reactive Blue 4	0.03%	Handling Tint

[00160] The monomer was dosed into the moulds accurately using a Hamilton dispenser. The moulds were then angled at 60 degrees and rotated at 2rpm for 30 seconds. This was done to wet the mould surface with the monomer. The HPMA/GMA monomer has a lower surface tension than HEMA, HEMA/MA and HEMA/GMA (traditionally used materials) and thus produced a smoother well

defined lens edge. No instances of non-wetting were recorded when processing this material due to the lower surface tension.

[00161] The HPMA/GMA material was polymerised using UV light and was further hardened using a heated post cure. The formulation also contained a diluent which enabled the polymer chains to remain mobile for longer, helping to convert more of the species into the cross-linked matrix. This polymerisation produced a lens containing very low residuals. This is of key importance when producing a lens for frequent replacement modality as it reduces the dose of potentially sensitising species.

[00162] The hard lens was relatively stress free because the HPMA molecule, being larger than the more traditionally used HEMA molecule, results in a lower volume change. This produced lenses with very high quality focuses and no instances of distortion.

[00163] The lens was hydrated in borate buffered saline and within 30 minutes released from the mould. The material had both a high modulus and was very extensible, more so than HEMA/GMA. This prevented chipping, splitting and distortion at the lens edge and provided a lens surface free of the pit marks traditionally seen on lenses made by this method of manufacture. This made the visual quality and efficacy of the lens high, making for a consistently comfortable lens in the field. Yields were increased and the need for labour intensive inspection reduced. The lenses were therefore lower cost and higher quality.

Example 2: an ionic lens

[00164] A monomer formulation was prepared as follows:

Constituent	Level	Purpose
Glycerol Methacrylate	34.448%	Co-Monomer
2 - Hydroxypropyl Methacrylate	51.672%	Co-Monomer
Sodium methacrylate	2.37%	Co-monomer
Glycerol	7.00%	Diluent
Water	3.00%	

Constituent	Level	Purpose
Benzoin Methyl Ether	0.60%	Initiator
Ethylene Glycol Dimethacrylate	0.50%	Cross-linker
Divinylbenzene	0.40%	Cross-linker
D&C Violet #2	0.01%	Handling Tint

[00165] The monomer was dosed into the moulds accurately. The moulds were then angled at 60 degrees and rotated at 2rpm for 30 seconds. This was done to wet the mould surface with the monomer.

[00166] The lens was hydrated in borate buffered saline and within 30 minutes released from the mould. The lens also achieved its design water content and diameter without the need for a formal neutralisation step.

ADDITIONAL ASPECTS

[00167] As previously mentioned, the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA).

[00168] It has been found that in addition to the use of the principal polymerisable monomers HPMA and GMA, various modifications of the prior art process steps have resulted in the production of a highly optimised contact lens. These improvements to the process steps may be applied more generally to the production of contact lenses other than those produced from the principal polymerisable monomers HPMA and GMA.

[00169] Additional aspects of the present invention are now discussed in the following sections. It is to be noted that these aspects are not necessarily limited to polymerisable mixtures having as their principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA). For these aspects in their broadest sense examples of other polymerisable monomers that may be used include any one or more of: (alkyl and cycloalkyl) acrylates; (alkyl and cycloalkyl) methacrylates; free-radical polymerisable olefinic acids, including alkoxy-, alkylphenoxy-, alkylphenoxy-(polyethyleneoxide)-,

vinyl ester-, amine substituted (including quaternary ammonium salts thereof), nitrile-, halo-, hydroxy-, and acid substituted (for example phospho- or sulpho-) derivatives thereof; and other suitable ethylenically unsaturated polymerisable moieties; including combinations thereof. Preferably the alkyl and cycloalkyl groups contain up to 20 carbon atoms, e.g. (C_1-C_{20} alkyl and C_1-C_{20} cycloalkyl) acrylates, and (C_1-C_{20} alkyl and C_1-C_{20} cycloalkyl) methacrylates.

[00170] In more detail, examples of other polymerisable monomers include any one or more of methyl acrylate, ethyl acrylate, n-propyl acrylate, isopropyl acrylate, n-butyl acrylate, isobutyl acrylate, t-butyl acrylate, isobornyl acrylate, pentyl acrylate, hexyl acrylate, octyl acrylate, iso-octyl acrylate, nonyl acrylate, lauryl acrylate, stearyl acrylate, eicosyl acrylate, 2-ethylhexyl acrylate, cyclohexyl acrylate, cycloheptyl acrylate, methyl methacrylate, ethyl methacrylate, hydroxymethylacrylate, hydroxymethylmethacrylate, propyl methacrylate, n-butyl methacrylate, t-butyl methacrylate, isobutyl methacrylate, pentyl methacrylate, hexyl methacrylate, cyclohexyl methacrylate, 2-ethylhexyl methacrylate, isobornyl methacrylate, heptyl methacrylate, cycloheptyl methacrylate, octyl methacrylate, iso-octyl methacrylate, nonyl methacrylate, decyl methacrylate, lauryl methacrylate, eicosyl methacrylate, dodecyl acrylate, pentadecyl acrylate, cetyl acrylate, stearyl acrylate, eicosyl acrylate, isodecyl acrylate, vinyl stearate, nonylphenoxy-(ethyleneoxide)$_{1\text{-}20}$ acrylate, octadecene, hexadecene, tetradecene, dodecene, dodecyl methacrylate, pentadecyl methacrylate, cetyl methacrylate, stearyl methacrylate, eicosyl methacrylate, isodecyl methacrylate, nonylphenoxy-(ethyleneoxide)$_{1\text{-}20}$ methacrylate, acrylic acid, lithium acrylate, sodium acrylate, potassium acrylate, methacrylic acid, lithium methacrylate, sodium methacrylate, potassium methacrylate, fumaric acid, crotonic acid, itaconic acid, fumaric anhydride, crotonic anhydride, itaconic anhydride, maleic acid, maleic anhydride, styrene, alpha-methyl styrene, vinyl toluene, acrylonitrile, methacrylonitrile, ethylene, vinyl acetate, vinyl chloride, vinylidene chloride, acrylamide, methacrylamide, methacrylamide 2-cyanoethyl acrylate, 2-cyanoethyl methacrylate, dimethylaminoethyl methacrylate, dimethylaminopropyl methacrylate t-butylaminoethyl methacrylate, glycidyl acrylate, glycidyl methacrylate, glyceryl acrylate, 2,3–dihydroxypropyl methacrylate , benzyl

acrylate, benzyl methacrylate, phenyl acrylate, phenyl methacrylate, vinyl pyridine, vinyl pyrrolidine, siloxanes, silanes, and hydroxyethyl methacrylate (HEMA) and mixtures thereof. Other polymerisable monomers are disclosed in U.S. Patent Nos. 2,879,178; 3,037,006; 3,502,627; 3,037,969 and 3,497,485.

[00171] Preferred polymerisable monomers include any one or more of 2,3–dihydroxypropyl methacrylate (GMA), (2,2 dimethyl-1,3-dioxolan-4-yl) methyl methacrylate (GMAK), hydroxypropyl methacrylate (HPMA), methacrylic acid, lithium methacrylate, sodium methacrylate, potassium methacrylate, acrylic acid, lithium acrylate, sodium acrylate, potassium acrylate, glycidyl methacrylate (GYMA), N-vinyl pyrrolidone, alkyl methacrylates (such as C_{1-20} alkyl methacrylates, more preferably C_{1-15} alkyl methacrylates, more preferably C_{1-10} alkyl methacrylates, more preferably C_{1-5} alkyl methacrylates, such as methyl methacrylate), alkyl acrylates (such as C_{1-20} alkyl acrylates, more preferably C_{1-15} alkyl acrylates, more preferably C_{1-10} alkyl acrylates, more preferably C_{1-5} alkyl acrylates, such as methyl acrylate), aryl methacrylates, aryl acrylates, diacetone acrylamide, acrylamide, methacrylamide, N-alkyl acrylamides (such as C_{1-20} N-alkyl acrylamides, more preferably C_{1-15} N-alkyl acrylamides, more preferably C_{1-10} N-alkyl acrylamides, more preferably C_{1-5} N-alkyl acrylamides, such as methyl acrylamide), N-alkyl methacrylamides (such as C_{1-20} N-alkyl methacrylamides, more preferably C_{1-15} N-alkyl methacrylamides, more preferably C_{1-10} N-alkyl methacrylamides, more preferably C_{1-5} N-alkyl methacrylamides, such as methyl methacrylamide), vinyl acetate, vinyl esters, styrene, other substituted olefins, N-dialkyl acrylamides (such as C_{1-20} N-dialkyl acrylamides, more preferably C_{1-15} N-dialkyl acrylamides, more preferably C_{1-10} N-dialkyl acrylamides, more preferably C_{1-5} N-dialkyl acrylamides, such as N N dimethyl acrylamide), N-dialkyl methacrylamides (such as C_{1-20} N-dialkyl methacrylamides, more preferably C_{1-15} N-dialkyl methacrylamides, more preferably C_{1-10} N-dialkyl methacrylamides, more preferably C_{1-5} N-dialkyl methacrylamides, such as N N dimethyl methacrylamide), 3-methacryloxypropyl tris (trimethysilyl siloxy) silane (TRIS monomer), fluoro substituted alkyl and aryl acrylates and methacrylates (preferably wherein the alkyl is C_{1-20} alkyl, more preferably C_{1-15} alkyl, more

preferably C_{1-10} alkyl, more preferably C_{1-5} alkyl), and hydroxyethyl methacrylate (HEMA).

[00172] More preferred polymerisable monomers include any one or more of 2,3–dihydroxypropyl methacrylate (GMA), hydroxypropyl methacrylate (2-HPMA), acrylic acid, sodium acrylate, methacrylic acid and sodium methacrylate.

[00173] The lists of polymerisable monomers also include substituted derivatives of those monomers, such as halogenated monomers, especially fluorinated monomer derivatives, and acetal and ketal derivatives.

USE OF METHACRYLIC ACID SALTS

[00174] In a broad aspect, the present invention provides for a simplified process for the production of ionic contact lenses that require no additional neutralisation steps.

[00175] One disadvantage of the use of methacrylic acid (MAA) in a contact lens formulation aimed at producing an ionic lens is the need to neutralise the methacrylic acid component within the resultant copolymer in order for the polymer to reach its designed water content.

[00176] This is usually performed by hydrating the xerogel lens in a solution containing a basic component such as sodium bicarbonate or sodium carbonate, and generally entails an additional step in the manufacture of a lens.

[00177] Alternatively, it is possible to package the un-neutralised lens in a buffered saline and allow the neutralisation occur within the sealed package, as exemplified in U.S. Patent No. 5,080,839, in which a contact lens prepared from a copolymer of HEMA and methacrylic acid is initially hydrated in deionised water, inspected, then placed in its package along with a buffered saline..

[00178] This approach is however problematic, particularly in a packaging design that contains a minimum quantity of saline (less than 0.2ml, as compared with the 1-2ml used in typical blister packages), since such a small quantity of saline will, by necessity, have a low buffer capacity. This may lead to pH variations across the range of differing lens designs (ranging from a high plus power to a high minus power) due to the differing masses of polymer. A second potential problem in dry-packing a MAA containing lens is that the final water

content will only be achieved after prolonged contact with the buffered packaging saline.

[00179] One potential solution to this particular problem is to use an alkali metal salt of MAA, for instance, sodium methacrylate (SMAA) in place of the unionised MAA. The fact that the resultant polymer will be fully ionised in the xerogel lens negates the need to either perform a separate neutralisation step, or the use of a carefully formulated packaging saline.

[00180] A second potential benefit of using SMAA in place of MAA is the direct polymerisation of the salt of methacrylic acid (rather than the methacrylic acid itself) will result in a different polymer structure, with the SMAA moieties more evenly distributed along the polymer chain.

[00181] This may be inferred from the Alfrey and Price Qe scheme for estimating polymer reactivity ratios, i.e.:

$$K_{12} = P_1 Q_2 \exp(-e_1 e_2)$$

where K_{12} = the copolymerisation rate constant, P1 = measure of resonance stabilization of M_1 radical, Q2 = measure of resonance stabilization of M_2 monomer, e_1 = measure of polar properties of M_1 radical and e_2 = measure of polar properties of M_2 monomer

[00182] From this, and the general copolymerisation equation may be derived the following:

$$r_1 r_2 = \exp[-(e_1 - e_2)^2]$$

where r_1 and r_2 are the reactivity ratios of monomer M1 and M2 respectively.

[00183] From this, it can be clearly seen that anything that affects the polar nature of the monomer (i.e. the "e" term) will have a drastic effect on the monomer reactivity ratio. Such a change in the polar nature of methacrylic acid will be provided by its conversion to, for instance, sodium methacrylate. This difference in polarity may be easily seen by the shift in chemical shifts for the

vinyl protons for methacrylic acid (δ 6.2 and δ 5.7) and sodium methacrylate (δ 5.6 and δ 5.3) in the ^{1}H proton NMR spectra.

[00184] This change in polarity will also be manifested in a change to the polymer structure, with the result being a copolymer prepared with sodium methacrylate is likely to have the methacrylate moieties more homogenously distributed along the polymer chains (i.e. to be less blocky). A change in distribution will be manifested in differences in water content.

[00185] This is exemplified in Table 1, which gives the molar percentages for an etafilcon formulation. Formulation A is a standard etafilcon monomer, whereas formulations B, C and D are similar formulations, but using sodium methacrylate in place of methacrylic acid.

[00186] As may be seen, a larger molar percentage of sodium methacrylate (2.343 mol%) is required to achieve a similar water content to a lens containing 2.048 mol% methacrylic acid.

[00187] A series of contact lens formulations, (based on an etafilcon material) were prepared, using either methacrylic acid or sodium methacrylate as the ionic component, as shown in Table 1.

Table 1

	Weights taken (g)			
	A	B	C	D
2-Hydroxyethyl methacrylate	96.65	96.65	96.65	96.65
Methacrylic acid	1.65	0.00	0.00	0.00
Sodium methacrylate	0.00	2.10	2.40	2.67
Ethylene glycol dimethacrylate	0.48	0.48	0.48	0.48
Trimethylolpropane trimethacrylate	0.02	0.02	0.02	0.02
2-(Benzoyl-3-hydroxyphenoxy)ethyl acrylate	0.69	0.69	0.69	0.69
2,2-Azobisisobutyronitrile	0.50	0.50	0.50	0.50
Water	3.00	3.00	3.00	3.00

[00188] The formulations were then placed in identical two part polypropylene moulds, and then polymerised thermally by heating in an oven held at 110°C for 45 minutes. The moulds were then removed from the oven and allowed to cool to room temperature. The lenses were then removed from their moulds. Lenses prepared from formulation A were hydrated for 3 hours in a

saline solution to which had been added 0.1% sodium carbonate. Following extraction and neutralisation, the lenses were then transferred to a standard buffered saline solution, and left a further hour to equilibrate.

[00189] Lenses from formulations B, C and D were hydrated in a standard buffered saline for 3 hours. Following hydration and equilibration, the diameters and water contents of the lenses, were determined.

[00190] Table 2 gives the molar percentages of each of the formulations, along with the measured water contents and diameters of the resultant lenses.

Table 2

	Mol% A	B	C	D
2-Hydroxyethyl methacrylate	79.337	79.332	79.100	78.871
Methacrylic acid	2.048			
Sodium methacrylate		2.056	2.343	2.623
Ethylene glycol dimethacrylate	0.259	0.259	0.258	0.257
Trimethylolpropane trimethacrylate	0.006	0.006	0.006	0.006
2-(Benzoyl-3-hydroxyphenoxy)ethyl acrylate	0.236	0.236	0.235	0.235
2,2-Azobisisobutyronitrile	0.325	0.325	0.324	0.323
Water	17.786	17.785	17.733	17.682
Ionic monomer:HEMA ratio	0.026	0.026	0.030	0.033
Lens diameter (mm)	14.1	13.8	14.1	14.3
Water content (%)	53.2	51.5	53.3	54.35

HIGH SPEED WETTING

[00191] In a broad aspect, the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said process, comprises, in the following order, the steps of:

(i) dosing the polymerisable mixture into a mould;

(ii) spinning the mould at a speed of at least 600 rpm; and

(iii) curing the polymerisable mixture.

[00192] Contact lenses are typically made either by machining or moulding. A moulding process such as the free-forming moulding process (using spin-casting) will typically comprise a dosing stage followed by a spinning and curing

stage. Typically spuncast lenses are made using a liquid polymerisable mixture comprising one or more polymerisable monomers which is dosed into a mould. Typical dose values are 10-40 microlitres. The mould is then spun and the polymerisable mixture is polymerised by curing to form a contact lens. Typical spin speeds are 200 to 500 rpm.

[00193] To ensure that upon spinning the polymerisable mixture spreads across the mould to the full lens diameter, the moulds may be pre-wet in a mould wetting stage between the dosing stage and the spinning and curing stage. It is known in the prior art to perform the mould wetting stage by placing the moulds at an angle and rotating them slowly to force the monomer out to the lens edge. Typical angles are between 20 and 120 degree from the vertical. Typical speeds are from 0.1 to 10 rpm.

[00194] This aspect of the present invention represents an improvement over the prior art. This aspect of the present invention relates to a technique which allows moulds to be pre-wet by the polymerisable mixture by way of an inline high speed spin prior to the spin and cure stage.

[00195] According to this aspect of the invention, the moulds are dosed with a polymerisable mixture and then spun at high speeds initially to force the polymerisable mixture out to the edge using centrifugal force. Typical wetting speeds are 600 to 3000 rpm. Typical durations are 5 seconds to 15 minutes. The duration for optimal wetting depends on the wetting speed and on the viscosity of the polymerisable mixture.

[00196] This technique is easier to automate and does not require additional movements of the lens to be spun.

[00197] In one aspect, the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA) and wherein said process comprises a high speed spin step prior to a curing step.

[00198] The term "high speed spin step" means a step wherein a mould containing the polymerisable mixture is spun at a speed of at least 600 rpm.

[00199] In a preferred aspect, the process is a spin-casting moulding process or a free-forming moulding process. In a highly preferred aspect, the process is a spin-casting moulding process.

[00200] In one aspect, the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA) and wherein said process, comprises, in the following order, the steps of:

(i) dosing the polymerisable mixture into a mould;

(ii) spinning the mould at a speed of at least 600 rpm; and

(iii) curing the polymerisable mixture.

[00201] Preferably step (ii) is spinning the mould at a speed of from 600 to 3000rpm, preferably at a speed of from 600 to 2000rpm. In another aspect preferably step (ii) is spinning the mould at a speed from 1000 to 2000rpm, such as from 1500 to 2000rpm.

[00202] Preferably step (ii) is carried out for from 5 seconds to 15 minutes, such as from 5 seconds to 10 minutes or from 5 seconds to 5 minutes, or from 5 seconds to 3 minutes, more preferably 5 seconds to 1 minute. In another aspect preferably step (ii) is carried out for from 1 minute to 15 minutes, such as from 5 minutes to 15 minutes or from 10 minutes to 15 minutes.

Example 3

[00203] A PVC mould is dosed with 17 microlitres of hydroxypropyl methacrylate (HPMA) based monomer. The moulds are then moved to a spinning area and spun for 6 minutes at 700rpm to pre-wet the mould contact lens surface. The speed is then reduced to 400 rpm for 7 minutes to allow an equilibrium state to be reached and therefore set the shape of the contact lens. Now at that speed the lens is illuminated for 15 minutes by low intensity UV radiation to provide a cured xerogel contact lens ready for processing.

Example 4

[00204] A polystyrene mould is dosed with 17 microlitres of hydroxypropyl methacrylate (HPMA) based monomer. The moulds are then moved to a

spinning area and spun for 10 seconds at 1200rpm to pre-wet the mould contact lens surface. The speed is then reduced to 400 rpm for a further 10 seconds to allow an equilibrium state to be reached and therefore set the shape of the contact lens. Now at that speed the lens is illuminated for 40 seconds by high intensity, low wavelength UV radiation to provide a cured xerogel contact lens ready for processing.

Example 5

[00205] Using a polypropylene mould pre treated by corona discharge, the mould is dosed with 17 microlitres of hydroxypropyl methacrylate (HPMA) based monomer. The moulds are then moved to a spinning area and spun for 6 minutes at 700rpm to pre-wet the mould contact lens surface. The speed is then reduced to 400 rpm for 7 minutes to allow an equilibrium state to be reached and therefore set the shape of the contact lens. Now at that speed the lens is illuminated for 15 minutes by low intensity UV radiation to provide a cured xerogel contact lens ready for processing.

Example 6

[00206] Using a polypropylene mould pre treated by corona discharge, the mould is dosed with 17 microlitres of hydroxypropyl methacrylate (HPMA) based monomer. The moulds are then moved to a spinning area and spun for 10 seconds at 1200 rpm to pre-wet the mould contact lens surface. The speed is then reduced to 400 rpm for a further 10 seconds to allow an equilibrium state to be reached and therefore set the shape of the contact lens. Now at that speed the lens is illuminated for 40 seconds by high intensity, low wavelength UV radiation to provide a cured xerogel contact lens ready for processing.

GLYCEROL INCREASING COMPLETION

[00207] In a broad aspect the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein the polymerisable mixture comprises a diluent in an amount of less than 15% by weight of the polymerisable mixture.

[00208] In a further broad aspect the present invention provides use of a diluent for reducing the level of residual monomers present in a soft contact lens prepared by polymerisation of a polymerisable mixture comprising said diluent.

[00209] By the term "reducing the level of residual monomers" it is meant that the level of residual monomers is lower in a soft contact lens prepared by polymerisation of a polymerisable mixture comprising a diluent than in a soft contact lens prepared by polymerisation of a polymerisable mixture not comprising a diluent. Preferably the level of residuals will be reduced by at least 20%, more preferably by at least 50% and most preferably by 90% or more.

[00210] In a preferred broad aspect the present invention provides use of glycerol for reducing the level of residual monomers present in a soft contact lens prepared by polymerisation of a polymerisable mixture comprising glycerol, wherein the polymerisable mixture comprises glycerol in an amount of less than 15% by weight.

[00211] Soft contact lenses materials may be made by polymerising monomers to produce hydrophilic polymers. Typically this polymerisation reaction does not reach 100% completion and residual monomers and short chain polymeric species are left trapped in the lens matrix. It is believed that a key reason for non-completion is that the free monomer effectively plasticises the polymer as it is formed. As the polymerisation proceeds, the free monomer is consumed and is no longer available to plasticise the polymer, thus causing a rise in the effective polymer glass transition temperature. When the glass transition temperature reaches the temperature at which the polymerisation is being conducted, the mixture changes from a rubbery state to a glassy state (vitrification), at which point the diffusion of the free monomer molecules to the growing polymer chain ends is effectively stopped.

[00212] Unlike the lens polymer, these residuals, (monomers and short chain polymeric species) are not inert and can cause cytotoxic and/or sensitisation responses when contacted with the eye. Therefore it is highly desirable to reduce their incidence.

[00213] It is known in the prior art to form contact lenses from polymerisable mixtures which comprise a diluent. However, the prior art does not teach the use

of a diluent in a polymerisable mixture to increase the completion of the polymerisable reaction to reduce residual levels for the purposes of improving clinical safety, surface characteristics and mechanical properties.

[00214] By adding a diluent which may serve as a plasticizer for the polymer (e.g. glycerol) it has been found that the level of residual monomers has been greatly decreased. Residual monomers are known sensitisers and irritants which can cause clinical problems when in the eye. This problem is worsened when lenses are changed on a daily basis, as the exposure to these residuals is increased. Therefore the process of adding a diluent to the monomer greatly improves the safety of the devices and reduces the level of extraction required to render the product safe.

[00215] In one aspect the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA) and wherein the polymerisable mixture comprises a diluent.

[00216] Preferably the diluent is present in an amount of less than 15% by weight of the polymerisable mixture, more preferably in an amount of less than 10% by weight of the polymerisable mixture, such as less than 9% or less than 8%. In a highly preferred aspect, the diluent is present in an amount of 6% to 8% by weight of the polymerisable mixture, such as in an amount of about 7%.

[00217] In a preferred aspect the diluent is selected from the group consisting of glycerol, ethanol, isopropanol, ethyl lactate, N-methyl pyrrolidinone, solketal, ethylene glycol, diethylene glycol, triethylene glycol, propylene glycol, ethyl icinol, butyl icinol, diethylene glycol monomethyl ether, triethylene glycol monomethyl ether, boric acid ester, boric acid ester of glycerol, sorbitol and water.

Example 7

[00218] In the following example glycerol was added in varying amounts to a polymerisable mixture prior to polymerisation. Following polymerisation, the

level of residuals/free monomers was determined using high performance liquid chromatography.

Amount of Glycerol added to monomer mix	Level of free monomers in saline extract	Residual monomer in Xerogel
0%	1500ppm	7.1%
10%	150ppm	0.71%
20%	undetectable	0%

[00219] The level of free monomer in the saline was determined by HPLC using the sample preparation methodology given above. By knowing the volume of extractant, and the weight of monomer used to prepare the contact lens, the residual monomer present in the xerogel could be determined.

LOW WAVELENGTH RAPID CURE

[00220] In a broad aspect the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein the process comprises the step of irradiating the polymerisable mixture with low wavelength, high intensity UV light.

[00221] In this aspect preferably the polymerisable mixture comprises one or more polymerisable monomers selected from the group consisting of GMA, HPMA and MA.

[00222] Processes for the production of contact lenses typically comprise a curing stage during which polymerisable monomers in a polymerisable mixture are polymerised to form polymers. The curing stage typically involves the creation of free radicals which initiate the polymerisation reaction. Free radicals may be created by, for example, irradiating or heating the polymerisable mixture. Irradiation may be carried out using ultra-violet light.

[00223] According to this aspect of the present invention, a process for the production of a contact lens having an optimised curing stage is provided.

[00224] In one aspect the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl

methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA), wherein the process comprises the step of irradiating the polymerisable mixture with low wavelength, high intensity UV light.

[00225] The term "low wavelength" means having a wavelength of less than 400nm, such as from 250nm to 400nm. The term "high intensity" means having an intensity of more than 10mW/cm^2, such as between 10 and 1000mW/cm^2. Preferably the UV light has a wavelength of from 250nm to 400nm. Preferably the UV light has an intensity of from 10 to 1000mW/cm^2.

[00226] Preferably the UV light is collimated using a quartz lens. Preferably the UV light is collimated using a quartz lens having a focal length of from 5 to 50mm, such as from 5 to 25mm or from 5 to 15mm or from 5 to 10mm. Preferably the UV light is collimated using a quartz lens to produce a beam of light with a diameter of from 10 to 30mm, such as from 10 to 25mm or from 10 to 15mm.

[00227] Preferably the polymerisable mixture is irradiated for a period of from 10 to 1000 seconds, such as from 10 to 600 seconds or from 10 to 240 seconds or from 10 to 60 seconds.

[00228] It will be appreciated that the optimal curing time will depend on the initiator levels and the precise intensity and wavelength employed.

[00229] Use of low wavelength, high intensity UV radiation provides a number of advantages. The contact lens is typically cured in less then one minute. This allows rapid processing leading to a high capacity, low unit cost process for generating contact lenses. Furthermore the contact lens typically has low levels of residuals. The residual monomers can be controlled so that they are less than 0.5% in the resultant lens, showing a cure which has reached a high level of completions.

[00230] The low wavelength, high intensity ultra violet (UV) radiation is used to cure the contact lens. A low wavelength, high intensity light source may be used. This light source preferably produces UV light between 250nm and 400nm in wavelength at intensities between 10 and 1000mW/cm^2. In a preferred aspect the light is collimated using a quartz lens of a focal length between 5 to 50mm to produce a beam of light with a diameter between 10 and 30mm in diameter.

[00231] The light spread across the beam is Gaussian and therefore more intense in the middle and less intense to the periphery. The effect of this is helpful when controlling stresses created by such a rapid cure. The lens is cured more quickly in the centre than at the edge, allowing the shrinkage to be taken up by non-reacted material further out from the centre of the lens. This provides lenses with good optical characteristics.

[00232] Another method which may be employed is one whereby the periphery portion between 3 and 7mm from centre (these figures relate to the wet lens and will require scaling according to the swell factor of the material on hydration) is made to be the last section to finish curing. This means that shrinkage from both the centre and the edge is taken up by the periphery, hence keeping the more critical sections of the lens stress free. This may be achieved by masking or partially masking the periphery portion of the light beam for some or all of the cure duration.

[00233] Curing times range from 10 to 1000 seconds depending on the initiator levels and the precise intensity and wavelength employed.

Example 8

A co-monomer mixture of HPMA and GMA in 50/50 ratio are initiated with 0.5% 2-hydroxy-2-methyl propiophenone (HMP) and have 0.5% EGDMA cross linker. 17 microlitres are dosed into a polypropylene mould (pre treated by corona discharge) and spun at 400 rpm for 10 seconds. The monomer is then illuminated by UV light with an intensity of 120mW/cm2 for 40 seconds. The system is cured in an inert atmosphere. The resultant lens has good mechanical and optical properties and low residuals.

STEPPED INTENSITY CURE

[00234] In a broad aspect the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein the process comprises the steps of (a) irradiating the polymerisable mixture with UV light of a first intensity; and subsequently (b) irradiating the polymerisable mixture with UV light of a second intensity.

[00235] The unit costs for the production of ophthalmic devices, in particular contact lenses, have typically been low with respect to the period over which the device may be used. However, as with all products there has been a desire to reduce the unit cost. In the field of ophthalmic devices this desire has been increased by the provision of disposable contact lenses, such as monthly and daily disposable lenses.

[00236] One of the core costs in the production of polymer material such as ophthalmic devices and in particular contact lenses is the production time required for curing and the flexibility of production equipment. Typically curing apparatus is manufactured to strict tolerances and is consequently expensive. Minimising the time required to cure a polymer reduces the utilisation of the expensive apparatus and consequently reduces unit costs.

[00237] Rapid curing of monomers can result in polymers with short chain lengths, high residuals and high built in stresses. The inclusion in contact lenses of polymers having short chain lengths may lead to poor mechanical properties and such contact lenses tend to be weak and have poor elasticity. High residuals result from an incomplete polymerisation reaction and such residuals would need extracting from the contact lens to prevent them potentially causing toxic or sensitisation reactions when in the eye. Built in stresses can lead to poor surface form and therefore poor optical characteristics.

[00238] Some of these problems have been addressed in the prior art by methods which cause an uneven polymerisation reaction such that the centre of the contact lens polymerises faster than the periphery due to a greater exposure to UV light. In one prior art example, a source of UV light is shone directly down onto the back surface of the lens. The UV light is bent by a suitable lens into a rectangular line of light 0.5mm to 5mm in width, with a suitable length to completely cover the width of the contact lens. Therefore during spin casting UV light is always directed at the centre of the lens but only directed intermittently and rapidly at the periphery. This will therefore cause an uneven polymerisation reaction whereby the centre of the lens should polymerise faster due to a greater exposure to UV light.

[00239] The present invention relates in one aspect to optimised curing of a contact lens by varying the intensity of the radiation. This is referred to as a stepped intensity cure.

[00240] In one aspect the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA) and wherein the process comprises the steps of (a) irradiating the polymerisable mixture with UV light of a first intensity; and subsequently (b) irradiating the polymerisable mixture with UV light of a second intensity.

[00241] Preferably the first intensity and the second intensity are different. More preferably the first intensity is higher than the second intensity.

[00242] Preferably step (a) is carried out until the gel point is reached. Preferably step (b) is carried out until the glass point is reached.

[00243] The gel point may be determined for the polymerisation mixture by photocalorimetry, using for instance a TA Instruments Q100 Differential Scanning Calorimeter (DSC) fitted with a photocalorimetry accessory (PCA). The gel point is characterised by a sharp increase in heat output from the polymerising mixture.

[00244] The glass point can again be estimated for the polymerisation mixture by virtue of the fact that at this point, the polymerisation effectively ceases, and therefore the heat output will fall to zero.

[00245] Preferably step (b) is carried out until the polymerisation reaches at least 90% completion, preferably at least 95% completion.

[00246] In one embodiment, a high intensity burst of radiation initiates the cure to accelerate the cure to the gel point, the intensity is then dropped during gelation up to the glass point to control the stresses created as the material become a solid. In this embodiment typically the UV light is directed onto the lens at an angle on the same plane as the back/front surface of the contact lens and shone at high intensity until the polymerisation reaches the gel point. At this stage the light intensity is lowered and the cure completed.

[00247] Preferably in step (a) only a portion of the polymerisable mixture is irradiated. More preferably in step (a) only the portion of the polymerisable mixture which will correspond to the centre of the lens is irradiated.

[00248] In this embodiment a high intensity burst of radiation is directed at the central portion of the lens initially to initiate the reaction in the bulk of the material. The intensity is then lowered and applied to the whole lens. In this way the central portion of the lens cures first and the resultant shrinkage is taken up by the surrounding uncured material in the periphery of the lens. Typically a high intensity circular ray of UV light perpendicular to the back/front surface of the contact lens is directed onto the back surface of the lens such that no UV light is directed at the periphery. After a set period of time the light intensity is lowered and the circular beam of light expanded in diameter as to encompass the entire lens.

[00249] This process provides a number of advantages. A differential curing results in less stress generating by shrinkage and therefore superior optical qualities and little or no distortion. This process produces a contact lens which has good mechanical and optical properties.

STEPPED TIME CURE

[00250] In a broad aspect, the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein the process comprises, in the following order, the steps of (a) irradiating the polymerisable mixture for a period of time sufficient to provide an initial polymerisation; (b) resting for a period during which the polymerisable mixture is not irradiated; and (c) irradiating the polymerisable mixture for a period of time sufficient to provide further polymerisation.

[00251] As previously mentioned, the unit costs for the production of ophthalmic devices, in particular contact lenses, have typically been low with respect to the period over which the device may be used. However, as with all products there has been a desire to reduce the unit cost. In the field of ophthalmic devices this desire has been increased by the provision of disposable contact lenses, such as monthly and daily disposable lenses.

[00252] One of the core costs in the production of polymer material such as ophthalmic devices and in particular contact lenses is the production time required for curing and the flexibility of production equipment. Typically curing apparatus is manufactured to strict tolerances and is consequently expensive. Minimising the time required to cure a polymer reduces the utilisation of the expensive apparatus and consequently reduces unit costs.

[00253] Rapid curing of monomers can result in polymers with short chain lengths, high residuals and high built in stresses. The inclusion in contact lenses of polymers having short chain lengths may lead to poor mechanical properties and such contact lenses tend to be weak and have poor elasticity. High residuals result from an incomplete polymerisation reaction and such residuals would need extracting from the contact lens to prevent them potentially causing toxic or sensitisation reactions when in the eye. Built in stresses can lead to poor surface form and therefore poor optical characteristics.

[00254] In one aspect, the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA) and wherein the process comprises, in the following order, the steps of (a) irradiating the polymerisable mixture for a period of time sufficient to provide an initial polymerisation; (b) resting for a period during which the polymerisable mixture is not irradiated; and (c) irradiating the polymerisable mixture for a period of time sufficient to provide further polymerisation.

[00255] In one aspect the period of time sufficient to provide an initial polymerisation is from 0.01 to 30 seconds, such as from 0.01 to 25 seconds or 0.01 to 15 seconds. In one aspect the period of time sufficient to provide an initial polymerisation is from 0.01 to 10 seconds such as from 0.01 to 5 seconds or from 0.01 to 1.0 seconds.

[00256] In one aspect the period of time sufficient to provide a further polymerisation is from 0.01 to 30 seconds, such as from 0.01 to 25 seconds or 0.01 to 15 seconds. In one aspect the period of time sufficient to provide a

further polymerisation is from 1 to 30 seconds such as from 1 to 20 seconds, or from 1 to 5 seconds.

[00257] A process comprising at least the steps of curing, resting and curing will be referred to herein as stepped curing.

[00258] In one preferred aspect, the process comprises the steps of (a) (b) (c) (b) (c). In a further preferred aspect the process comprises the steps of (a) (b) (c) (b) (c) (b) (c).

[00259] One skilled in the art would understand that during step (b) the "resting period" it is not essential that the radiation has zero intensity. However, it must be substantially reduced when compared to the intensity of the source during the irradiation steps (a) and (c). In one aspect the intensity of the irradiation during step (b) is no greater than 10% of the intensity of the irradiation during step (a).

[00260] Preferably step (a) is carried out until the gel point is reached.

[00261] Preferably the polymerisable mixture is irradiated with radiation from a radiation source. The radiation source of the present invention may emit any suitable radiation for initiating polymerisation of the polymerisable mixture. Typically the radiation source will emit electro-magnetic radiation. In a preferred aspect the radiation source emits electro-magnetic radiation in the ultra-violet region.

[00262] The present invention is advantageous as it provides a process in which the polymerisation or curing of a polymerisable mixture may be improved. In particular the present invention provides a process in which the polymerisation or curing of a polymerisable mixture is performed more quickly than in the processes of the prior art. This is particularly surprising as the addition of a resting step to shorten the curing time is counter-intuitive.

[00263] Furthermore, the present invention has been found to allow the use of a given apparatus for a wider range of polymerisable mixtures as compared to the prior art and with particular polymerisable mixtures which have previously been regarded as difficult to process.

[00264] In addition the process of the present invention may provide a more complete polymerisation of the polymerisable mixture. This is of course desirable

to ensure economic use of the polymerisable mixture but also in certain application to ensure reduction or substantial elimination of residuals in the cured product.

[00265] It has been found that the process of the present invention may, in addition or in an alternative to shortening curing time, provide a contact lens having improved properties when compared to a contact lens prepared by a non-stepped curing process from the same polymerisable mixture. In particular a contact lens prepared by the stepped curing process typically has good mechanical and optical properties.

[00266] The stepped cure is achieved by curing the polymerisable mixture in time intervals. Gaps with no irradiation by UV are inserted to control the reaction rate and therefore the stresses. Typically the initial intensity burst would bring the cure up to the gel point. Following this there would be a pause to slow the reaction rate. The UV would then be reapplied in intervals to bring the lens up to the glass point. Once the glass point had been reached a final burst of UV would be applied to bring the cure as close to completion as possible.

Example 9

[00267] In this example co-monomers of HPMA and GMA are being used at a ratio 50/50. The initiator is HMP at 0.5% and the cross linker is EGDMA at 0.5%.

Time	Intensity
0.5s	120mW/cm2
0.5s	OFF
5s	120mW/cm2
2s	OFF
5s	120mW/cm2
2s	OFF
25s	120mW/cm2

DUAL CURE SYSTEM

[00268] In a broad aspect the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein the process comprises the steps of (a) irradiating the polymerisable mixture; and subsequently (b) heating the polymerisable mixture.

[00269] As previously mentioned, processes for the production of contact lenses typically comprise a curing stage during which polymerisable monomers in a polymerisable mixture are polymerised to form polymers. The curing stage typically involves the creation of free radicals which initiate the polymerisation reaction. Free radicals may be created by, for example, irradiating or heating the polymerisable mixture.

[00270] Typically the slower the rate of polymerisation the more complete the cure. A more complete cure results in a lower level of residual species which is desirable. However, in contact lenses,as in many other applications, it is preferable to have a very fast cure time with a high level of completion. Photo-initiated reactions are typically very rapid whilst heat initiated reactions can be more easily controlled.

[00271] In one aspect the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA), wherein the process comprises the steps of (a) irradiating the polymerisable mixture; and subsequently (b) heating the polymerisable mixture.

[00272] Preferably the polymerisable mixture contains a photoinitiator and/or a thermal initiator. Preferably the polymerisable mixture contains a photoinitiator and a thermal initiator.

[00273] Preferably the polymerisable mixture is irradiated with radiation from a radiation source. The radiation source of the present invention may emit any suitable radiation for initiating polymerisation of the polymerisable mixture. Typically the radiation source will emit electro-magnetic radiation. In a preferred aspect the radiation source emits electro-magnetic radiation in the ultra-violet

region. Thus, preferably in step (a) the polymerisable mixture is irradiated with UV light.

[00274] The UV source used is typically a fluorescent tube emitting light between 300 and 450nm in wavelength.

[00275] Preferably in step (a) the polymerisable mixture is irradiated with UV light having a wavelength of from 300 to 450nm such as from 300 to 400nm or from 300 to 350nm.

[00276] Preferably in step (a) the polymerisable mixture is irradiated with UV light having an intensity of less than $5mW/cm^2$, such as an intensity of less than $4mW/cm^2$, or less than $3mW/cm^2$.

[00277] Preferably in step (a) the polymerisable mixture is irradiated to provide an initial polymerisation.

[00278] Preferably in step (b) the polymerisable mixture is heated to a temperature of from 80 to 150°C, such as from 100 to 150°C, or from 120 to 150°C.

[00279] Preferably in step (b) the polymerisable mixture is heated to provide substantially complete polymerisation of the polymerisable mixture.

[00280] By the term "substantially complete polymerisation" it is meant that the percentage completion of the polymerisation reaction is greater than 95%, such as greater than 99%. The extent of polymerisation may be evaluated by measuring the level of residual monomers remaining after polymerisation. Thus the term "substantially complete polymerisation" preferably means the level of residual monomers remaining after the polymerisation is not more than 1.2% (or that there is at least 98.8% conversion of monomer to polymer).

[00281] In a preferred aspect the polymerisable mixture comprises a dual initiator system. Preferably the dual initiator system contains both a photo-initiator and a thermal-initiator. More preferably the photoinitiator is selected from the group consisting of benzoin methyl ether (BME), 2-hydroxy-2-methyl propiophenone (HMP), diethoxyacetophenone, 1-hydroxycyclohexyl phenyl ketone, 2,2-dimethoxy-2-phenylacetophenone, phenothiazine, diisopropylxanthogen disulfide, benzoin, whereas the thermal initiator is selected from the list consisting of 2,2'-azobisisobutyronitrile (AIBN), 2,2'-azobis(2-

methylpropionamidine) dihydrochloride, 1,1'-azobis(cyclohexanecarbonitrile (VAZO 88), 1,1'azobis(N,N-dimethylformamide), 4,4'-azobis(4-cyanovaleric acid), Perkadox 16 and Trogonox 141.

[00282] By use of this process a polymerisable mixture may be cured quickly and to a high level of completion.

[00283] This technique uses an initial irradiation step, typically a UV irradiation step to produce a photo-initiated reaction to harden the polymer and define its shape followed by a heating step to produce a thermally-initiated reaction to drive the polymerisation reaction closer to completion.

[00284] The UV source used is typically a fluorescent tube emitting light between 300 and 450nm in wavelength. Typically the UV levels used are up to 5mW/cm2 and the post cure temperatures are between 80 and 150°C.

Example 10

[00285] Expose monomer to 1.2 mW/cm2 of UV light for 15 minutes. Next take out hardened lenses and heat up to 120°C for 15 minutes further.

[00286] HPLC testing demonstrates a reduction of up to 50% in the residual monomers as a result of the heating step.

INFRA-RED POST CURE

[00287] In a broad aspect the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein the process comprises the steps of (a) irradiating the polymerisable mixture with UV light; and subsequently (b) irradiating the polymerisable mixture with infra-red light.

[00288] In a further broad aspect the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein the process comprises the steps of (a) performing an initial polymerisation of the polymerisable mixture; and subsequently (b) irradiating the polymerisable mixture with infra-red light.

[00289] As previously mentioned, processes for the production of contact lenses typically comprise a curing stage during which polymerisable monomers in a polymerisable mixture are polymerised to form polymers. The curing stage typically involves the creation of free radicals which initiate the polymerisation reaction. Free radicals may be created by, for example, irradiating or heating the polymerisable mixture.

[00290] As previously mentioned, in one aspect the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA) wherein the process comprises the steps of (a) irradiating the polymerisable mixture; and subsequently (b) heating the polymerisable mixture.

[00291] When heating a dry contact lens in a mould, the mould itself may act as a heat sink. In normal conditions it is desirable for both the mould and contact lens to reach a temperature in excess of 100°C. This can soften and distort the mould. Distortion of the mould is undesirable as it can lead to deformation of the contact lens.

[00292] These problems may be overcome by use of the following process.

[00293] In one aspect the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA) wherein the process comprises the steps of (a) irradiating the polymerisable mixture; and subsequently (b) heating the polymerisable mixture by irradiating the polymerisable mixture with infra-red light.

[00294] Preferably in step (a) the polymerisable mixture is irradiated with UV light.

[00295] Thus, in one aspect the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate

(GMA) wherein the process comprises the steps of (a) irradiating the polymerisable mixture with UV light; and subsequently (b) irradiating the polymerisable mixture with infra-red light.

[00296] Preferably in step (a) the polymerisable mixture is irradiated with UV light having a wavelength of from 300 to 450nm such as from 300 to 400nm or from 300 to 350nm.

[00297] The UV source used is typically a fluorescent tube emitting light between 300 and 450nm in wavelength.

[00298] Preferably in step (a) the polymerisable mixture is irradiated with UV light having an intensity of less than 5mW/cm^2, such as an intensity of less than 4mW/cm^2, or less than 3mW/cm^2.

[00299] Preferably in step (a) the polymerisable mixture is irradiated to provide an initial polymerisation.

[00300] Preferably in step (b) the polymerisable mixture is irradiated with infra-red light having a wavelength of from 700 to 1500nm, such as from 1000 to 1500nm, or from 1300 to 1500nm.

[00301] Preferably in step (b) the polymerisable mixture is irradiated with infra-red light to provide substantially complete polymerisation of the polymerisable mixture.

[00302] In a preferred embodiment, an infra red heater is used to heat the lens polymer after its initial cure under UV light. Without wishing to be bound by theory, it is believed that the heat expands and softens the network allowing movement of the molecules. This then produces a more complete cure whereby the remaining radical species can react and indeed more species can be created by thermal decomposition.

[00303] In a preferred embodiment, this technique uses an infra red heater which operates at wavelengths between 700 and 1500nm. It is believed that this infra red radiation excites and heats the lens polymer more so than the moulds, which is typically a polypropylene mould, because of the chemical structure of the lens polymer. This then allows the lens polymer to heat faster than the mould and harden off without causing distortion to the mould. This works best when the heater is positioned directly above the exposed lens surface.

UV TUBE ILLUMINATION

[00304] As previously mentioned, processes for the production of contact lenses typically comprise a curing stage during which polymerisable monomers in a polymerisable mixture are polymerised to form polymers. The curing stage typically involves the creation of free radicals which initiate the polymerisation reaction. Free radicals may be created by, for example, irradiating or heating the polymerisable mixture. Typically the polymerisable mixture is irradiated with radiation from a radiation source, for example ultra-violet radiation from a UV lamp.

[00305] UV lamps are known to require a period of time to warm up before reaching their optimal operating conditions. Minimising the time taken to carry out the process for preparation of a contact lens minimises the unit cost of the contact lens. It is therefore desirable to reduce the warm up period of UV lamps used in the curing stage of such a process.

[00306] In one aspect, the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA), wherein the process comprises the step of warming a UV lamp prior to irradiating the polymerisable mixture with UV light from said UV lamp.

[00307] Preferably the step of warming the UV lamp comprises the following steps:

(i) switching the UV fluorescent tube on quickly using a high frequency ballast (typical frequencies range from 5 – 100khz)

(ii) running the tube at 95% to 100% of its maximum operating voltage.

(iii) running the tube at about 80% of its maximum operating voltage.

[00308] Preferably step (ii) is performed for less than 2 minutes, such as less than 1 minute, such as less than 30 seconds.

[00309] Preferably step (ii) is performed until the tube warms up to operating temperature.

[00310] Following step (iii), the operating voltage is preferably modified in accordance with the following. In a preferred aspect, a UV detector is used to

create a closed loop whereby over the age of the tube the operating voltage is slowly increased to keep the output flux the same. Thus, preferably following step (iii), the operating voltage is increased in such a manner that the output flux remains substantially constant over time.

[00311] In a further preferred aspect, when the operating voltage exceeds about 90% of maximum, an alarm is set off.

[00312] Thus, in a preferred embodiment a high frequency ballast (typical frequencies range from 5 – 100khz) is used to switch the UV fluorescent tube on quickly. It is initially run at a high voltage, typically the maximum operating voltage. This is then run for a short period of time, typically up to 1 minute. This warms the tube up to operating temperature. The tube is then run at around 80% of its maximum operating voltage. A UV detector is used to create a closed loop whereby over the age of the tube the operating voltage is slowly increased to keep the output flux the same. When the operating voltage reaches an alarm state, typically 90% of maximum, the system alarms to indicate the need for a new UV tube.

CAMERA INSPECTION

[00313] In a broad aspect the present invention provides apparatus 16 (Figure 8) for inspecting a contact lens 4 in a mould 18 or the mould 18 alone (inspection of the mould can be used in free forming to predict the quality of the final lens) wherein the apparatus 16 comprises a camera 20 and a light source 22 set up such that the light passes through a circular aperture 24. This aperture may be imaged onto a CCD array and can be between 50% and 150% of the area of the imaged contact lens on that said CCD array. This embodiment preferentially highlights the edge section of the lens and optically images defects commonly seen in contact lenses such that they can be detected after processing of the image.

[00314] Contact lenses may sometimes be prepared with defects such as voids, splits, chips, surface damage or no lens. It is therefore desirable for the contact lens to be inspected and for defective contact lenses to be identified so that they can be disposed of.

[00315] In one aspect the present invention provides a process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA), wherein the contact lens is inspected.

[00316] Preferably the contact lens is inspected by use of photographic means, preferably a camera.

[00317] The term "photographic means" includes any suitable photographic imaging and/or recording means - such as a digital camera.

[00318] Preferably the contact lens is inspected in the xerogel state. Preferably the contact lens is inspected whilst still in the mould. Preferably the contact lens is inspected for defects. More preferably the contact lens is inspected for defects whilst still in the mould. More preferably the contact lens is inspected for one or more defects selected from; included contamination in the lens; contamination on the lens; edge defects; holes and no lenses whilst still in the mould.

[00319] Preferably the contact lens 4 is inspected by means of a camera 20 set up substantially as shown in Figure 8.

[00320] The lighting set up is critical to enable good inspection of the lens 4 and is arranged as follows (see Figure 8). A light source 22 is placed at least 100 mm from the lens/mould 4, 18 on the lens side. The source 22 is masked carefully using an aperture 24 to provide a disc of light which when imaged is preferentially smaller than the image of the contact lens diameter. This creates good contrast of lens defects at the edge such that light is internally refracted at the edge and reflected on a dark background. The optical system provides oblique illumination at the edge which is gives good contrast for abnormalities such as chips, splits and fractures and provides bright field illumination in the centre which gives good contrast for opaque contamination.

[00321] This lighting set up has been designed to provide best illumination for the different defects typically found in different areas on a moulded contact lens.

[00322] The lens 4 is imaged through the mould 18 using a long focal length lens with a small aperture 24 to provide good depth of focus across the sagittal depth of the lens.

[00323] Defects are processed using standard image processing tools and limits are set to provide a go/no go set up for inspecting contact lenses on a fast moving product line.

[00324] The present inspection system provides a number of advantages over the systems described in the prior art. The present system does not require the use of a diffuser to achieve defect detection but instead uses an aperture to vary the concentration of light over selected sections of the optical member examined. Furthermore the present inspection system may be used to inspect a lens in the xerogel state whilst still in the mould, which is a method more easily suited to a automated line process. Additionally the present inspection system examines and analyses the lens directly and does not require a step of subtracting a first image from a second image.

[00325] It will be understood that many, and sometimes all, of the foregoing aspects of the invention can be used in combination. All of the preferred embodiments may relate to any or all of the independently claimed processes and apparatus, taken either singly or in combination.

[00326] All publications mentioned in the above specification are herein incorporated by reference. Various modifications and variations of the described methods and system of the invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. The independent claims that follow provide statements of the invention. Although the invention has been described in connection with specific preferred embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments. Indeed, various modifications of the described modes for carrying out the invention which are obvious to those skilled in chemistry or related fields are intended to be within the scope of the following claim.

CLAIMS

1. A process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture has the principal polymerisable monomers hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA).

2. A process according to claim 1 wherein at least 75% of the hydroxypropyl methacrylate (HPMA) is the hydroxypropyl methacrylate (2-HPMA) isomer.

3. A process according to claim 1 or 2 wherein the HPMA and GMA are in a molar ratio of from 1:20 to 5:1.

4. A process according to any one of the preceding claims wherein the HPMA is present in an amount of from 5 to 80% by weight of the polymerisable monomers.

5. A process according to any one of the preceding claims wherein the HPMA is present in an amount of from 40 to 60% by weight of the polymerisable monomers.

6. A process according to any one of the preceding claims wherein the GMA is present in an amount of from 20 to 95% by weight of the polymerisable monomers.

7. A process according to any one of the preceding claims wherein the GMA is present in an amount of from 40 to 60% by weight of the polymerisable monomers.

8. A process according to any one of the preceding claims wherein the polymerisable mixture comprises an additional polymerisable monomer in an amount of less than 5% by weight of the polymerisable monomers.

9. A process according to claim 8 wherein the additional polymerisable monomer comprises acrylic acid and/or methacrylic acid.

10. A process according to claim 8 wherein the additional polymerisable monomer comprises an alkali metal salt of acrylic acid and/or methacrylic acid.

11. A process according to claim 8 or 9 wherein the additional polymerisable monomer comprises methacrylic acid.

12. A process according to claim 8 or 9 wherein the additional polymerisable monomer comprises an alkali metal salt of methacrylic acid.

13. A process according to any one of claims 1 to 7 wherein the polymerisable mixture comprises no polymerisable monomer other than the principal polymerisable monomers HPMA and GMA.

14. A process according to any one of the preceding claims wherein the polymerisable mixture comprises a diluent.

15. A process according to claim 14 wherein the diluent comprises glycerol.

16. A process according to any one of the preceding claims wherein the polymerisable mixture comprises a cross-linking agent.

17. A process according to claim 16 wherein the cross-linking agent comprises ethylene glycol dimethacrylate (EGDMA), divinyl benzene or mixtures thereof.

18. A process according to any one of the preceding claims wherein the process is a free forming moulding process.

19. A process according to any one of the preceding claims wherein the process comprises a high speed spin step prior to a curing step.

20. A process according to any one of the preceding claims wherein the process comprises three separate stages, each stage comprising the steps of dosing, spinning and curing.

21. A process according to any one of the preceding claims wherein the process comprises the step of irradiating the polymerisable mixture with low wavelength, high intensity UV light.

22. A process according to any one of the preceding claims wherein the process comprises the steps of (a) irradiating the polymerisable mixture with UV light of a first intensity; and subsequently (b) irradiating the polymerisable mixture with UV light of a second intensity, wherein the first intensity and the second intensity are different.

23. A process according to any one of the preceding claims wherein the process comprises, in the following order, the steps of (a) irradiating the polymerisable mixture for a period of time sufficient to provide an initial polymerisation; (b) resting for a period during which the polymerisable mixture is not irradiated; and (c) irradiating the polymerisable mixture for a period of time sufficient to provide further polymerisation.

24. A process according to any one of the preceding claims wherein the process comprises the steps of (a) irradiating the polymerisable mixture; and subsequently (b) heating the polymerisable mixture.

25. A process according to any one of the preceding claims wherein the process comprises the steps of (a) irradiating the polymerisable mixture with UV light; and subsequently (b) irradiating the polymerisable mixture with infra-red light.

26. A process according to any one of the preceding claims wherein the process comprises the step of warming a UV lamp prior to irradiating the polymerisable mixture with UV light from said UV lamp.

27. A process according to any one of the preceding claims wherein the contact lens is inspected for defects.

28. A process according to any one of the preceding claims wherein the contact lens is inspected for defects by use of photographic means, preferably a camera.

29. A contact lens obtainable from the process according to any one of the preceding claims.

30. A contact lens obtainable from the process according to any one of claims 1 to 28, wherein said contact lens is packaged.

31. A contact lens obtainable from the process according to any one of claims 1 to 28, wherein said contact lens is packaged in a flat package.

32. A contact lens according to any one of claims 29 to 31, wherein the contact lens has a free monomer residual of less than 2%, preferably less than 1%.

33. A contact lens according to any one of claims 29 to 32, wherein the contact lens has an elastic modulus of between 0.1MPa and 1.0MPa, preferably between 0.2MPa and 0.5MPa.

34. A contact lens according to any one of claims 29 to 33, wherein the contact lens has a tensile strength of between 0.1MPa and 1.0MPa, preferably between 0.3MPa and 0.6MPa.

35. A contact lens according to any one of claims 29 to 34 wherein the contact lens has an extensibility between 25% and 300%, preferably between 150% and 250%.

36. A contact lens according to any one of claims 29 to 35 wherein the contact lens has a wetting angle of between 2° and 45° (H_2O).

37. A contact lens according to any one of claims 29 to 36, wherein the contact lens has shrinkage/swell characteristics such that the contact lens will swell from the dry state to the fully equilibrated state with a swell factor of between 1.0 and 1.5, more preferably between 1.2 and 1.5.

38. A contact lens according to any one of claims 29 to 37, wherein the contact lens is a toric contact lens.

39. A process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said process, comprises, in the following order, the steps of:

(a) dosing the polymerisable mixture into a mould;

(b) spinning the mould at a speed of at least 600 rpm; and

(c) curing the polymerisable mixture.

40. Use of a diluent for reducing the level of residual monomers present in a soft contact lens prepared by polymerisation of a polymerisable mixture comprising said diluent

41. The use of claim 40 whrerein the diluent comprises less than 15% by weight of the polymerisable mixture.

42. The use of claim 40 wherein the diluent comprises glycerol.

43. A process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein the process comprises the step of irradiating the polymerisable mixture with low wavelength, high intensity UV light.

44. A process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein the process comprises the steps of

(a) irradiating the polymerisable mixture with UV light of a first intensity; and subsequently

(b) irradiating the polymerisable mixture with UV light of a second intensity different than the first intensity.

45. A process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein the process comprises, in the following order, the steps of

(a) irradiating the polymerisable mixture for a period of time sufficient to provide an initial polymerisation;

(b) resting for a period during which the polymerisable mixture is not irradiated; and

(c) irradiating the polymerisable mixture for a period of time sufficient to provide further polymerisation.

46. A process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein the process comprises the steps of

(a) irradiating the polymerisable mixture; and subsequently

(b) heating the polymerisable mixture.

47. A process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein the process comprises the steps of

(a) irradiating the polymerisable mixture with UV light; and subsequently

(b) irradiating the polymerisable mixture with infra-red light.

48. A process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein the process comprises the steps of

(a) performing an initial polymerisation of the polymerisable mixture; and subsequently

(b) irradiating the polymerisable mixture with infra-red light.

49. An apparatus for inspecting a contact lens in a mould wherein the apparatus comprises a camera and a light source set up such that the light passes through a circular aperture and wherein a diffuser is not used.

50. An apparatus for inspecting a contact lens mould wherein the apparatus comprises a camera and a light source set up such that the light passes through a circular aperture and wherein a diffuser is not used.

51. A process according to any one of claims 1 to 28 or 39 to 48 wherein said contact lens is an ionic contact lens.

52. A contact lens according to any one of claims 29 to 38 wherein said contact lens is an ionic contact lens.

53. An apparatus according to claim 49 wherein said contact lens is an ionic contact lens.

54. An unhydrated contact lens comprising a polymer containing an alkali metal salt of (meth)acrylic acid.

55. The contact lens of claim 54 wherein the alkali metal salt of (meth)acrylic acid comprises sodium methacrylate.

56. A hydrated, ionic contact lens capable of being produced by hydrating the unhydrated contact lens of claim 54 in a saline solution with a pH less than 7.50.

57. A contact lens of claim 56 produced by hydrating the unhydrated lens of claim 54 within a lens package designed for delivering the lens to a wearer.

58. A packaged contact lens of claim 57 wherein the package also contains a physiologically acceptable saline solution.

59. A process of preparing an unhydrated contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture includes an alkali metal salt of (meth)acrylic acid.

60. The process of claim 59 wherein the contact lens requires no exposure to a solution of pH greater than 7.50 to achieve its final water content.

61. The process of claim 59 wherein the alkali metal salt of (meth)acrylic acid comprises sodium methacrylate.

62. The process of claim 61 wherein the contact lens requires no exposure to a solution of pH greater than 7.50 to achieve its final water content.

63. The process of claim 56 wherein the contact lens may achieve its final equilibrium water content when placed in package designed for delivering the lens to a wearer.

64. The process of claim 63 wherein the package contains a physiologically acceptable saline solution.

65. A process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture comprises polymerisable monomers of

i) hydroxypropyl methacrylate (HPMA),

ii) 2,3–dihydroxypropyl methacrylate (GMA) and

iii) an alkali metal salt of (meth)acrylic acid.

66. The process of claim 65 wherein the monomers of hydroxypropyl methacrylate and 2,3–dihydroxypropyl methacrylate together comprise at lease 80% of the polymerisable monomers in the mixture.

67. The process of claim 66 wherein the monomer of alkali metal salt of (meth)acrylic acid comprises sodium methacrylate monomer.

68. A process of preparing a contact lens comprising polymerising a polymerisable mixture, wherein said polymerisable mixture comprises polymerisable monomers of hydroxypropyl methacrylate (HPMA) and 2,3–dihydroxypropyl methacrylate (GMA) and is substantially free of fluorine containing monomers.