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(54) **LENTILLE INTRAOCULAIRE SOUPLE EN UN MATERIAU ACRYLIQUE HYDROPHILE**

(54) **FLEXIBLE INTRAOCULAR LENS MADE OF HYDROPHILIC ACRYLIC MATERIAL**

(57) La présente invention a pour objets de nouvelles lentilles intraoculaires souples en un matériau acrylique hydrophile et leur procédé de préparation. Ledit matériau acrylique hydrophile qui constitue leur optique, voir leur optique et haptique, est un copolymère réticulé de méthacrylate d'hydroxyéthyle (HEMA) et de méthacrylate d'éthyle (EMA).

(57) The invention concerns novel flexible intraocular lenses made of an hydrophilic acrylic material and the method for preparing them. Said hydrophilic acrylic material which constitutes their optic part, or even their optic and haptic parts, is a cross-linked copolymer of hydroxyethyl methacrylate (HEMA) and of ethyl methacrylate (EMA).

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(54) Titre: LENTILLE INTRAOCULAIRE SOUPLE EN UN MATERIAU ACRYLIQUE HYDROPHILE

(57) Abstract

The invention concerns novel flexible intraocular lenses made of an hydrophilic acrylic material and the method for preparing them. Said hydrophilic acrylic material which constitutes their optic part, or even their optic and haptic parts, is a cross–linked copolymer of hydroxyethyl methacrylate (HEMA) and of ethyl methacrylate (EMA).

(57) Abrégé

La présente invention a pour objets de nouvelles lentilles intraoculaires souples en un matériau acrylique hydrophile et leur procédé de préparation. Ledit matériau acrylique hydrophile qui constitue leur optique, voir leur optique et haptique, est un copolymère réticulé de méthacrylate d'hydroxyéthyle (HEMA) et de méthacrylate d'éthyle (EMA).

Flexible intraocular lens made of hydrophilic acrylic material

The present invention relates to novel flexible intraocular lenses made of hydrophilic acrylic material, and to their method of preparation. Such flexible intraocular lenses made of hydrogel are foldable and can be put into place through incisions of small size (3 mm to 4 mm).

The material that is still at present in the most widespread use for manufacturing intraocular lenses (IOLs) is polymethylmethacrylate (polyMMA). The first IOLs of this material were made at the beginning of 1950s. Harold Ridley chose said material because, during the Second World War, he had observed that pieces of polyMMA canopy found in the eyes of pilots after an accident were tolerated very well, giving rise neither to inflammation nor to reaction. Over more than 40 years' use, this material (polyMMA) has demonstrated its excellent biocompatibility in satisfactory manner. As mentioned above, it continues to be the material that is the most used in this application. Nevertheless, its lack of flexibility constitutes a major drawback. Lenses made of said material are not suitable for novel surgical techniques that are less invasive than those of past years, such as phacoemulsification. The trend is to reduce the size of the incision required for extracting the natural lens, particularly for the purpose of minimizing post-operative consequences such as astigmatism as much as possible. At present, the size of the incisions made is about 3 mm. It also appears that the lens cannot be smaller in size than the diameter of the pupil at maximum aperture: which is about 4.5 mm. This makes it necessary nowadays to fold lenses in order to enable them to be inserted through small incisions. Since it is not possible to fold lenses made of polyMMA, attempts have been made for the purpose of retaining the advantages of polyMMA, to make such lenses out of said material, but that are oval in shape. Nevertheless, such lenses have not given the expected results: surgeons report a greater frequency of disturbances to vision amongst patients who have received oval IOLs. Such disturbances have been attributed to the existence of a critical diameter for an IOL, below which the retina also receives light that has been diffracted by the edges of the lens (light diffraction by the lens is caused by the fact that the diameter of the pupil can be greater than the diameter of the lens). Since it is accepted that the optical portion of an intraocular lens cannot have a diameter of less than 5 mm (which value includes a certain amount of safety margin), it is therefore necessary to fold said lens in order to be able to insert it into the capsule (via an incision of size that is

smaller than 5 mm), and it is therefore essential to make said lens out of a material that is flexible.

At present, to make flexible lenses, two large families of material are used: silicones, or more precisely polysiloxanes; and acrylic polymers. Said acrylic polymers include polymers that are hydrophilic, known as "hydrogels", and polymers that are not hydrophilic. Said hydrophilic acrylic polymers appear to present the advantage of limiting the adhesion of cells and thus the proliferation of cells. The person skilled in the art is well aware that the major complication encountered in cataract surgery is anarachic proliferation of epithelial cells, which ends up by giving rise to a secondary cataract.

As long ago as 1984, Alcon launched a first generation of intraocular lenses made of poly(hydroxyethyl methacrylate) (polyHEMA), under the trade name Iogel®. That material gave rise to mechanical problems, and the use of Iogel® implants has been abandoned.

At present, two companies on the market are selling intraocular lenses in which all or part of the lens is made of a hydrophilic acrylic material: Storz and Mentor.

Storz sells such lenses, as described in application EP—A—0 492 126, under the name Hydroview®. The material constituting the optical portion of such lenses is a copolymer of hydroxyethyl methacrylate (HEMA) and hydrohexyl methacrylate (HHMA). Said copolymer is obtained from two hydrophilic monomers: one of which is very hydrophilic (HEMA) and the other of which is much less hydrophilic (HHMA). At equilibrium, the water content of said copolymer is 18%.

Mentor has been selling such lenses under the trade name Memorylens®, and in particular as described by William J. Fishkind, MD, in Chapter 11 (pp. 197-211) of the book "Foldable intraocular lenses", published by RG Martin, JP Gilles and DR Sanders, with the Slack, Thorofare publishing house in 1993. The copolymer involved is a copolymer of hydroxyethyl methacrylate (HEMA) and methyl methacrylate (MMA). In that case, the hydrophily of hydroxyethyl methacrylate (HEMA) is reduced by the inclusion of a hydrophobic monomer (MMA). At equilibrium, the water content of said copolymer (poly(HEMA/MMA) : hydrophilic/hydrophobic) is 20%. Said lenses made out of said copolymer (poly(HEMA/MMA) cannot be folded at ambient temperature (unlike the above-described Hydroview® lenses)). The implant must initially be preheated.

In this context, the Applicant has, for its part, developed intraocular lenses made in full or in part out of a hydrophilic acrylic material. It proposes making such lenses out of an original material which gives them highly advantageous mechanical and optical properties that are "optimized". In the context of the present invention, said material has been developed while taking special account of the five parameters below:

· breaking strength: the lenses of the invention should not be damaged by the handling they receive before and during an operation;

· breaking elongation;

· "elasticity" as measured by a modulus of the Young's modulus type (mean modulus): lenses of the invention must be easy to fold while still presenting sufficient rigidity to hold properly in the eye;

· refractive index: the higher the value of the refractive index, the smaller the thickness required for the lens;

· coefficient of expansion on being hydrated: a small coefficient makes it easier to control the method of manufacturing lenses; and

· water content at equilibrium.

In conventional manner, intraocular lenses of the invention comprise both optical portions and haptics. Such an optical portion, or indeed such an optical portion plus haptic, is made out of a flexible hydrophilic acrylic material. In this respect, said intraocular lenses or implants of the invention, whether made as a single piece or as composite structures, are lenses that are flexible, foldable, and of the same type as lenses of the prior art as discussed above.

In characteristic manner, said "optimized" hydrophilic acrylic material (constituting at least the optical portion of the lens, and possibly the optical portion plus the haptic) is a cross-linked copolymer of hydroxyethyl methacrylate (HEMA) and of ethyl methacrylate (EMA).

Said hydroxyethyl methacrylate (HEMA) imparts the hydrophilic nature to lenses of the invention, together with the flexibility thereof, while said ethyl methacrylate (EMA) serves to optimize the mechanical properties thereof. It turns out that the contribution of EMA in accordance with the invention is considerably more advantageous than the contribution of MMA in accordance with the prior art. Quantitatively, said contribution must clearly remain within reasonable limits so as to avoid compromising the hydrophilic nature of the final copolymer. It is shown below that said final copolymer is generally obtained by copolymerizing the following, for 100 parts by weight of the HEMA + EMA monomers: 77.5 to

87.5 parts by weight (advantageously 80 to 85 parts by weight) HEMA and 12.5 to 22.5 parts by weight (advantageously 15 to 20 parts by weight) of EMA. In a particularly advantageous variant, the material is obtained by copolymerizing 82.5 parts by weight of HEMA and 17.5 parts by weight of EMA.

Thus, the acrylic copolymer which constitutes at least the optical portion of intraocular lenses of the invention comprises [HEMA] structural units and [EMA] structural units in the ratio R where:

$$R = \frac{[HEMA]}{[EMA]}$$

that generally lies in the range 3.0 to 6.1, advantageously in the range 3.5 to 5, and in a preferred variant, equal to 4.1.

As specified above, said poly[HEMA/EMA] copolymer is cross-linked. Such cross-linking is essential to provide the material with cohesion and stability. An effective quantity of a two-function cross-linking agent therefore needs to be used during copolymerization of the HEMA and EMA monomers. This effective quantity, generally not more than a few parts by weight, usually 0.5 to 5 parts by weight, advantageously 0.5 to 2.5 parts by weight, per 100 parts by weight of the monomers HEMA + EMA, must naturally remain reasonable. The cross-linking agent used should not constitute a comonomer giving rise to a consequent modification to the properties, and in particular the mechanical properties, of the poly(HEMA/EMA) copolymer.

In any event, the person skilled in the art is well aware that increasing the quantity of cross-linking agent reduces the water content of hydrogels and increases their vitreous transition temperature.

It is specified at this point that said cross-linking agent is generally used in a quantity such that its contribution to the structure of the copolymer is such that the following ratio:

$$R' = \frac{\text{total number of reactive functions of said cross-linking agent}}{\text{total number of reactive functions (methacrylates) of the reagents (HEMA, EMA)}}$$

lies in the range 6×10^{-3} to 60×10^{-3}. Advantageously, said ratio R' is equal to 10^{-2}.

The reactive functions of said cross-linking agent are advantageously acrylate and/or methacrylate functions. The person skilled in the art is aware of numerous cross-linking agents that carry such functions, and in particular:
butanediol dimethacrylate and diacrylate;
hexanediol dimethacrylate and diacrylate;
decanediol dimethacrylate and diacrylate;

ethylene glycol dimethacrylate (EDMA); and

tetraethylene glycol dimethacrylate.

In the context of the present invention, it is recommended in non-limiting manner, to use the above-listed cross-linking agents, and in particular to use EDMA.

Thus, the poly(HEMA/EMA) copolymer constituting the optical portion or both the optical portion and the haptic of an intraocular lens of the invention is cross-linked by cross-linking agents of this type (or of an equivalent type) and naturally traces thereof are to be found on the backbone of the copolymer.

It is generally possible to find traces of another monomer chemically bound to said backbone. The person skilled in the art is aware of the advantage of stabilizing a UV filter in the structure of an intraocular lens. Thus, in an advantageous variant, the reticulated poly(HEMA/EMA) copolymer constituting the optical portion (or indeed the optical portion and the haptic) of an intraocular lens of the invention contains an effective quantity of a UV filter that is chemically bonded (in stable manner) to its backbone. To form such a chemical bond, the compound used (which possesses a chromophore) must naturally present a suitable reactive chemical function of the double bond type, an acrylate or methacrylate function, ...

The person skilled in the art knows such compounds, and several are commercially available, in particular:

4-(2-acryloxyethoxy)-2-hydroxy benzophenone;

4-methacryloxy-2-hydroxy benzophenone (MOBP);

1,3-bis-(4-benzoyl-3-hydroxyphenoxy)-2-propyl)acrylate; and

2-(2'-methacryloxy-5'-methylphenyl)benzotriazole.

In the context of the present invention, all of these compounds are suitable, however the Applicant has made more particular use of MOBP insofar as it has been handling this UV filter for many years when making intraocular lenses out of silicone.

The concentration of the UV filtering monomer generally lies in the range 0.5 to 5 parts by weight (and advantageously 0.5 to 2 parts by weight) in the monomer mixture that gives rise to the poly(HEMA/EMA) copolymer, which is the original component for intraocular lenses of the invention (per 100 parts by weight of the monomers: HEMA + EMA).

In the paragraphs above, mention is made of <u>one</u> cross-linking agent and of <u>one</u> UV filter, insofar as the use of a single additive of each of those two types of

additive is preferable, in order to simplify the final formulation. However it is quite clear that within the context of the present invention, it is entirely possible to use a mixture of at least two additives of each of those two types, or to make use of a single additive that is suitable for performing both functions.

The cross-linked poly(HEMA/EMA) copolymer constituting at least the optical portion of an intraocular lens of the invention is advantageously obtained by copolymerizing the following monomers:

main monomer:

HEMA generally representing 77.5 to 87.5 parts by weight (advantageously 80 to 85 parts by weight); and

comonomer:

EMA generally representing 12.5 to 22.5 parts by weight (advantageously 15 to 20 parts by weight);

said main monomer plus comonomer (HEMA + EMA) constituting 100 parts by weight;

cross-linking agent such as EDMA:

used as an additive in effective quantity (generally lying in the range 0.5 to 5 parts by weight and advantageously in the range 0.5 to 2 parts by weight); and

advantageously, UV filter, such as MOBP, used as an additive in an effective quantity (generally in the range 0.5 to 5 parts by weight, and advantageously in the range 0.5 to 2 parts by weight);

the parts by weight given above for the cross-linking agent and for the UV filter being given per 100 parts by weight of the main monomer plus the comonomer: HEMA + EMA.

In a particularly preferred variant, said cross-linked copolymer is obtained using 82.5 parts by weight of HEMA and 17.5 parts by weight of EMA.

It is explained above that intraocular lenses of the invention can be in one-piece form or in composite form. In the first variant, the optical portion thereof and the haptic are therefore both made of poly(HEMA/EMA) copolymer as defined above (and generally the same copolymer, however it is not beyond the ambit of the invention for two copolymers of this type to be associated). In the second variant, only the optical portion thereof is made of such a poly(HEMA/EMA) copolymer. The haptic is made of some other material, which material must naturally be compatible with the optical portion and must not

compromise biocompatibility, flexibility, or indeed the general mechanical and optical properties of the assembly, ...

In a preferred embodiment of the second variant, an intraocular lens of the invention associates an optical portion made of said poly(HEMA/EMA) copolymer with a haptic made of polyMMA.

In a second aspect, the present invention also provides a method of preparing intraocular lenses as described above.

The said method comprises:

· preparing at least one block of cross-linked poly(HEMA/EMA) copolymer by copolymerizing a mixture of HEMA and EMA monomers in the presence of effective quantities both of a polymerization initiator and of a cross-linking agent, and advantageously in the presence of a UV filter whose chemical formula includes at least one reactive function; and

· cutting out the optical portion, or both the optical portion plus the haptic, of said intraocular lens from said copolymer block.

Said method is generally implemented in one or other of the two advantageous variants specified below.

In the first advantageous variant, a single block of copolymer of the cross-linked poly(HEMA/EMA) type is used. The intraocular lens of the invention (i.e. the optical portion plus the haptic) is cut (carved) out from said block. Said one-piece lens as cut out in this way is generally milled so as to optimize its surface state.

In the second advantageous variant, use is likewise made of a single block of cross-linked poly(HEMA/EMA) copolymer. The optical portion of an intraocular lens of the invention is made therefrom. A haptic made of a different material of some other type (e.g. polyMMA) is then fitted in conventional manner to said optical portion made of cross-linked poly(HEMA/EMA). It is also possible to prepare an intraocular lens of the invention of this type, i.e. a composite lens in which the optical portion is, in characteristic manner, made of poly(HEMA/EMA) and the haptic is made of a material of some other type, by using the technique described in European patent application EP—A—0 734 319.

Indeed, it would not be totally outside the ambit of the invention to prepare "one-piece" intraocular lenses of the invention using the above techniques for making composite lenses, starting from two different copolymer blocks, both of the cross-linked poly(HEMA/EMA) type. The optical portion of the intraocular

lens would be made from one of said blocks while the haptic is made from the other.

In general, the appropriate block of material is obtained (or the appropriate blocks of material are obtained) by copolymerizing in a mold a reaction mixture that contains, in characteristic manner, the monomers HEMA and EMA. As mentioned above, said reaction mixture also contains:

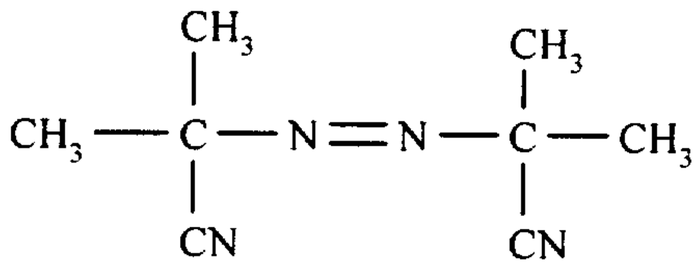
· an effective quantity of a cross-linking agent such as EDMA (generally 0.5 to 5 parts by weight and advantageously 0.5 to 2 parts by weight per 100 parts by weight of the monomers: HEMA + EMA). Said EDMA may constitute, in particular, 0.8 parts by weight. Other cross-linking agents, as mentioned above, could be used instead of said EDMA; and

· advantageously, an effective quantity of a UV filter such as MOBP (generally 0.5 to 5 parts by weight, advantageously 0.5 to 2 parts by weight, per 100 parts by weight of the monomers: HEMA + EMA). Said MOBP can be used in particular at a concentration of one part by weight. Other UV filters, as mentioned above, could be used instead of said MOBP.

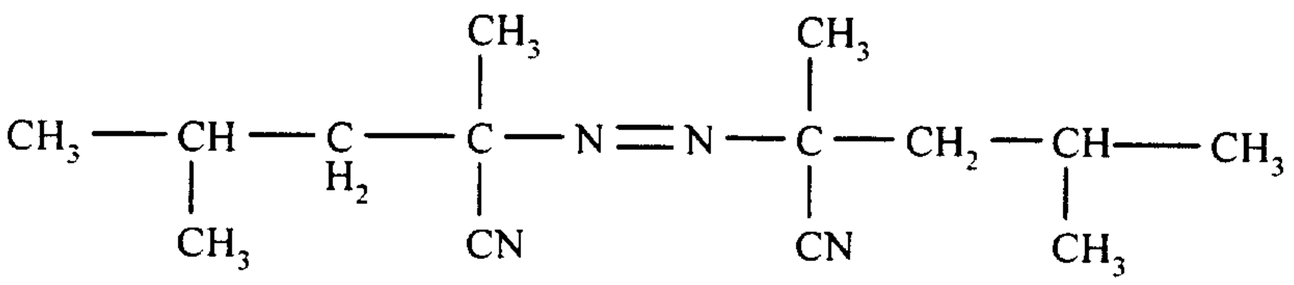
In conventional manner, said reaction mixture also contains at least one radical polymerization initiator. The person skilled in the art is well aware that for initiation purposes, the polymerization of acrylics requires a source of free radicals. In accordance with the invention, radical initiators of HEMA-EMA copolymerization can be the following in particular:

· a mixture of sodium phosphite and sodium phosphate (or any other redox pair) or

· an azo compound such as azobisisobutyronitrile (AIBN) or 2,2'-azobis (2,4-dimethylvaleronitrile) (AIVN), in particular as sold by Wako under the reference V65, having the following developed formulae:



AIBN



AIVN

The AIVN compound is particularly preferred because of its low toxicity, and because of the low toxicity of its degradation products (nevertheless, in general, it should be observed that said polymerization initiator is used in very small quantities and is generally eliminated by the end of the method of preparing intraocular lenses of the invention); and

· a peroxide, such as benzoyl peroxide.

The person skilled in the art knows how to control the quantity of said radical polymerization initiator used (generally less than 1 part per weight per 100 parts by weight of the monomers: HEMA + EMA), and in general knows how to control the polymerization kinetics of the reaction mixture. In particular, given that oxygen neutralizes the action of said polymerization initiator, it is highly preferable to eliminate oxygen from the reaction mixture before raising its temperature. It is strongly recommended to bubble an inert gas through said reaction mixture. The heating program can be optimized using the ordinary skills of the person skilled in the art.

The preferred ratios of the main reagents: the HEMA and EMA monomers, are given above in the present text.

As already mentioned above, intraocular lenses of the invention associate good optical properties with good mechanical properties. In particular, they can have breaking strengths lying in the range 3 MPa to 3.5 MPa, which is entirely comparable with the strengths of the silicone intraocular lenses sold by the Applicant.

The invention is illustrated by the following example. The advantage thereof is shown up by the results given in a "comparative study" of:

· IOL of the invention, poly(HEMA/EMA); and

· IOL of the prior art, poly(HEMA/MMA).

<u>Manufacturing an IOL of the invention</u>

82.5 grams (g) of hydroxyethyl methacrylate (HEMA), 17.5 g of ethyl methacrylate (EMA), 1 g of 4-methacryloxy-2-hydroxybenzophenone (MOBP), 0.8 g of ethylene dimethacrylate glycol (EDMA), and 0.2 g of benzoyl peroxide were poured into a beaker.

The reaction mixture was homogenized and argon was bubbled through it for 2 minutes. The solution that had had its oxygen removed in this way was then put into molds, and the molds were then subjected to:

· 48 hours in a water bath of 40°C;

· 48 hours in a water bath of 60°C; and then

· 48 hours in an oven at 100°C.

After cooling, the resulting material was unmolded. It was then rinsed, cut to size, and milled to provide an intraocular lens of the invention.

The said material had breaking strength of 3 MPa.

Manufacture of a prior art IOL

The Applicant set out to prepare an IOL whose material (poly(HEMA/MMA)) had identical breaking strength (3 MPa).

This result was obtained by implementing polymerization as described in the preceding paragraph using:

83.2 g of hydroxyethyl methacrylate (HEMA); and

16.8 g of methyl methacrylate (MMA).

Properties of said IOLs

The results obtained are given in the following table:

IOL / Properties	poly(HEMA/EMA) (invention)	poly(HEMA/MMA) (prior art)
Breaking strength (MPa)	3	3
Breaking elongation (%)	420	290
Refractive index	1.465	1.462
Mean modulus of elasticity (MPa)	0.78	0.98
Water content (%)	25.6	27.8
Coefficient of expansion (%)	10.2	12.2

These results clearly show the advantage of the invention. For equivalent (and acceptable) breaking strength, the material made using EMA is:

· more flexible;

· presents a higher refractive index (thus making it possible to make optical portions of the same power that are smaller in thickness);

· presents smaller water content and expansion coefficient; and

· presents greater elongation on breaking.

CLAIMS

1. An intraocular lens having an optical portion and a haptic, at least said optical portion, or said optical portion and said haptic, being constituted by a flexible hydrophilic acrylic material; said lens being characterized in that said flexible hydrophilic acrylic material is a cross-linked copolymer of hydroxyethyl methacrylate (HEMA) and of ethyl methacrylate (EMA).

2. The intraocular lens according to claim 1, characterized in that said cross-linked copolymer has [HEMA] structural units and [EMA] structural units in the ratio:

$$R = \frac{[HEMA]}{[EMA]}$$

said ratio R lying in the range 3.0 to 6.1, advantageously in the range 3.5 to 5, and being equal to 4.1 in a particularly preferred variant.

3. The intraocular lens according to claim 1 or 2, characterized in that said cross-linked copolymer contains an effective quantity of a UV filter bonded to its backbone.

4. The intraocular lens according to any one of claims 1 to 3, characterized in that said cross-linked copolymer is obtained by reacting the following per hundred parts of weight of the monomers: HEMA + EMA:

- 77.5 to 87.5, advantageously 80 to 85, parts by weight of HEMA; and
- 12.5 to 22.5, advantageously 15 to 20, parts by weight of EMA,

in the presence of an effective quantity of a cross-linking agent, and advantageously an effective quantity of a UV filter whose chemical formula includes at least one reactive function.

5. The intraocular lens according to claim 4, characterized in that said cross-linked copolymer is obtained by reacting 82.5 parts by weight of HEMA with 17.5 parts by weight of EMA.

6. The intraocular lens according to any one of claims 1 to 5, characterized in that its haptic is made of a hydrophilic material such as polymethyl methacrylate (polyMMA).

7. A method of preparing an intraocular lens according to any one of claims 1 to 6, characterized in that it comprises:

- preparing at least one block of cross-linked poly(HEMA/EMA) copolymer by copolymerizing a mixture of HEMA and EMA monomers in the presence of effective quantities both of a polymerization initiator and of a cross-

linking agent, and advantageously in the presence of a UV filter whose chemical formula includes at least one reactive function; and

· cutting out the optical portion or the optical portion plus the haptic of said intraocular lens from said copolymer block.

8. The method according to claim 7, characterized in that the quantities of the HEMA and EMA monomers used are as follows:

77.5 to 87.5, advantageously 80 to 85, and in particularly preferred manner 82.5 parts by weight of HEMA; and

12.5 to 22.5, advantageously 15 to 20, and in particularly preferred manner 17.5 parts by weight of EMA;

per 100 parts by weight of the mixture of monomers: HEMA + EMA.