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Use of Silicone Materials in Modern Structures of Highly Functional Technical Means of Rehabilitation

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Abstract. The choice of silicone materials for manufacturing of technical means of rehabilitation of high functionality has been validated. Comparison of physical mechanical properties of domestically produced high-temperature silicones with the materials produced by leading European companies has been carried out. The use of the particular brand of domestically produced high-temperature silicones is recommended according to strength and elastic properties for different groups of products. Efficiency of use of high-temperature silicones in manufacturing of components for prostheses, including bionic ones, has been specified.

Introduction

Among a wide range of new effective polymers, the second most important, after thermoplastics, in the orthopedic industry are silicone materials, which are most often used for the manufacture of individual products by vacuum modeling of the gypsum model [1, 2]. This is due to the fact that recently there have been a number of high-temperature silicones that have a set of positive properties: a wide range of hardness, fairly high deformation and strength characteristics in combination with elasticity.

In orthopedic techniques, as a rule, silicone rubbers are used, both low-temperature (liquid rubbers) and high-temperature, which as a result of vulcanization are transformed into elastic rubber-like materials.

For the functioning of prosthetic and orthopedic products to materials based on both types of silicone rubbers are strict requirements to ensure the following characteristics:

– good mechanical properties in combination with elasticity;

– excellent adhesion to human skin, which prevents damage to the skin due to piston movements during operation of the product;

– excellent opportunities for care of a product as silicones are steady against pollution, are easily cleared by water and household detergents. Due to heat resistance in the temperature range from minus 50 ºC to plus 200 ºC it is possible to clean products by boiling;

– water resistance and chemical resistance to weak solutions of acids, alkalis and salts, which provides a wide range of applications of orthopedic products in the household of a disabled person, in particular, during dirty agricultural work or in workshops;

– resistance to the environment of sweat;

– no allergic reactions;

– good compatibility between different types of silicones, which allows to provide different hardness of individual parts of the product, without losing the homogeneous structure of the material;

– manufacturability, which provides the possibility of making a stand by traditional methods for prosthetic construction [3].

Low-temperature and high-temperature silicone rubbers differ in their technological and physical-mechanical characteristics. Low-temperature silicone rubbers are liquid two-component systems (cold catalyst rubber).

High-temperature silicone rubbers are dough-like one-component or two-component materials, the vulcanization of which occurs at high temperatures. Due to their consistency, these rubbers can be easily modeled on gypsum positive.

Low-temperature silicones have much lower characteristics of deformation-strength properties and lower hardness compared to high-temperature silicones.

Table 1 shows the characteristics of silicones of different types [4].

Table 1. Characteristics of silicones of different types

Type of silicone	Shore hardness, [c.u.]	Tensile strength, [MPa]	Relative elongation, [%]	Tear resistance, [N/mm]
Low temperature silicones	0-20	1.5-4.0	350-700	1.0-4.0
High-temperature two-component silicones	20-64	5.0-16.0	900-1300	18-46
High-temperature one-component silicones	20-65	2.8-7.0	500-1200	9-16

A wide range of properties allows you to choose the right combination of brands of silicone, which would fully meet the requirements for functionality, comfort and reliability of the product [4]. So for products which in the course of operation are exposed to considerable mechanical loading (foot prostheses (Fig. 1), outer sleeves of prostheses of the upper and lower extremities (Fig. 2), cosmetic hands, orthoses of the top and lower extremities (Fig. 3)), materials with high strength, hardness and tear resistance are required. For softening elements of prosthetic and orthopedic products (orthopedic insoles, liners, individual inserts (Fig. 4) in the prosthesis of the foot and leg) require materials with low hardness, and the strength requirements are less stringent.

Today, in the world practice of prosthetics, the most widely used high-temperature silicones for the manufacture of internal (contact) sleeves of prostheses of the lower and upper extremities [5].

Fig.1. Silicone foot prosthesis

Fig. 2. Frame outer sleeve of the hip prosthesis with a silicone contact sleeve

The consumer market of silicones in Ukraine, today, is largely based on domestic one-component materials of peroxide vulcanization, namely high-temperature silicone brand Termosil (manufactured by DNDI "Elastic"), which is much cheaper than foreign counterparts. In UkrNDIprosthetics the technology of processing of this material in individual POV, including in individual internal sleeves of prostheses of the upper extremities is developed [6, 7].

Fig. 3. Silicone orthosis on the ankle joint

Fig. 4. Closed sleeve with local application of a softening layer of "Thermosil" 52-1194

Main Part

In the course of the study, the properties of vulcanizates obtained in different ways at the same temperature-time regimes (vulcanization of 10 minutes at 100 ^{0}C, thermostating for 2 hours at 145 ^{0}C) were studied in Table 2.

Table 2. Properties of vulcanizates obtained in different ways

Indicator	Method of vulcanization		
	At atmospheric pressure	Under the action of vacuum	Under pressure in the mold
Shore hardness, A, [c.u.]	40	48	49
Conditional tensile strength, [MPa]	5.4	6.7	8.6
Relative elongation at break, [%]	540	510	750
Tear resistance, [N/mm]	12.8	16,1	30
Modulus of elasticity, [MPa]	0.70	0.93	1.45

As can be seen from the table, vulcanizates obtained at atmospheric pressure and under the action of vacuum, have similar physical and mechanical properties, which are slightly lower than those of vulcanizates obtained under pressure in the mold, but, at the same time, they fully meet the requirements prosthetic construction. However, it should be noted that the samples of vulcanizates obtained at atmospheric pressure had a significant number of bubbles, the surface of the samples was uneven, hilly. Therefore, for the manufacture of prosthetic and orthopedic products, one of the main requirements of which is a complete repetition of the relief of the stump of a disabled person, this method cannot be used.

Due to the fact that vulcanization under the influence of vacuum is complicated technologically, as it requires a vacuum in the thermal cabinet, the possibility of vulcanization of the rubber mixture at atmospheric pressure with prior vacuuming at room temperature was studied. Samples of silicone rubber mixture were vacuumized for 1 hour. The samples were then placed in thermal cabinet and vulcanized at atmospheric pressure and a temperature of 100 °C. for 30 minutes. followed by temperature control at 145 °C for 2 hours. Comparative characteristics of the vulcanizates obtained by evacuation at the stage of vulcanization, and by pre-vacuum are shown in table 3.

According to the data in the table, the properties of the samples have almost the same values. Therefore, if it is impossible to provide vacuum to the thermal cabinet, the vulcanization of silicone rubber mixtures can be carried out at atmospheric pressure with preliminary vacuuming at room temperature on the forming surface.

Table 3. Comparative characteristics of vulcanizates obtained by different methods of vacuum

Indicator	Method of vacuum	
	at the stage of vulcanization	pre-vacuum
Shore hardness, A, [c.u.]	19	17
Conditional tensile strength, [MPa]	2.73	2.3
Relative elongation at break, [%]	830	800
Tear resistance, [N/mm]	8.6	7.0

Table 4 shows the properties of different brands of high-temperature silicone Thermosil.

Table 4. Physico-mechanical properties of vulcanized rubber compounds "Thermosil"

Indicator	Norms			
	Ciphers			
	52-1193	52-1194	52-1195	52-1196
Conditional tensile strength, [MPa], no less	1.1	2	3	5.0
Relative elongation at tension, [%],no less	700	650	600	600
Shore hardness, A, [c.u.]	14	25	30	35
Tear resistance, [kN/m], no less	5	12	13	21.0

Based on the requirements for the functionality and reliability of a particular product, recommendations were made for the use of Thermosil brands for certain groups of products, including internal sleeves of prostheses of the upper extremities, which are shown in table 5.

Table 5. Silicones, which are recommended for use in the manufacture of various groups of products

Product type	Brand of silicone
Internal sleeve of the upper limb prosthesis	«Thermosil» 52-1196
Ankle orthosis	«Thermosil» 52-1196
Internal thigh sleeve	«Thermosil» 52-1196
Local application to the surface of the thigh sleeve	«Thermosil» 52-1194

The developed technology of Thermosil processing in the manufacture of internal sleeves of prostheses of the upper extremities consists of the following operations:

– vacuuming the silicone sleeve blank on the positive for 1 hour;

– vulcanization in a thermal cabinet at a temperature of 100 °C for 1 hour;

– after raising the temperature in the thermal cabinet to 145 ± 5 °C, temperature control for 2 hours.

Thus, domestic high-temperature silicone meets strict requirements, as it provides:

– good mechanical properties in combination with elasticity, as shown in table 3;

– excellent adhesion to human skin, which prevents damage to the skin during operation of the product;

– excellent opportunities for product care, ease of cleaning;

– water resistance and chemical resistance to weak solutions of acids, alkalis and salts;

– resistance to the sweat and the absence of allergic reactions;

– good compatibility between different types of silicones, which allows to ensure the compatibility of individual parts of the product of different hardness (see table 4);

– due to the one-component material has a high manufacturability, which simplifies the manufacturing process and provides the opportunity to use traditional methods for processing prosthetics.

Among the disadvantages that limit the scope of domestic high-temperature silicone, it is possible to highlight the following:

– lower strength characteristics of the material compared to two-component foreign high-temperature silicones;

– impossibility to receive a thin sheet (from 0,5 to 2 mm) at processing on rollers;

– one-color coloring.

In the domestic market of polymeric materials there are also two-component high-temperature and low-temperature silicones, suppliers of which are leading, mainly European companies Wacker, Dow Corning Corporation, Streifeneder. The properties of silicone from different global companies are shown in table 6.

Table 6. Characteristics of low-temperature and high-temperature silicones

Name	Type	Shore hardness, [c.u.]	Tensile strength, [MPa]	Relative elongation, [%]	Tear resistance, [N/mm]
ELASTOSIL P7684/60 (Wacker, Germany)	Low temperature, two-component	10–12	1.48	450	3.31
CHLOROSIL 85P11 (Otto Bock, Germany)	High temperature, two-component	20	8.3	1200	28.0
CHLOROSIL 85P21 (Otto Bock, Germany)	High temperature, two-component	35	9.0	1300	35.0
SILASTIC Q7-4720 (Dow Corning Corporation)	High temperature, two-component	22	9.29	1283	32.2
EPISIL 80E11 (Streifeneder, Germany)	High temperature, two-component	24	3.82	970	18.3

According to these tables, two-component high-temperature silicones are superior to domestic Thermosil in terms of physical and mechanical properties, namely, have higher tensile strength, tensile strength and relative elongation. The disadvantages of these materials include:

– significantly higher price (approximately 10 times) compared to domestic Thermosil;

– low interlayer adhesion, which eliminates the possibility of repairing the product;

– the need for thorough mixing of components;

– dependence of the vulcanization process on temperature conditions and the presence of any impurities.

However, in the manufacture of internal (contact) sleeves for bionic prostheses requires high strength characteristics and hardness of 50-60 conventional units according to Shore A.

Such properties are possessed by two-component high-temperature silicone materials of foreign production. The brands of these materials that are present on the domestic market were mentioned above, but there is no ELASTOSIL processing technology in Ukraine. The UkrNDI of prosthetics has developed a technology for making individual silicone inserts (liners) from high-temperature silicone material CLOROSIL for high-performance prostheses of the upper extremities, including with an external energy source (bionic) (Fig. 5).

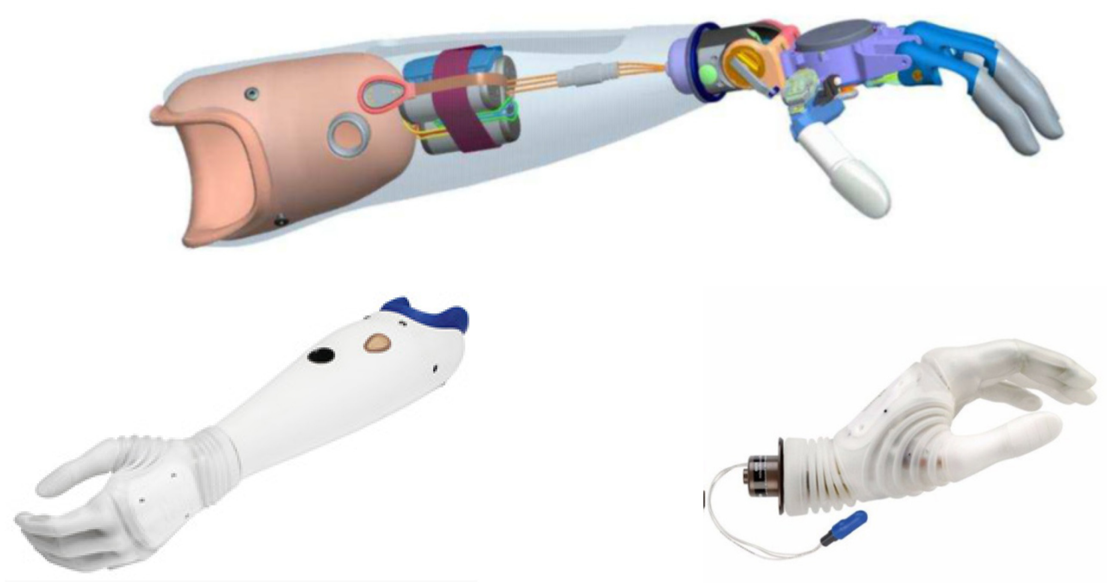

Fig. 5. Bionic prosthesis of the upper limb (prosthesis with external energy source) and integral part of the bionic prosthesis – a brush

The technology of processing CHLOROSIL in the manufacture of the inner sleeve, or individual liner (Fig. 6, 7) contains the following operations:

– evacuation of the silicone sleeve blank on the positive for 1.5 hours;

– initiation of the workpiece in the thermal cabinet at a temperature of (72-75) ^{0}C for 8 hours;

– temperature control of the workpiece in the thermal cabinet after raising the temperature to 95 ^{0}C for 2 hours,

– cooling of a sleeve in a thermal cabinet.

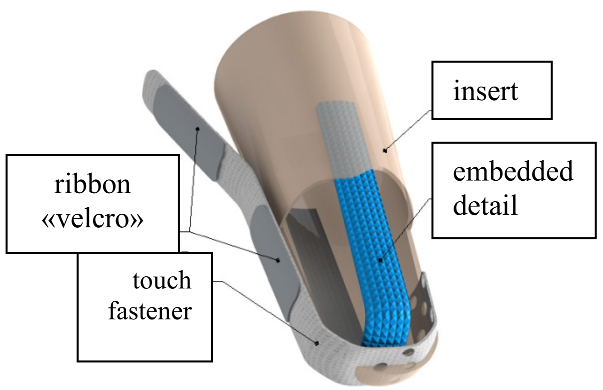

Fig. 6. Individual silicone liner with external fastening

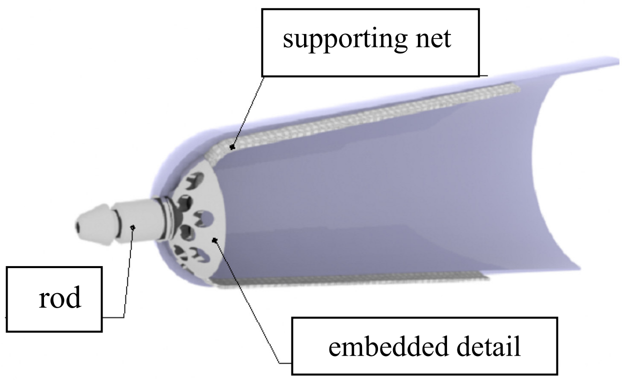

Fig. 7. Individual silicone liner with locking mechanism

Thus, in the world experience of prosthetics of patients with defects of the upper extremities, in almost all complex clinical cases, foreign specialists use silicone compositions with different properties:

– from elastic soft silicone of small thickness that allows to roll an individual liner on a stump and to stick reliably with a leather cover;

– from elastic harder silicone that allows to make an internal contact sleeve of container type with gentle properties for stump fabrics.

At the same time they integrate into a material of sleeves and inserts of a fastener (Fig. 8), connecting elements (Fig. 9), functional parts of control systems, etc.

Fig.7. Prosthesis after isolation in the elbow joint

Fig. 8. Prosthesis after isolation in the shoulder joint

Summary

As a result of the work, based on the requirements for functionality and reliability of a particular product, the principle of choosing the type of silicone for certain groups of products was formulated:

1. Inserts (orthopedic insoles). These products in the course of operation are exposed mainly to normal (vertically directed) loading that allows to use materials with low indicators of tensile strength. But the necessary requirement is softness and elasticity, because one of the functions of inserts is to reduce the specific load and redistribution of the load on the plantar surface of the foot by dosing the load in the subdural part and local unloading of painful areas. To meet these requirements can be used materials with Shore hardness A (10-15) c.u. – for the insole, (20-25) c.u. – for the supinator and (5-10) c.u. for local unloading of painful areas of the foot, namely – low-temperature liquid silicones.

2. For the manufacture of internal sleeves of individual prostheses of the lower extremities are more acceptable high-temperature silicones with Shore hardness A (15-45) c.u., tensile strength (2.5-5.0) MPa and tear resistance of at least 10 N / mm, both one-component (Thermosil) and two-component, which, if necessary, can be combined with inserts of low-temperature silicones with a Shore hardness A (5-10) c.u. for softening or Shore hardness A (30-50) c.u. to ensure the discharge of the painful place of the stump or bony protrusion. But, as mentioned above, the developed technology of Thermosil processing is simpler and cheaper than foreign high-temperature two-component silicones.

3. The inner sleeves in the prostheses of the upper extremities are designed to hold the outer (bearing) sleeve on the stump of the upper limb. Since the inner sleeve must hold this sleeve, and prevent the rotational movement of the prosthesis on the stump, the material from which it is made, must be sufficiently rigid and strong. These requirements are met by high-temperature silicones with Shore hardness A (45-70) c.u., tensile strength of not less than 6.0 MPa and tear resistance of not less than 15 N / mm [2–4]. And it is these requirements that CLOROSIL meets, the processing technology of which in the manufacture of internal sleeves of high-performance bionic prostheses of the upper extremities was developed by UkrNDIprosthetics.

Thus, in accordance with the global trends described above, one of the most relevant areas of applied chemistry today is the development of technological solutions for the use of elastic high-temperature silicones in the manufacture of high-performance rehabilitation equipment, such as bionic prostheses (external energy prostheses). and lower extremities.

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