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THE POLYVINYLPIRROLIDONE GRAFT COPOLYMERS AND SOFT CONTACT LENSES ON THEIR BASIS

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The graft polymerization of 2-hydroxyethyl methacrylate in presence of polyvinylpyrrolidone, which occurs through a stage of complex formation between the reactants, was investigated. The basic performance properties of hydrogel copolymers depending on their composition were investigated. A hydrogel polymeric material “Akrylan-LPI” for soft contact lenses was developed. Clinical testing confirmed the effectiveness of using of such lenses for vision correction as well as for eye injuries and burns treating

Keywords: polyvinylpyrrolidone, 2-hydroxyethyl methacrylate, cross-linked copolymer, hydrogel, permeability, contact lenses, eye trauma

Досліджено прищеплену полімеризацію 2-гідроксіетилметакрилату у присутності полівінілпіролідону, яка відбувається через стадію комплексоутворення між реагентами. Досліджено основні експлуатаційні властивості гідрогелів залежно від їхнього складу. Розроблено гідрогелевий полімерний матеріал “Акریان-ЛПІ” для м'яких контактних лінз. Клінічні випробування підтвердили ефективність використання таких лінз для корекції зору, а також для лікування травм і опіків ока

Ключові слова: полівінілпіролідон, 2-гідроксіетилметакрилат, рідко зшитий кополімер, гідрогель, проникність, контактні лінзи, травма ока

1. Introduction

The intensive development of polymeric chemistry and technology has resulted in wide introduction of polymers in various areas of human activity, the special interest among which represents the use of polymers in medicine [1]. At early stages of development of biomedical polymers they were only substitutes of already known materials, later – as medicines, in the production of instrumentation, stomatological instruments, and synthetic bodies of a human body (synthetic bones and joints, blood vessels, heart valves, lungs, kidneys). The basic demands to synthetic bodies are absolute harmlessness for an organism, absence of cancerogenic or allergic influence, constancy of properties in time etc. Besides depending on specificity of that or other synthetic body, the material should also meet many other specific demands.

Besides mentioned above synthetic bodies the mankind is in great need of ophthalmologic implants, treating as well as correctional contact and intraocular lenses.

2. Analysis of published data and the formulation of the problem

The contact lenses are made in two modifications – solid and soft [2]. Their well-known advantage is hyper permeability for an eye-water liquid and oxygen, the property which appreciably reduces a discomfort of lenses at use. In their turn, the soft contact lenses are made either from hydrogels, or from silicones [3, 4]. The silicone lenses have a hyper permeability for oxygen, but they moisten badly, are impenetrable for an eye-water liquid and are rather inconvenient for long using.

Investigations of the creation of contact lenses of long usage, are directed on the development of materials, which should have a necessary permeability for oxygen and eye-water liquid, as well as provide high optical and mechanical characteristics at minimum thickness and mass of a lens. For more than 35 years already the Department of Chemical Technology of Plastics Processing of the Lviv Polytechnic National University in close cooperation with Lviv Railway Hospital carries out investigations in the field of synthesis and application of medical polymers, for ophthalmology including. Basically, these investigations are directed on synthesis of new and modification of already existing polymers [5, 6]. After long approbation, polyvinylpyrrolidone (PVP) has been chosen as the base starting product. Uniqueness of its properties and application of PVP are caused by its structure and physical-chemical properties - the presence of carbamate group promotes high selective-sorption properties, complex formation with iodine and other inorganic and organic compounds, formation of and ionic form of macromolecules in an aqueous medium (Fig. 1) [7].

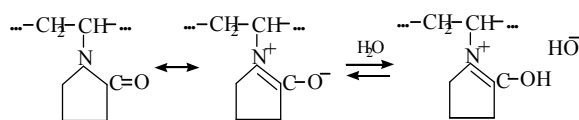


Fig. 1. Scheme of the formation of PVP macromolecules ionic forms

Besides PVP is non-toxic and biologically compatible, it is successfully applied in medicine as a substitute of a blood plasma. Alongside with the expected physiological activity and its function ability PVP positively influences the character of polymerization reaction in the synthesis of its copolymers.

The purpose of this work was to investigate regularities of graft copolymers of methacrylic esters polyvinylpyrrolidone obtaining, establish the connection between synthesis condition, structure and properties of copolymers and on this basis develop a polymer material for soft contact lenses with improved performance characteristics.

3. Materials and methods

2-Hydroxyethyl methacrylate (HEMA, Bisomer) were vacuum distilled before use, Poly(ethylene glycol) dimethacrylate (PEGDMA-13, Aldrich) purified by chromatography through a double column of Al_2O_3 , Benzoyl peroxide (BPO, 97 %, Fluka) was twice recrystallized from ethanol. Polyvinylpyrrolidone (PVP, MW=12,600, Polyvidone, Sintvita), Butanol, Cyclohexanol, Diethylen glycol, Dimethyl sulfoxide, Ethylen glycol (all – Sfera Sim) were used as received.

Hydrogel lens materials were obtained by block-polymerization of compositions that were prepared as follows: severally in 1/5 of HEMA benzoyl peroxide was dissolved; in the remaining amount of HEMA – others (cross-linking agent PEGDMA-13 and PVP). Both solutions were mixed, deaerated, poured into cylindrical polyethylene molds and polymerized.

Polymerization temperature range:

- composition heating at 50 °C for 4 h;
- temperature increase to 60 °C at speed 0,5 °C·min⁻¹;
- polymerization at 60 °C for 1 h;
- temperature increase to 78–80 °C at speed 0,5 °C·min⁻¹;
- endurance at 78–80 °C for 3 h;
- cooling in thermostat to 30...35 °C.

Structural parameters of the polymeric net in hydrated state were estimated by means of the molecular weight of macro chain section (M_n) between neighboring cross-linking nodes determined using module of high elasticity.

The molecular weight of chain section between neighboring cross-linking nodes was investigated by the procedure described in [8].

Oxygen permeability of the synthesized hydrogels was investigated by the polarographic method on changing the concentration of oxygen that penetrated through the hydrogel film with thickness of 0,5 mm. For this, a special polarographic cell was designed (Fig. 2).

The amount of oxygen that penetrated through the hydrogel was determined using a calibration graph. Compartment 1 camera with saline was purged with argon for 40 min. to remove dissolved oxygen. The completeness of removal was checked by polarographic method. Then to disoxygenated solution the equal amounts of solution saturated with oxygen were added successively and relevant polarograms were filmed.

Based on the data of the solubility of oxygen in water [9] and taking into account the initial volume of the disoxygenated solution and volume of added solution saturated with oxygen, oxygen concentration in the resulting solution was calculated. Based on these data dependency of polarographic wave height on the concentration of oxygen in solution was built.

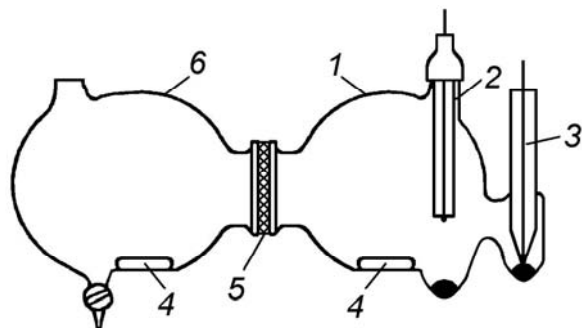


Fig. 2. Scheme of cell for hydrogel oxygen permeability investigation: 1, 6 – compartment; 2 – dripping mercury electrode; 3 – mercury electrode; 4 – magnetic stirrer; 5 – hydrogel

Study of oxygen diffusion through the hydrogel samples was carried out follows. The sample was placed between compartments 1 and 6 after which they were filled with saline and purged with argon to remove oxygen from the solution and the sample. The completeness of oxygen removal was checked by polarography. The solution was then decanted from the compartment 6, compartment was filled with saline and bubbled by air compressor for oxygenation. From that moment the countdown of experiment time began. For uniform distribution of diffused oxygen throughout the solution a magnetic stirrer was used. At regular intervals polarograms of solution were filmed. Using calibration curve oxygen concentration in the solution was found. Based on the volume of the solution and its concentration amount of diffused oxygen was calculated. Then the dependency of diffused oxygen amount on the time was built and the rate of oxygen diffusion through the

hydrogel sample was determined using Deynes-Barrer method [10]:

$$D = \frac{l^2}{6 \cdot \theta},$$

where l – sample thickness, m; θ – “delay time” (time from the experiment beginning to oxygen appearance in compartment 1), s.

Permeability of hydrogels for water and NaCl was investigated by the procedure offered by Karelin [11], optical transparency – by the standard procedure [12].

4. Results and Discussion

The synthesis of PVP copolymers develops in two directions: in the first statistical copolymers of N-vinylpyrrolidone with hydrophilic or hydrophobic monomers (as a rule, acrylic), are received; in the second – attached copolymers on the basis of PVP containing monomer compositions are received. In most cases these copolymers are rarely structured and are swelling to some extent in water and organic solvents. According to their properties, block and graft copolymers are close, but from the point of view of adaptability to manufacture polymer – monomer composition sand attached copolymers are more attractive. When using the reaction mixtures PVP – monomer for the synthesis of copolymers, positive effect of the complex formation with charge transfer (CCT) between monomer and polymeric matrix was fixed [8]. It plays a role of initiating system, efficient even in the absence of additional traditional peroxide initiators or N-compounds.

Investigations carried out at the Department of Chemical Engineering of Plastics Processing of the Lviv Polytechnic National University in the direction of the establishment of hydrogels with controlled structure and permeability, found that HEMA polymerization in the presence of PVP going through a stage of complex formation between them, which actively affect the rate of polymerization (Table 1).

Table 1

The influence of the solvent nature on complexation parameters and on the rate of polymerization (V) of HEMA-PVP composition

No	Solvent	Constant of complex formation, K_C , $\text{dm}^3 \cdot \text{mole}^{-1}$	Viscosity*, $\eta \cdot 10^3$, Pa·s	$V^{**} \cdot 10^4$, $\text{mole} \cdot \text{dm}^{-3} \cdot \text{s}^{-1}$ (at 60 °C)
1	Dimethyl sulfoxide	0	2,4	0
2	Cyclohexanol	0,06	17,6	0,6
3	Ethylen glycol	0,17	14,4	1,1
4	Diethylen glycol	0,21	22,3	1,5
5	Water	0,28	5,3	3,8

* HEMA : PVP : solvent = 9:1:10 mass. p.; ** without initiator.

The resulting HEMA-PVP complex acts as a initiating system that is highly effective even in the absence of more traditional initiators of peroxide type or nitrogen-containing compounds and is largely independent of changes of the viscosity of the reaction mixture, caused by the nature of the solvent (Table 1). In this case, the polymerization proceeds in a complex-radical matrix mechanism with formation of rarely-cross-

linked copolymers [13]. In the dry state the following (co)polymers are solids. Due to absorption of water they swell, resulting in the formation of biphasic systems consisting of chains of polymer, chemically and physically interconnected, and water that fills the free intermacromolecular space (Fig. 3), normally resulting in physical transition from glassy state of initial copolymer to highly elastic state.

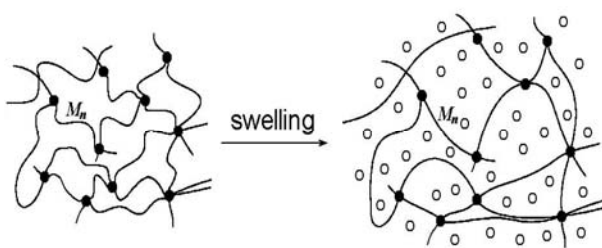


Fig. 3. Scheme of the hydrogel's swelling (● – knot stitching, ○ – water molecule)

As a result of such swelling, hydrogel becomes permeable to water and substances dissolved in it. The higher water absorption of hydrogel, the higher its permeability.

Another CCT effect in polymerization of HEMA in a composition with PVP was found out by the researches. It shows that the constant of complex formation K_C is interconnected with structural parameters of copolymer grid (Table 2).

Table 2

Dependence of PVP inoculation efficiency (f) and molecular weight of net internodal fragment (M_n) from a constant of complex formation (K_C) in the system PVP–HEMA – a dissolvent

No	$K_C, \text{dm}^3 \cdot \text{mole}^{-1}$	$M_n, \text{kg} \cdot \text{mole}^{-1}$	$f, \%$
1.	0,28	24	87
2.	0,13	34	60
3.	0,05	46	47
4.	0	64	35

Using these two revealed effects, we have developed ways of regulated synthesis of PVP copolymers with hydroxyethyl methacrylate and dimethacrylate, which are characterized by high sorption and selective diffusive properties (Table 3, 4). Thus, it is necessary to note, that owing to a sorption of a considerable quantity of water, must of them are subjected to essential morphological changes because of physical transferring from glass figurative in highly elastic condition. This makes possible for them to gain new physical properties and reach high compatibility with alive tissues of an organism.

It was mentioned, that during water sorption optical properties of copolymers change differently depending on structure. The conditions of copolymers synthesis and their compositions have been determined and they are characterized during hydration by stability of optical properties. This enables to use them as starting materials for optical correctional contact lenses. At the same time, large attention was attached to the dependence of physical-mechanical characteristics of the obtained materials on synthesis conditions and copolymers composition (Table 4).

The application of bifunctional oligomer products of a PEGDMA-13 type allows essentially increase hardness of hydrogels, however thus the elasticity of materials is reduced, that is caused by appreciable influence TGM-3 on pattern arrangement of copolymers.

The physical-mechanical characteristics of copolymers in equilibrium – swollen state can change over a wide range and the task of researchers was definition optically transparent compositions, which should provide necessary hardness and elasticity of materials. Thus the opportunity of obtaining materials with varying hardness and elasticity which are characterized by varying equilibrium water content or identical water content was found out.

It is necessary to note, that the change of the structure and composition of copolymers may considerably influence the size of refraction index n_D . This was consequently used for optimization of copolymers composition for contact lenses. It allowed to receive correctional soft contact lenses “Akrylan-LPI” with the following operational properties (Table 5).

Table 3

Properties of hydrogels

No	Composition content for hydrogel synthesis mass. p.				$K_{\text{H}_2\text{O}} \cdot 10^4, \text{m}^3 \cdot \text{m}^{-2} \cdot \text{h}^{-1}$	$K_{\text{NaCl}}, \text{mole} \cdot \text{m}^{-2} \cdot \text{h}^{-1}$	σ, MPa	$\varepsilon, \%$
	HEMA	PVP	H ₂ O	DMSO				
1	100	–	100	–	5,1	80	0,53	165
2	80	20	100	–	52,3	181	0,40	235
3	80	20	95	5	54,6	193	–	–
4	80	20	90	10	56,5	212	0,41	240
5	80	20	80	20	62,4	240	0,41	245
6*	80	20	200	–	74,2	234	0,38	245
7*	80	20	300	–	90,3	263	0,37	255
8	70	30	100	–	71,4	232	0,31	270
9	50	50	100	–	102,1	274	0,22	295

DMSO – Dimethyl sulfoxide; coefficient of light for polymers permeability of composition: 1-5, 8, 9 – 90–96 %; * – opaque polymer; $K_{\text{H}_2\text{O}}$ – water permeability; K_{NaCl} – coefficient of NaCl permeability; f – tensile strength; ε – relative elongation under rupture.

Table 4

The dependence of physical-mechanical characteristics and permeability of the hydrogels from composition content

No	Composition content for hydrogel synthesis, mass. p.			Water content, %	$K_{O_2} \cdot 10^{10}$, $m^2 \cdot s^{-1}$	σ , MPa	ε , %
	HEMA	PVP	PEGDMA-13				
1	100	–	–	39,2	0,29	0,53	160
2	100	20	–	42,3	1,13	0,32	190
2	100	40	–	44,1	1,51	0,22	240
4	100	20	5	40,9	0,45	0,15	73
5	100	20	10	40,6	0,42	0,12	61

 K_{O_2} – coefficient of oxygen permeability; σ – tensile strength; ε – relative elongation under rupture

Table 5

The characteristics of a polymeric material for soft contact lenses “Akrylan-LPI”

No	Properties in hydrated condition	Parameter meaning
1	Absorption of water, %	51
2	Oxygen permeability, $10^{10} m^2 \cdot s^{-1}$	1,2
3	Water permeability, $10^4 m^3 \cdot m^{-2} \cdot h^{-1}$	52
4	NaCl permeability, $mole \cdot m^{-2} \cdot s^{-1}$	180
5	Toughness at a stretching, MPa	0,4
6	Relative tensile elongation, %	250
7	Permeability of light, %	96
8	Refraction index n_D	1,4253

At the expense of increased oxygen permeability and high refraction index n_D of a lens differ by comfort at operation, that allows to transfer them on an eye a long time without fatigability.

Good permeability for series of substances, including medicinal solutions, compatibility with alive tissues and acceptability has caused use of the synthesized copolymers for medical ophthalmologic elements of the various forms.

5. Clinical trials of the synthesized copolymers as contact lenses “Akrylan-LPI”

The comparative clinical tests of a condition of an acuteness of vision an eye without correction and portable spectacle correction were carried out in Lviv Railway Clinical Hospital. From 163 patients having without correction an acuteness of vision less 0,1 after corrections by contact lenses an acuteness of vision has increased more than in 80 % and has made 0,85–1,0. Researches of a condition of an epithelial integument of a cornea carried out in a various line after acclimatization at all patients has shown that infringement of integrity crates membranes of an epithelium of a cornea does not occur. And only at 6 patients after long continuous application of lenses (more than 3 day) was observed mild inflammation of an epithelium.

In this, application of soft hydrophilic contact lenses in treatment of eye diseases is a new promising approach. It substitutes surgical methods in treatment of burns, prevents a symbrepharon formation, allows a late keratoplastic, improves results and decreases treatment duration with high social and economic impact.

Clinical trial batch of 460 soft contact lens material of “Akrylan-LPI” in the Laboratory of contact correction of the Filatov Institute of Eye Diseases and Tissue Therapy (Odesa) has been conducted. The comparative study on eye visual acuity, corrected with

soft contact lens material “Akrylan-LPI” lenses and contact lens from polyHEMA has been held on 180 eyes in order to evaluate the optical correction of soft contact lenses. In 69 % of patients the results of the use of soft contact lenses with “Akrylan-LPI” and elements polyHEMA contact lenses coincided, in 30 % of patients visual acuity with lenses of “Akrylan-LPI” was reported higher and only 1 % of patients visual acuity with soft contact lenses polyHEMA was observed higher by 0,1 in comparison with “Akrylan-LPI” lenses.

6. Conclusions

A performed investigation allows developing hydrogel material “Akrylan-LPI” for soft contact lenses. Such lenses excel increased oxygen, water and ion permeability that provides their effective application. Clinical testing confirmed the effectiveness of using of such lenses for vision correction as well as for eye injuries and burns treatment.

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