Development of human gingiva phantom material for minimally invasive robotic-assisted surgery

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Abstract. The article describes the technological process of manufacturing the material for the phantom of human gingiva for subsequent use as a part of a prototype of a robotic system for laser maxillofacial surgery. The prototype of the experimental setup is presented, which allows automating the process of manufacturing the material for this phantom. A preliminary comparison of cuts on the phantom material of gingiva with the biological material of a pig gingiva was made. It has been experimentally proven that the material is well suited for creating gingiva phantoms with complex geometric surface shapes in ways similar to the molding of plastics into silicone molds.

1. Introduction

Nowadays, in medicine, the tasks of improving the quality of surgical operations [1, 2], reducing the time of operations, as well as helping a surgeon to perform them, are becoming increasingly important. One of the ways to solve these tasks is to use robots for surgical operations. In this case, performing the following tasks becomes possible: rigid fixation of the medical instrument in the required position, its precise positioning and movement along the trajectory set by a surgeon. In addition, the use of robots can significantly improve the quality of operations, by minimizing the influence of "human factor". In surgical practice, there is a large number of operations in which a robot can be used to assist a surgeon. Therefore, due to the rapid development of robotics at present, the topic of robotics in surgery is relevant.

However, the robotization of any operation requires preliminary studies, the approbation of the operating modes of the medical robotic system, software debugging, etc. [3] In this regard, medical phantoms are necessary, which would imitate certain properties of a human body with sufficient credibility when performing a surgical operation. The practice of phantom use in medicine existed long before the advent of robots and the beginning of their use in surgery. However, the specificity of the use of robots in medicine often requires the use of qualitatively new phantoms for testing certain aspects of an operation. In some cases, the development of such phantoms may be comparable in complexity to the process of robotization of a medical operation.

2. Methods and materials

During the course of the development of the prototype of the robotic maxillofacial surgery system [4] with a laser instrument, the authors of this article faced the task of searching for a suitable material for making a human gingiva phantom. The following characteristics set the main requirements for the phantom material in this system:

- the material should have mechanical characteristics similar to biological tissue (primarily
hardness;
- the material should have a close to the biological tissue absorption coefficient of electromagnetic radiation in the wavelength ranges, determined by the type of laser medical equipment used.

From the analysis of existing articles and patents, it is possible to conclude, that today the following materials are used to imitate human gingiva as a phantom material:
- curable liquid rubber [5];
- silicone rubber [6].

These phantom materials suitably model the mechanical characteristics of biological tissues, especially hardness and elasticity. However, their interaction properties with electromagnetic radiation do not allow fully using these materials when developing medical operations using surgical laser equipment. In particular, experimentally, the authors found, that the absorption coefficient of electromagnetic radiation of these materials at a wavelength corresponding to diode lasers (980-1400nm) common in maxillofacial surgery for these materials is not sufficient to form a stable cut as the laser moves along the required trajectory. Therefore, these materials can not adequately simulate the effect of laser radiation on biological tissues.

3. Implementation

The following substances were selected as components based on a series of preliminary experiments:
- hydrolyzed animal protein (gelatin);
- albumin;
- thickener (carboxymethylcellulose) binding solvent (water);
- food coloring (E122);
- preservative (propionic acid).

According to the results of experiments conducted by the authors, the specified set of components allows developing a material that satisfactorily simulates the interaction of laser radiation with biological tissue of the gingiva.

The main chromophore of the proposed composition for the wavelength range from 980-1400nm (diode lasers) is hydrolyzed animal protein, which also gives the material mechanical properties similar to biological tissue. Food dye azorubine (E122) gives the composition a color that is visually similar to a human gingiva. Propionic acid inhibits the development of microorganisms and prolongs the life of the finished composition. Water provides the connection of all components of the solution to each other, and also serves as a secondary chromophore (a substance that absorbs electromagnetic radiation).

It has been experimentally established, that in order to successfully model the interaction of laser radiation with the biological tissue, the mass fraction of hydrolyzed animal protein in the composition should be in the range of 15-25%. At a concentration of less than 15%, the resulting composition is excessively soft, and at a concentration of more than 25%, it is excessively hard. The concentration of preservative and dye in the composition does not exceed 2-3% of the total mass and, as practice has shown, does not have a significant impact on its mechanical and optical properties.

After the final selection of components, one proceeds to the stage of selection of the technological process of connecting the starting components. In the case of artificial gingiva material, the process is reduced to dissolving all components of the composition in water inside an environment isolated from external influences at a temperature of 35-50 °C and continuous mixing of the starting components. The preparation time of the composition is 40-60 minutes. The foundry properties of the composition are maintained for 5-10 minutes after readiness. The curing time of castings from the composition depends on the temperature of the external medium and averages 1.5-2 hours.

The main difficulty arising in the preparation of the composition is the dissolution of gelatin (all other components have a high solubility in water). The solubility of gelatin under normal conditions is significantly lower than the required concentration in the finished solution, which requires an increase in the temperature of the solution during preparation as the concentration of gelatin increases. Powdered gelatin also consists of several fractions differing in molecular weight and granule size. The lower weight fraction has better solubility in water, while the coarse fraction tends to form lumps in solution.
These difficulties in dissolving the components of the composition can be solved if a special installation is used for preparing the composition, which implements the following main functions:

- regulation and control of the heating temperature of the composition;
- ability to set the frequency of rotation of the mixer;
- collection and recording of all the main parameters of the material manufacturing process (temperature, humidity, pressure, stirrer speed).

The prototype of the installation that implements the above functions is presented in Figure 1. It consists of a sealed vessel (1), in which the process of mixing and dissolving the components, the heating element (2), the signal processing unit (3) and the operator’s computer (4) take place.

On the upper part of the hermetic vessel (1), there is a drive of the mixer (5) and a filling hole (6) through which the primary components are fed into the vessel. The prototype of the installation also provides the possibility of pumping air out of the vessel through the hose (7), which reduces the number of gas bubbles in the finished composition and positively affects its mechanical properties.

The signal processing unit in the prototype installation is based on the Atmega controller.

![Figure 1. Prototype of the experimental setup, which allows producing the material of gingiva phantom](image)

The pressure and relative humidity sensors are located on the lid of the vessel (1). The signals from these sensors are transmitted to the controller via the I2C interface.

The thermistor with a linear characteristic, located at the bottom of the vessel (1), is used as the composition temperature sensor. The voltage signal from the resistor outputs is digitized using an external multi-channel ADC.

To integrate the installation with the operator computer (4), special software was developed that allows connecting to the Arduino Uno R3 board via USB and cycle through a predetermined period to poll all sensor settings, as well as controlling the rotation speed of the mixer and the operation of the vacuum pump. In the developed application, it is possible to record all indications in a separate text file in the form of a protocol.

Figure 2a shows a general view of a jaw phantom with an insert made from the developed material. A commercial jaw model was used as a base for the phantom, and a gingiva phantom served as a model for creating the soft insert from the developed material.
Creating a soft insert for a jaw phantom took place in two stages. At the first stage, a mold was created from a polymer compound, which reflected the geometry of the initial gingiva phantom. Then, the developed material was poured into the mold. After curing, the obtained insert was transferred to the basis. The resulting casting mold was used to cast artificial gingiva from the developed material (figure 2, b).

The experiments have shown that the developed material has a satisfactory fluidity in the hot state, which allows using forms with complex geometry and producing phantoms for various surgical operations.

4. Results
The qualitative comparison of the material of artificial gingiva and biological tissue according to visual criteria showed the suitability of the following material: 76% water; 15% gelatin; 7% dry protein (albumin) and 2% carboxymethylcellulose.

In the quantitative determination of the compliance of the selected material of the phantom with the gingiva of a pig, two tests of the material of the phantom and two tests of the gingiva of a pig were conducted:

a) Stability test for producing holes in the phantom material (immersion depth of the tip of the optical waveguide is the same on all holes).
b) Test to obtain holes from different depths of immersion on the phantom material.
c) Stability test for making holes in biological tissue (the depth of the tip of an optical waveguide is the same for all holes).
d) Test to obtain holes from the depth of immersion on biological tissue.

Figure 2. Jaw phantom with developed artificial gingiva material

Figure 3. Test cuts made on various materials of a phantom as well as on the biological tissue of a pig
The exposure time of the laser radiation is the same in all experiments on all holes. Tables 1 and 2 show the diameters of the static effects of laser radiation.

**Table 1. Average diameter of the holes and the variation for the stability test**

| Sample   | Average diameter of craters | Scatter of diameter values |
|----------|-----------------------------|---------------------------|
| Material №1 | 1.1 mm                     | ±0.07 mm                  |
| Material №2 | 0.71 mm                   | ±0.065 mm                 |
| Pig's gingiva | 0.47 mm               | ±0.06 mm                  |

**Table 2. Average diameter of craters and the spread for the test over the entire range of immersion values**

| Sample   | Average diameter of craters | Scatter of diameter values |
|----------|-----------------------------|---------------------------|
| Material №1 | 1.14 mm                   | ±0.135 mm                 |
| Material №2 | 0.69 mm                 | ±0.065 mm                 |
| Pig's gingiva | 0.48 mm              | ±0.04 mm                  |

5. Conclusion
The above experimental results show that the developed material of a gingiva phantom is an acceptable analog of biological tissue when studying the effects of laser radiation on it. The presented prototype of the installation for the automated manufacturing of the gingiva phantom material allows obtaining acceptable repeatability of its main characteristics.

6. Acknowledgments
This work was supported by the Ministry of Science and Higher Education of the Russian Federation as part of State Assignment no. 9.3408.2017/4.6. This work was carried out using equipment provided by the Center of Collective Use of MSTU "STANKIN".

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