

Silicone Rubber Used for Lower Limb Prostheses

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Abstract. The liner is one of the most important part of the lower limb prostheses, whose role is to maintain the contact between the residual limb and the socket. Taking into account the residual limb has a variable volume, we have analysed the closed-cell prototype of the liner made of silicon rubber RTV-2. The mechanical properties of this material could provide the requirements imposed for the lower limb prostheses. Meantime it is innocuous for the human body, especially for skin contact and could be used for medical devices manufacturing.

1 Introduction

Nowadays over 1.6 million individuals demand limb prosthesis only in the United States and over the world this number could be increased in few years. There are multiple causes such as injuries and vascular diseases caused by cardiovascular dysfunction. The limb prostheses are the only solution for rehabilitation of amputees, so that there are many concerns in improving their functionality.

The lower limb prostheses have to be made up of three main parts (Fig. 1): 1 - the liner surrounding the remaining part of the limb; 2 - the subassembly for the liner protection; 3 – subassembly for reducing the friction; 4 – flexible socket; 5 – mechanical system for securing the socket.

The socket has to be designed for each patient due to: the volume variation of the residual lower limb during the day and night; long term volume variation caused by the increasing of patient weight for instance; the shape of surgical operation. All of them depend on the patient weight and his physical activities, taking into account that generally speaking they were active persons. Meantime the socket with the liner have to distribute the stress between the prosthetic limb and the bony skeleton during the physical activities when some loads are acting, so that the tissue has not been affected by this auxiliary new lower limb.

The suspension system of the prosthesis could provide all the necessary conditions for the movement of patient in safe conditions, and it has to assure the avoidance of all the

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mechanical and physical parameters for excessive movements such as translation and rotation in all working planes. The suspension system has two main subassemblies: the liner and the lock system. The liners made of silicone are widely used for fixing the socket on the residual limb. For the lock system there are many technical solutions such as magnetic system, internal pin/lock system and some other systems working at very low pressure. The latter are called suction by hypobaric seals. For all these solutions there are some conditions for designing: first of all the safety for the patient, comfort, functionality of all the components, durability, external shape for good looking and the lower price [2].

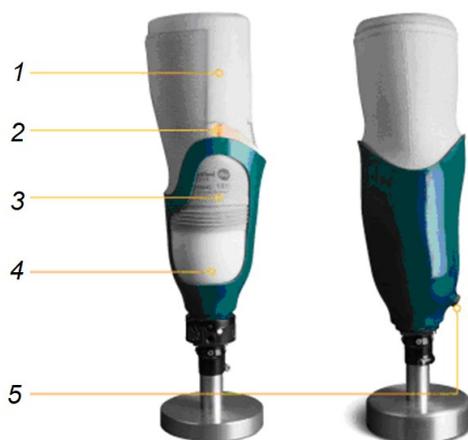


Fig. 1. The main components of lower limb prosthesis [1].

The pressure is acting over the liner that is placed inside the socket in order to maintain the contact between the residual limb and the prostheses. The pressure value has to be very well controlled, and it should act uniformly around the entire surface.

From the designing point of view, the stress has to be distributed along two directions: pressure perpendicular to the skin and shear stress tangential to the skin. The technical solutions for assuring the contact between the socket and the tissue should not exceed 60 mm Hg for pressure otherwise some occlusions of blood flow could appear. If the shear stress is applied with friction on the surface contact could appear some blisters and epidermal abrasions. So, it is recommended to be applied a shear stress over a bigger surface without slip. This kind of shear stress is called tangential stress.

Another important aspect is the way this stress is acting on the skin. Some medical statistics provided the recommendations such as the shear stress should be applied intermittently, not continuously. If there are frictional loads, it is better to apply low level of forces for a long time. There are several clinical researchers who investigated the critical values of pressure during the wear of prosthesis when some external loads influenced it. [3].

The liner lateral external surface is an interface made of closed-cell made of polyethylene, urethane or silicone-based material. The liners made of Pelite or Plastezote are silicon-based materials and there are mouldable materials, so that there are easily 3D printed, but the disadvantage of losing their initial shape should be taken into account. Elastomeric liners, such as urethane, silicone elastomers and silicone gels are employed recently [3].

The paper aims to present a solution for the liner material in order to improve the pressure values acting on the skin of the patient. The liner is made of a number of closed-cells equally distributed around the residual limb and the material the cells are made of is the silicone rubber Zhermack. The properties of this new material could provide the requirements imposed for lower limb prosthesis.

2 The new prototype for the cell of the liner

In order to provide the pressure control around the lateral surface of the liner, it has been proposed the solution of using the closed-cell made of Zhermack and inside of each cell is acting the controlled value of pneumatic pressure. This new material is a silicone elastomer made as a combination of linear polymers, reinforcing agent, cross linker and a catalyst, so the mechanical properties are improved. As the processing temperature is the room temperature this type of silicone rubber is called Room Temperature Vulcanization (RTV). Because it has two component of silicone it is called RTV-2.

The parts made of this material ensure long term durability and reliability even though they are working in a wide range temperature variation, humidity and UV. Another capability is the high elongation before the breaking point and the products will be highly durable [4]. Moreover, it is innocuous for the human body, especially for skin contact, so that there are some medical devices which have used it until now. There are some products for skin care made of this type of rubber and they could be kept a long period of time in contact with the skin. Comparing the RTV-2 with Polyurethane we have to mention the capability of fire resistance too as another requirement for medical using.

If there are some dilatation during the working stage of this silicon rubber, the stress will not be created, so that it is essential for our purpose where the stress is the most important factor. Due to its mechanical properties, especially the low external surface tension, very complex shapes could be mould by using the 3D printers.

We have moulded the closed cells made of RTV-2, as they are presented below. The first one has the theoretical shape presented in Fig. 2 nearby its mould box.

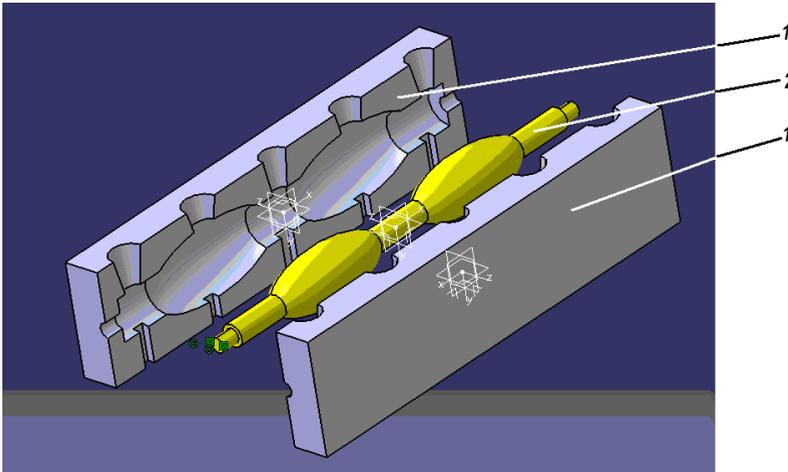


Fig. 2. The mould box and the mould casting (1 – moulding box; 2 – moulding core).

After the process of molding, the final part, as we have to use for the liner external surface, is presented in Fig. 3.

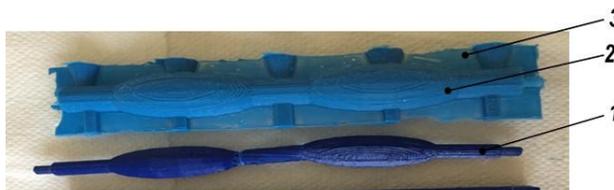


Fig. 3. The moulded castings for the closed cell (1- moulding core; 2 – moulded part; 3 – moulding pipe).

As we may observe, the shape of this cell has two working sections: the first section is cylindrical with the diameter of 15 mm, and the second section is elliptical with the two semi axes denoted $a = 7.5$ mm and $b = 12.5$ mm. The thickness of the wall is $t = 2$ mm.

During the working process of the liner inside the lower limb prostheses, the pressure enters at first in the cylindrical cavity and during the second stage it is working inside the elliptical cavity.

3 Results and discussions

The goal of this research stage is to analyse the properties of this material when the pressure is acting. The paper [5] presents the variation of modulus of elasticity as function of hardness degrees (Fig. 4) and the value of Poisson ratio $\nu = 0.497$ [6].

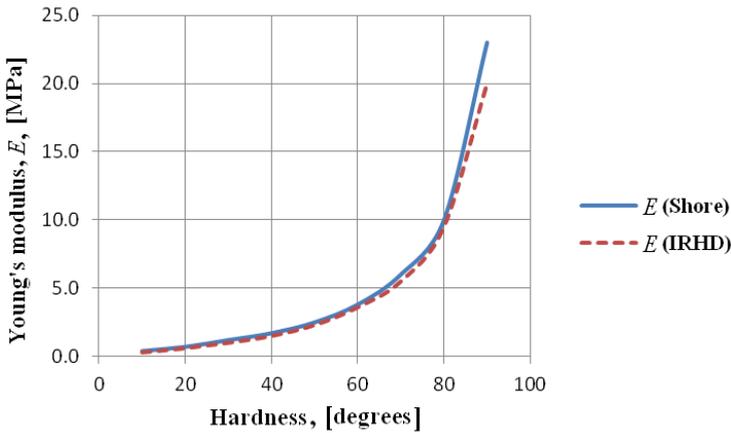


Fig. 4. The variation of Young’s modulus vs. the elastomer hardness degree.

Based on equation presented in [7] we have computed the normal stress on the cell surface and the strains. We have denoted: σ_1 – meridional membrane stress acting parallel to the meridian; σ_2 – membrane stress acting parallel to the circumference; q – internal pressure; s – stretch. The consequence of these stresses, there will be meridional and circumferential strains leading to axial and radial deflections and changes in meridional slope. We have considered toroidal shells with simple closed-form solutions with a limited range of parameters, which could be analysed with numerical solutions. The following equations were used for corrugated tube under internal pression $q = 0.97066e+05$ [N/m²]:

$$S = 2.45(1 - \nu^2)^{1/3} \cdot \left(\frac{a}{t}\right)^{4/3} \cdot \left(\frac{b}{t}\right)^{1/3} \cdot \frac{b \cdot q}{E} \tag{1}$$

$$(\sigma_2)_{\max} = 0.955 \cdot q \cdot (1 - \nu^2)^{1/6} \cdot \left(\frac{a \cdot b}{t^2}\right)^{2/3} \tag{2}$$

The computed results are:

$$S = 1.3773 \text{ [mm]}$$

$$(\sigma_2)_{\max} = 9,82 \text{e} + 07 [\text{N/m}^2]$$

where: E – modulus of elasticity (Young’s modulus) ; ν – Poisson’s ratio. The other notations have been explained before. The value computed for $(\sigma_2)_{\max}$ is in the range of required values for the liner as part of lower limb prosthesis.

From the obtained results we may infer that the material used for the closed cells of the liner has the imposed mechanical properties affording its working at the optimum pressure values. Moreover this material is suitable for the medical devices for skin direct contact for a medium period of time.

4 Conclusions

The paper presents a solution for using the closed cells that are made of silicon rubber RTV-2, for the liners of the lower limb prostheses. The mechanical properties required for this prostheses type could be provided by the material we have used. This material ensures long term durability and reliability, even though it is used in a wide range of temperature values. It is innocuous for the human body and could be in contact with the skin for a long time. We have molded the cell prototype as molded cast-ing and we have analyzed the values for circumferential stress and strain. Finally, the obtained results prove the capability of using this material for our goal.

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References

1. <https://www.ortho-europe.com/product/one-transtibial-system/>
2. H.Gholizadehh, A.Osman, A.Eshraghi, S.Ali, N.Arifin, *Biomed. Eng. Online*, **13**, 1(2014)
3. J. Sanders, *Stump-socket interface conditions*, in: *Bader, D.L., Bouten, C., V., Colin, D., Oomens, C., W.*, (Pressure Ulcer Research, Springer 2005)
4. <https://www.silicones.elkem.com>
5. D.O. Fediuc, M.Budescu, V.Fediuc, V.M.Venghiac, *Bulet. Inst. Politehnic Gh. Asachi Iasi*, **LIX** (LXIII), Fasc. 2 (2013)
6. A.Woolf, P.Descamps, *ASTM Special Tech. Pub.*, **1422**, pp. 132 – 142 (2002)
7. W.Young, R.D.Budynas, *Roark’s Formulas for Stress and Strain* (McGraw-Hill Ed., 2002)