

## MEDICO-APPLIED CHARACTERISTICS OF SOME BICOMPONENT POLYMER SYSTEMS. SECOND COMMUNICATION. POTENTIAL DERMO- IRRITATIVE PROPERTIES OF HIGH-STRENGTH SYSTEMS

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*The potential dermo-irritative properties of bicomponent polymer systems based on a hydrophilized unsaturated polyester resin were clinically and experimentally investigated. For that purpose, forecasting tests for both irritation and allergization effect of cosmetic products and raw materials on volunteers' skin were used. Polymer compositions possessing a definite complex of properties such as low toxicity, small relative mass and high-strength parameters in combination with good appearance were considered appropriate. To this end, polymer composites which had already demonstrated in previous investigations a low toxicity after peroral and intraperitoneal introduction in animals and possessed appropriate deformation-strength behaviour as established in the present paper were selected. The analyzed polymer systems did not demonstrate any potential irritative and human-skin contact-sensibilizing properties at all.*

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**Key-words:** Bicomponent polymer systems, hydrophilized unsaturated polyester, irritation, allergization, deformation-strength characteristics

### INTRODUCTION

The elaborated polymer compositions (3, 4, 9, 10) present bicomponent systems of macromolecular networks of different compatibility degree. Materials based on them are plaster-like and have a good

appearance. That is why there exist preconditions for their application in orthopaedical and stomatological practice as probable substitutes of medical plaster.

The first and obligatory precondition for such an usage consists in their low oral and dermal toxicity. That is why the initial stage of the investigations is related with establishing this effect (5). The favourable results from the determination of the acute toxicity of polymer composites in case of oral and intraperitoneal manner of

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introduction into animals permit to continue the medical trend of studies of these materials. The performance of a comparative strength-deformation analysis of polymer system samples and of various kinds of Paris plaster used in medical practice is of substantial importance. This task is of a conjuncture character, however, its results enable the choice of competition-capable high-strength compositions, the so-called "resin plaster". For these reasons there exist scanty polymer specimens which correspond concretely to the conditions laid down and are used in clinico-experimental examinations on humans. The application of a forecasting test concerning the irritative action of cosmetic derivatives and raw materials on volunteers as well as of a forecasting test concerning the allergization effect of cosmetic preparations and raw materials on volunteers' skin presents the next cardinal stage of research in the direction looked for.

The purpose of the present work is to investigate the eventual irritative and allergizing properties of polymer compositions with proved high-strength parameters.

## MATERIAL AND METHODS

The study covers the hydrophilized unsaturated polyester resin (HUPR) (3, 9) as well as the bicomponent systems based on it either with carbamide-formaldehyde resin (CFR) (10), or with melamine-formaldehyde resin (MFR) (4), respectively, which possess the capacity to form polymer mixtures or intrapenetrating polymer networks.

In order to determine strength parameters (in case of shock and static bending), experimental Paris plaster specimens are prepared as follows: binding medical plaster (Plaster Ltd. Koshava) and super hard medical plaster (Silky Rock, Kentucky 40217, USA), along with HUPR and bicomponent polymer systems based on it (HUPR/CFR and HUPR/MFR) in different mass ratios. Samples of all materials are cast in a sheet polypropylene former according to the BSS 6737-75.

Irritative action test is performed on 10 healthy volunteers by means of single application of the complete derivatives of the systems as follows: HUPR/H<sub>2</sub>O = 75/25, HUPR/CFR = 70/30, and HUPR/MFR = 70/30 after the method of closed epicutaneous chamber tests (1, 2). Results are read on the 48<sup>th</sup> hour as both irritative activity and threshold skin-irritating concentration of polymer materials are estimated.

Sensibilization test is carried out on a total of 25 healthy volunteers' skin by using the maximizing test (6 - 8) for forecasting the contact sensibilization of the skin by raw materials and cosmetic derivatives. Finished products of polymer materials from HUPR/H<sub>2</sub>O, HUPR/CFR, and HUPR/MFR in the aforementioned ratios are used for preliminary indication. Closed epicutaneous tests are done fivefold in these cases. The finished products are also used for permitting concentration after lauryl sulphate application, respectively. Results are read on the 48<sup>th</sup> and 72<sup>nd</sup> hour.

**Table 1**  
**Strength parameters of some medical and polymer materials**

Material designation	Bending strength (in MPa)	Shock resistance (in KPA.m)
Plaster binding medical	32	1.8
Plaster superhard medical	44	3.0
HUPR/H <sub>2</sub> O = 75/25	49	2.9
HUPR/CFR = 70/30	65	2.5
HUPR/MFR = 70/30	65	2.5

## RESULTS

Table 1 indicates the results from the investigations of both shock resistance and bending strength for the medical plasters compared with that for three different plaster-like polymer compositions - the HUPR cross-linked in the presence of 25 per cent of water as well as the polymer systems of HUPR.CFR = 70:30 and HUPR.MFR = 70:30.

These results can serve, on the one hand, the establishing a definite tendency as they give a quantitative idea when comparing the examined strength parameters of medical plaster specimens with "resin plaster" ones. It is obvious that the incorporation of 25 per cent of water into the composition of HUPR does not reduce the strength properties of this resin as compared with those of the high-strength medical plaster which ratio of mixing with water after prescription instructions is of 100:22 as expressed in mass units. On the other hand, this investigation is of orientation nature in relation to the selection of appropriate polymer derivatives aiming at performing clinical experiments with them. That is why only

compositions possessing relatively high strength patterns are applied.

## DISCUSSION

Our results do not reveal any changes of the irritative parameters when these polymer systems (HUPR:H<sub>2</sub>O = 75:25, HUPR:CFR = 70:30, and HUPR:MFR = 70:30) are concerned. Absent positive results in any test areas indicate the absent potential irritative effect of the aforementioned polymer composites. No positive samples of the sensibilization test are established when a total of 25 closed epicutaneous tests for every polymer system examined are concerned.

## CONCLUSIONS

1. Based on the strength-deformation analysis of different samples it is proved that the concrete polymer compositions such as HUPR/H<sub>2</sub>O = 75/25, HUPR/CFR = 70/30, and HUPR/MFR = 70/30 possess better mechanical properties than traditionally used medical plasters.

2. Based on the results from the forecasting irritative test it can be

concluded that the aforementioned high-strength polymer systems do not exert any irritative effects on human skin.

3. Having in mind the negative results from the forecasting allergization test with

these polymer systems a conclusion can be drawn that they do not possess any human-skin contact-sensibilizing properties at all.

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### **Medizinisch-angewandte Charakteristik einiger bikomponenten Polymersysteme. Zweite Mitteilung. Potentielle hautreizende Eigenschaften der hochfesten Systeme**

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**Zusammenfassung:** Es wurden klinisch-experimentelle Untersuchungen der potentiellen hautreizenden Eigenschaften einiger bikomponenten Polymersysteme, die aufgrund eines hydrophilisierten nichtgesättigten Polyesterharzes aufgebaut worden waren, durchgeführt. Zu diesem Zweck wurden Vorhersageteste für eine hautreizende und allergisierende Einwirkung kosmetischer Produkte und Rohstoffe auf die Haut von Freiwilligen in Gebrauch genommen. Die Polymerzusammensetzungen, die eine bestimmte Konstellation von Eigenschaften (niedrige Toxizität, kleine relative Masse und hohe Festigkeitsparameter in Kombination mit gutem äusseren Aussehen) besitzten, waren dafür geeignet. Mit Rücksicht darauf wurden die Polymerkompositionen, die bei vorherigen Untersuchungen eine niedrige Toxizität bei oraler und intraperitonealer Einführungsweise in den Versuchstieren aufgewiesen hatten und dabei geeignete Deformierungsfestigkeitscharakteristiken besitzten, welche in der vorliegenden Arbeit festgestellt worden waren, ausgewählt. Die analysierten Polymersysteme

übten keine potentiellen hautreizenden und kontaktsensibilisierende Einwirkungen beim Menschen aus.

**Application médicale des caractéristiques des certains systèmes polymériques à deux composants. Deuxième communication. Effets d'irritation dermique potentiels provoqués par systèmes de haute résistance**

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**Résumé:** On a fait des expériences en clinique avec des systèmes polymériques à deux composants à la base de la résine polyester insaturée hydrophilisée afin d'analyser leurs effets potentiels d'irritation dermique. On a expérimenté sur la peau de volontaires des tests pronostiques d'effets irritant et allergène relatifs aux produits cosmétiques et aux matières premières. On a estimé nécessaire la présence de tout un complexe de propriétés des compositions polymériques appliquées, à savoir: basse toxicité, petite masse moléculaire et haute résistance en combinaison avec une bonne apparence. Dans cette optique on a sélectionné des compositions polymériques qu'on avait introduits per os et par voie intra-péritonéale chez des animaux et qui ont manifesté une basse toxicité et des caractéristiques appropriées des résistance aux déformations. Les systèmes polymériques étudiés ne font pas preuve d'effets irritants potentiels ni de sensibilisation de la peau humaine aux contacts.