ENSURING HIGH-PRECISION TESTING OF IMPLANTS IN THE REGULATION OF INTRA-EYE PRESSURE

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Abstract: Among the diseases that lead to partial or complete loss of visual function is glaucoma, which is characterized by increased intraocular pressure (IOP) due to changes in the structures of the eye and the human body, which inevitably leads to blindness. According to the WHO in 2020. more than 5 million people suffer from vision loss in glaucoma, which accounts for 13.5% of all cases of blindness in the world. Today this figure in Ukraine reaches more than 200 thousand patients. Visual problems significantly reduce the level of information perception and cause a pathological condition with progressive death of ganglion cell axons, which causes a decrease and complete loss of the visual field. Known methods of glaucoma treatment use drug therapy, laser therapy and surgical implantation of drainage devices. It was found that the main cause of the disease is a decrease in the speed of movement and outflow of intraocular fluid through the trabecular system of the eye, due to a significant increase in pressure. The optimal rate of fluid formation is normally 2-2.5 μl / min., Ie during the day through this natural system of the patient should be released in a controlled manner and about 3 ml. It is obvious that the implantation of drainage devices in glaucoma is performed after previous unsuccessful treatment procedures and is the last chance to preserve the patient's vision, provided that the rate of fluid leakage is successfully regulated. Therefore, there is often a need for preoperative individual selection of implants with the necessary parameters.

Keywords: glaucoma, intraocular fluid, intraocular pressure measurement, implant, automation of blood pressure control process, working range of intraocular pressure (IOP).

1. Introduction

Among the known surgical methods of glaucoma treatment is the implantation of drainage devices of various designs and types. Currently, the Ahmed valve system is widely used in Ukraine [1-3], which provides for the removal of intraocular fluid from the anterior chamber of the eye in glaucoma and the creation of sufficient fluid reserve in the eye chamber space for gradual resorption and evacuation through existing ducts. Known such devices and methods of verification of preoperative testing of drainage valves are described and presented in the form of separate patents and protocols [3,4]. The valve drainage system, which is simplified, is a silicone membrane, which opens at the outlet of the device with increasing pressure, and then closes. The main disadvantages of such a system were identified, namely - the lack of individual selection of parameters and regulation of fluid excretion, which as a result after some time of use took place and there were complications for the patient after surgery. The aim of the work was to create a prototype of the implant testing system for individual selection and regulation of the parameters of intraocular fluid excretion at the predicted rate for a patient with glaucoma.

2. Synthesis and construction of a prototype system for individual selection of implants

To achieve this goal, the authors analyzed the existing methods and identified shortcomings and proposed on the basis of elements of microsystem technology to create a functional diagram and prototype of an automated system for measuring and controlling the required parameters of implants. This approach provides: simplification of the technical solution of the scheme with the possibility of automating the process of preoperative examination of implants of known systems Ahmed, Krupin and other structures; to increase the sensitivity and accuracy of measurement and objectivity in determining the individual parameters of implants; determine their individual suitability for use in medical and surgical practice on the parameters of fluid removal, namely the minimum pressure of the valve opening, closing and reproducibility characteristics with the probable re-inclusion, which will increase the efficiency of operations; will reduce the time of inspection of the implant with the ability to save information about its parameters, their deviation. Therefore, the synthesis of the required scheme with a reasonable range of parameters was performed. Figure 2 shows the developed functional diagram of the prototype of the automated testing system of Ahmed implants to verify their individual characteristics, taking into account the compatibility and adaptation of the patient for optimal regulation of intraocular pressure within the required limits [4].

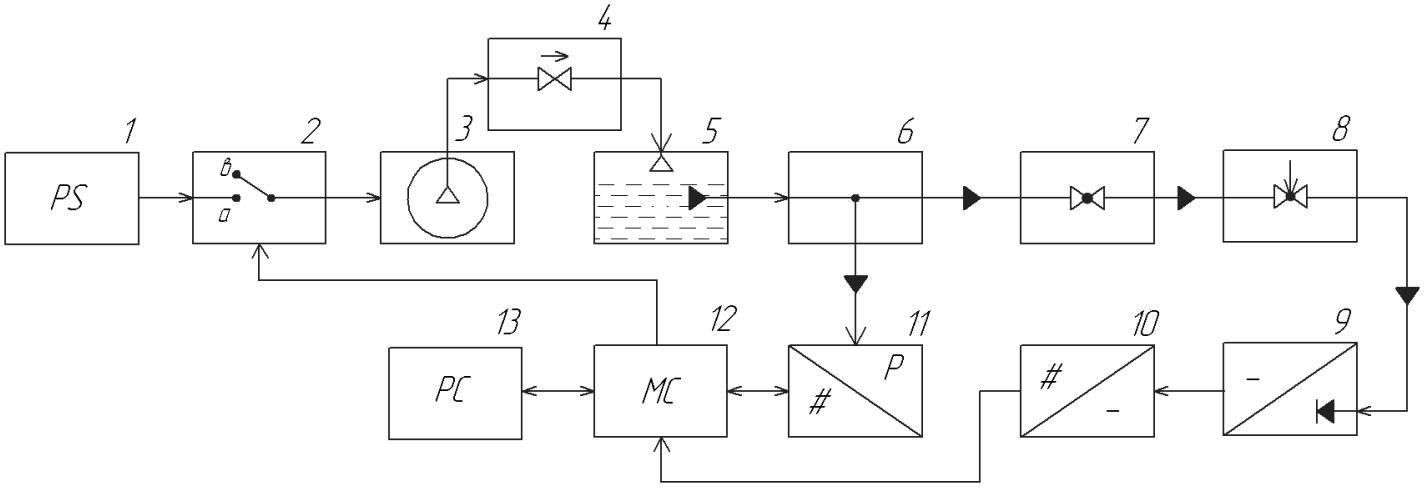

Fig. 2 Functional scheme of the implant testing system for the regulation of intraocular pressure.

The proposed testing system includes: power supply 1, electronic key 2, miniature compressor 3, connected through a check valve 4 to a tank filled with saline 5, inlet manifold 6, with electromechanical pressure gauges 11 connected to it, final data transfer with the implant 8. To the output of the implant is connected a liquid detector 9 and an ADC 10, which is connected to the input of the microcontroller 12. The first output, which is connected to the input of the computer 13, and the other from the input of the electronic control key 2.

The presented system of testing implants works as follows. First, the implant was connected to the cannula, which was connected to the multiple overlap of the supply of saline 7. In computers 13 includes the mode of checking the implant, the microcontroller 12 through the electronic key 2, the compressor 3 to increase the pressure in the tank 5 by means of the pre-valve 4 air does not go to the compressor from the tank. The pressure in the system gradually increases and is continuously monitored by its value by microelectromechanical pressure gauges 11, the pressure level continues to be read by the microcontroller and recorded in the computer memory taking into account the graphical pressure. The pressure in the system is close from zero to the value of the implant being tested. During the time of simplification of the implant for its upbringing meets the fluid that flows to the fluid detector 9, then the pressure level of the opening of the implant is fixed. The signal of the detector 9 through the ADC 10 is transmitted in digital form and fed to the microcontroller 11, which by means of an electronic key 2 stops the compressor 3 to turn off the supply voltage. The value of the pressure, its dynamics changes and opens and closes the microcontroller 11 is fixed and remembers the parameters of the computer 3. Due to the open valve the pressure in the system gradually decreases, the dynamics changes throughout the time controlled by microelectromechanical measuring pressures 11 and is introduced into the computer. 'ютер. When the valve is closed, the pressure is set at constant levels, which means the closing of the electromechanical pressure gauge 6, which is transmitted to the microcontroller 11 and entered into the computer. Using the software, the computer plots the pressure of this implant and determines the operating pressure range in which it can operate. The pressure in the system is monitored until the initial discharge of the fluid in which the fluid sensor is registered is implanted. At the time of passage of fluid through the implant system, the pressure level is determined, when it begins to enter the fluid during the test mode, after the detector of the fluid system registers the parameters of implant opening, and after achieving results or need to stop its supply. Opening the valves gradually reduces the pressure level in the system until they are completely closed. Thus, the sensitivity of the systems to the establishment of the necessary parameters, including the rate of fluid introduction, increases. All results are recorded in the computer's memory in graphical form or figures of all achieved pressure parameters, which is then used for documentation.

To ensure the modes of operation of the prototype systems, a product database was selected. The microcontroller uses the ATmega8L-8PU chip, which controls the SPS-15RF-172KP stepper motor using the Texas Instruments DRV8825 motor driver. The redundancy function uses a dispenser. Important elements of the system are the pressure gauge, which requires the required accuracy - microelectromechanical pressure gauge ST Microelecronics LPS33HW and microcontroller ST Microelecronics STM32F103RET6 uses its function. The microcontroller uses meters to access the SPI interface and communicates with the computer. The pressure measurement when using the basic elementary base is 0.075 mm Hg. Art. or 0.25% at the maximum determination of the pressure in the tanks. As a liquid detector used a resistive liquid detector WAVGAT MH RD with the size of the sensor part of 4 cm x 5 cm, with an ADC based on the comparator LM393, where the supply voltage is 5 V, the response speed of the comparator is 1.3 μs. The conversion characteristic for the analog output of such a sensor is a discrete function of the presence of liquid on the sensor plastic detector with a view:

$$\begin{cases} y = 0, \; npu - w = 0 \\ y = 1, \; npu - w \neq 0 \end{cases}$$

0 or 1 is generated at the digital output, in the absence or presence of fluid in the system, and the sensitivity is adjusted by changing the operating modes during debugging.

3. The methods of processing

For testing it was necessary to create an algorithm of the system, the block diagram of which is presented in Figure 3. Algorithm of the testing system which shows the sequential steps starting from the start and subsequent actions in the system of implant testing [4].

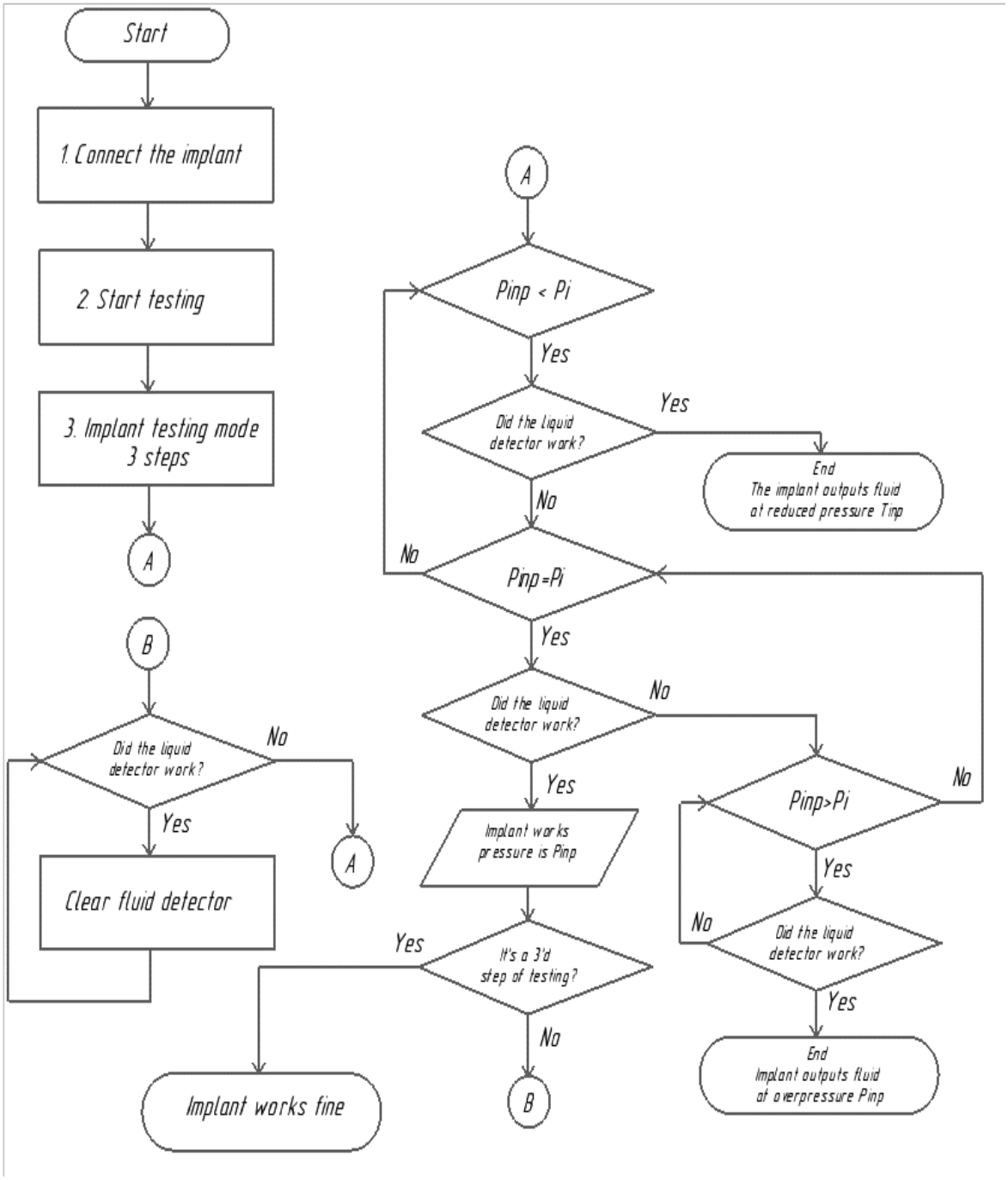

Fig. 3 Algorithm of the implant testing system for the regulation of intraocular pressure.

The quality of the implant testing system is ensured depending on the quality and rigidity achieved by the manufacturer, which affects different removal rates, when the pressure in the system changes before the removal of fluid by the implant, it is registered by the fluid sensor. As fluid passes through the implant, the system determines the pressure level at which the implant begins to drain fluid. After the fluid detector is activated, the system registers the implant opening pressure and stops fluid delivery at certain points.

In the process of testing, the parameters and conditions are checked, which are very important for further quality assurance of implants and three possible variants of the obtained result. Figure 4 shows the graphs of the pressure parameters for several instances of implants of different hardness, denoted by the symbols a, b and c.

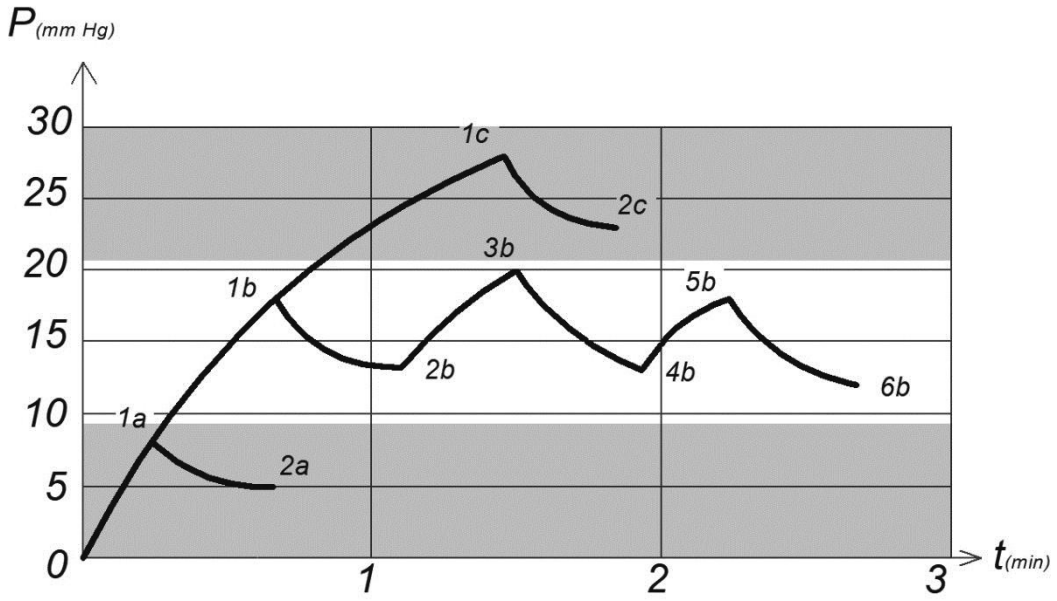

Fig.4. Graph of pressure change during tests of implants of different modification: a, c - conditionally defective, b - serviceable implant

The first implant a (pictured) has a reduced degree of hardness and is characterized by a pressure change of 8 mm Hg. Art. (valve opening point 1a) up to 5 mm Hg. Art. (closing point 2a). The test cycle of such an implant can last up to 1-2 minutes. Activation of the fluid detector at this stage is a sign of implant failure with the risk of hypotension after surgery, so such drainage is not suitable for use.

The second implant, denoted by the symbol b has a higher hardness, and therefore for its opening occurs at a higher pressure level also increases the test time. The change in the pressure parameters of the second implant points 1b and 2b are within the norm of 18–13 mm Hg. Art. Activation of the fluid sensor indicates that the implant operates within the normalized intraocular pressure range of 9–21 mm Hg. Art. After determining the implant that meets the regulatory requirements, the reproducibility of the parameters is checked by repeatedly increasing the pressure. To do this, the operator removes the fluid from the indicator plate of the detector and turns on the system again, until the operation of the fluid detector, which again fixes the moment of reopening of the implant at point 3b. The signal from the detector stops the compressor, after which the pressure of the open valve decreases and stabilizes at point 4b. This step is then repeated (points 5b and 6b). In the case of reproducibility of the characteristic due to three tests, the drainage is recognized as high quality and can be used for its intended purpose.

The third implant c is characterized by high rigidity and a change in operating pressure in the range of 28–23 mm Hg. Art. at points 1c and 2c, which exceeds the set range of intraocular pressure. Activation of the liquid detector due to a certain pressure indicates a malfunction of the implant.

The proposed version of the prototype system allowed for a short time (several minutes) to conduct a preoperative examination of Ahmed Glaucoma Vision implants to determine individual compatibility and controlled removal of intraocular fluid for a particular patient. It has the feature of ensuring the success of the operation and preserves the vision of patients with glaucoma for a long time due to the individual selection of implants with the necessary parameters of intraocular fluid excretion.

4. Conclusion

In this publication, the authors propose a method and tools that improve the known technical solutions for the construction of schemes with the possibility of automating the process for preoperative examination of implants of different types. A functional diagram of a prototype of the automated system for testing Ahmed implants has been developed to verify their individual characteristics, taking into account compatibility and adaptation of the patient for optimal regulation of intraocular pressure. An algorithm of the testing system was created and a prototype was built on which the software was tested and the automated testing system was tested, which allows to increase the sensitivity, measurement accuracy and objectivity of determining the parameters of implants; determination of their individual suitability for the patient with use in medical surgical practice on parameters of removal of liquid, namely pressure of opening, closing and reproducibility of the characteristic at repeated operation that will promote increase of efficiency of the carried out operations; reduction of time of check and selection of an implant. It is possible to save information about the fixed parameters and the final results of the inspection of implants of different types.

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