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ПРИЛАДИ І СИСТЕМИ БІОМЕДИЧНИХ ТЕХНОЛОГІЙ

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AUTOMATED TESTING SYSTEM FOR IMPLANTS TO REGULATE INTRAOCULAR PRESSURE

[1)]Oleksiy Yanenko, [2)]Andriy Tkachuk, [2)]Roman Tkachuk
[1)]National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute", Kyiv, Ukraine
[2)]Ternopil Ivan Pul'uj National Technical University, Ternopil, Ukraine
E-mail: op291@meta.ua

Purpose of work. *The implantation of drainage devices in glaucoma is usually performed after previous unsuccessful treatments and is the patient's last chance to save his vision. The article describes the device that allows automating the process of a preoperative check-up of implants of different types used for intraocular fluid withdrawal in case of glaucoma. This device will help increase the success of the operation and help preserve the vision of the patients with glaucoma due to the pre-test of the implants for serviceability and intraocular fluid withdrawal parameters.*

Methodology. *To realize the goal, the authors developed a functional scheme of the automated system for measuring and controlling the parameters of the intraocular pressure regulation implants based on the microsystem technology elements.*

The results. *Depending on the implant's material and hardness, there are three possible cases in which the implant opens earlier, and there is a risk of hypotension to the patient's eye. Later, there is a risk of hypertension, and the implant works in the normal pressure zone. The authors provide testing graphs of three implants of varying levels of hardness and a graph of the reproducibility of the characteristics of the non-faulty implant.*

Scientific innovation. *The method of testing implant parameters by way of hardware overpressure creation with the possibility of automated control parameters of preoperative testing the implants is proposed*

Practical significance. *The developed automated system for preoperative testing of implants, which provides: simplification of the scheme with the simultaneous possibility of automating the process of preoperative testing of implants of different types; allow getting an increase of sensitivity, measurement accuracy, and objectivity of implant parameters determination; determination of their suitability for use in the medical-surgical practice by the parameters of fluid withdrawal, exactly opening pressure, closing pressure and reproducibility of the characteristics during the repeated operation, which will contribute to the efficiency of the performed operations; reducing the time of implant check, which is limited by 2-3 minutes, and the possibility to save information about the parameters both in electronic (computer) and paper forms.*

Keywords: *glaucoma; intraocular pressure; implant; pressure measurements; testing; process automation; microsystems engineering.*

Introduction

Glaucoma is one of the most severe diseases in ophthalmology and often leads to loss of vision and is the second most frequently occurring disease [1]. The leading cause of glaucoma is uncontrolled changes in the passage of intraocular fluid through the trabecular network; in the case of pathology, this leads to an increase in intraocular pressure (IOP) and eye nerve damage. During this disease, an essential means of preserving the patient's vision is to control IOPs to take timely IOP normalization measures. Such control can be performed on an outpatient basis (one-time) or using an implanted microchip, e.g., 1.2-2.4 mm in size with regular IOP information transmission at 914 MHz or 2.2 GHz [2, 3]. However, it should be noted that the use of the microchip is currently in the process of experimental research approbation but is not widespread.

The last, most effective method of IOP normalization is the implantation of drainage devices (valves), which is usually performed after previous unsuccessful treatments and is the patient's last chance to save his vision. Installation of the valve is carried out in the process of a complex surgical operation.

The last, most effective method of IOP normalization is the implantation of drainage devices (valves), which is usually performed after previous unsuccessful treatments and is the patient's last chance to save his vision. Installation of the valve is carried out in the process of a complex surgical operation.

Molteno (Molteno Ophthalmic Ltd, New Zealand), Baerveldt (Advanced Medical Optics, USA), Ahmed (New World Medical Inc, USA), and Krupin (Hood Laboratories, USA) valves are used as implants [4]. Timely actuation of the valve and pressure reduc-

tion ensures the storage of the optic nerve in working condition.

However, some parameters of the implants may have considerable variation. It is also important to maintain their stability overtime during the usage of the product [5]. The normal range of intraocular pressure at which no pathological lesions occur and the implant should react is within the range of 9-21 mm Hg, but it can fluctuate, even up to 60 mm Hg. [6].

Therefore, testing existing implants before surgery is an actual task for ophthalmologists and implant designers. Evaluation of implant parameters before implantation is one of the components of successful surgical intervention and preservation of the patient's vision [7]. The testing procedure consists of measuring the pressure parameters at which the intraocular fluid is output by the implant before insertion into the human eye. It improves the selection and helps identify deviations in the intraocular fluid output parameters in the implant and make predictions about its further performance when used.

Literature review

Modern methods and tools for implant operability testing provide for hardware creation of overpressure of physiological solution and its passing through the controlled valve with analog or digital control devices, which can significantly differ in structural construction, accuracy, and resolution of pressure parameters determination. Equally important are metrological parameters and the simplicity and availability of such equipment for a preoperative check before implantation.

Currently, there are several well-known methods of testing implants for workability and measuring equipment built on their principles.

Currently, there are several well-known methods of testing implants for workability and measuring equipment built on their principles.

Thus, for example, in [8] is considered testing of implants without a pressure sensor; instead of it, an operator manually lifts a reservoir with a saline solution to a given programmed height. The disadvantages of this technical solution include inaccuracy and subjectivity of the reference when setting the pressure and the lack of automation.

In work [9], the device of preoperative testing has in its composition a tank with a saline solution, 3-inlet splitter, analog manometer, cannula 30G (external diameter 0.3112 mm, and an internal diameter 0.159 mm), connecting tubes. The tank with a saline solution connects to the input of 3 inputs splitter, the first output connects to the manometer, and the second output connects through the cannula with the valve input. By raising or lowering the saline solution tank, the ground gravity increases the system's pressure to pass the solution through the AGV valve and fixes the pressure values of its actuation. The disadvantages of this device are the significant inaccuracy and subjectivity of the pressure reading and the assessment of the valve functionality for implantation.

The paper [10] describes two preoperative testing methods of drainage valves, presented in the form of two protocols.

One of them realizes the influence of a change of world gravitation, and in the other, overpressure creates by the engine connected to the tank with saline which exit through a connecting tube and 3-inlet splitter connects to a pressure balancing tube, the manometer, and AGV. Insufficient sensitivity and complexity of registration the operation moment of the valve which depends on the professionalism of the operator, and accordingly, some subjectivity in definition of implants parameters reduces the efficiency of the definition of their suitability for use should attribute to lacks of the considered device.

A more complicated verification system described in [11], a reservoir creates excess pressure in it with a saline solution in the form of an infusion pump – the created pressure controlled by two manometers analog and digital. This system is also equipped with a high-speed digital camera with a microscope used to record the solution's flow through the implant.

The disadvantage of the described device and method of verification is the high cost and complexity due to the use of infusion pump, video camera, and microscope, which are necessary to record the time and parameters of the valve actuation, as well as the focus on the detection of fluid passage only with the implant type AGV, which limits their mass use.

Shortcomings of previous devices have corrected in the device [12]. The system based on a microcontroller, a stepper motor with a worm gear, a tank with saline, a microelectromechanical pressure gauge, a liquid detector, and an ADC connected accordingly.

The system provides a significant increase in the sensitivity and accuracy of implant parameters determination. At the same time, the weak point of this technical solution is the use of mechanical elements, such as a stepper motor with worm gear and a piston in a saline reservoir. The presence of these elements limits the use of such a system more in stationary conditions at implant manufacturing enterprises or specialized ophthalmological treatment centers. However, the development of ophthalmological care and the availability of many centers require the creation of highly accurate but affordable devices for preoperative verification and testing of such implants in clinics and outpatient clinics. The testing process should be more natural and closer to the physiological processes of intraocular pressure changes.

Purpose

The authors set the task to develop a simple and reliable measurement scheme based on the aforementioned device and to provide high sensitivity, accuracy and objectivity in determining the parameters of im-

plants to increase the efficiency of their use in medical and surgical practice.

Methods

Fig. 1 shows the authors' proposed functional scheme of the implant testing system for regulating intraocular pressure.

The system includes a power supply unit (accumulator) 1, electronic key 2, miniature compressor 3 connected through the passage valve 4 with a reservoir with saline solution 5, 3-input splitter 6, with an electromechanical pressure sensor 11 with a shut-off valve of saline solution 7, and a canula with the implant 8. To the output of the implant is connected liquid detector 9 and ADC 10 connected to the microcontroller 12. The first output of the microcontroller connected to computer input 13, and the second output connected to electronic key control input 2.

The implant testing device for intraocular pressure regulation works as follows. First, the implant connected to the cannula. Cannula connected to the stopping tap of the saline solution supply 7.

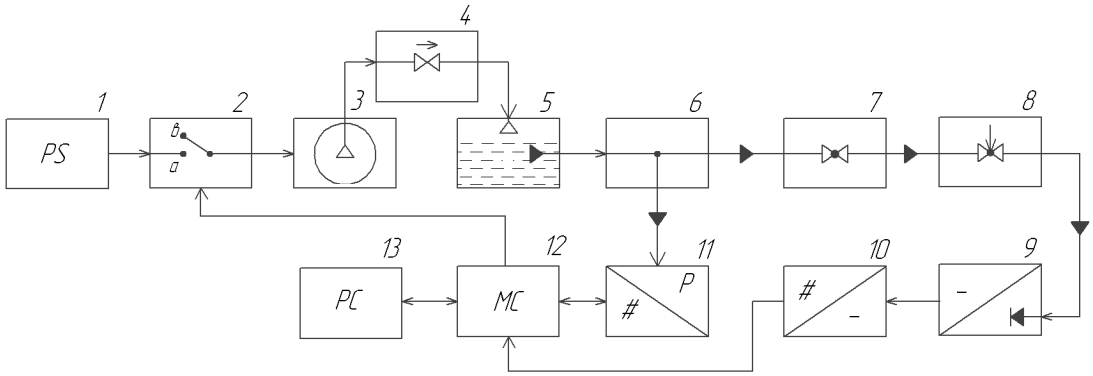

Fig. 1. Functional scheme of the implant testing system for the regulation of intraocular pressure

The computer 13 switches on the implant testing mode, microcontroller 12 switches on the compressor 3 via the electronic key 2 to increase the pressure in the reservoir 5, due to the throughput valve 4 the air cannot return to the compressor from the reservoir. The pressure in the connection system gradually increases and is continuously monitored by a microelectromechanical pressure sensor 11, the level of pressure is continuously read by microcontroller 12 and recorded in the computer memory as a pressure graph. The system pressure rises from zero to the trigger value of the implant.

When the implant is activated, the liquid appears on the implant outlet, which falls on the liquid detector 9, this fixed the implant opening pressure level. The signal of the detector 9 is converted into digital form via ADC 10 and sent to the microcontroller 11, which stops the compressor 3 turning off the power supply due to its electronic key 2. The computer saves the value of opening pressure from microcontroller 11.

When the valve is open, the system's pressure gradually decreases; the dynamics of pressure change are monitored continuously by the microelectromechanical pressure sensor 11 and input into the computer 13. When the valve is closed, the pressure stops to a constant level; the value of closing pressure from the electromechanical pressure sensor 6 transmitted to microcontroller 11 and input into the computer 13. The computer programs are drawn up a graph of the change of pressure of this instance of the valve and determined the working range of pressure in which the valve can operate

$$P_3 = P_2 - P_1 \ , \qquad (1)$$

Where P_1, P_2, – is the value of the opening and closing pressure of the valve.

Also, the system provides the ability to check the reproducibility of the received valve parameters. After the first step information taken by a computer, multiple test cycles are activated, the average value of the dynamic range determined; for example, for $n_{(3)}$ measurements:

$$\Sigma P_n = (P_{n1} + P_{n2} + P_{n3}) / n \ , \qquad (2)$$

Where P_{n1}, P_{n2}, P_{n3} – pressure variation ranges for repeated 3-times measurements and the scattering percentage of each measurement.

The obtained values compared with the standard ones (9-21 mm Hg), the results summed up according to the implant conformity or non-conformity with the established norms, and filled in the testing protocol.

Fig. 2 shows the testing algorithm, which contains the steps for starting and working on the implant checking system.

In the first step, the operator will connect the cannula with the implant to the crane. In the second stage, the operator will open the tap. The third step starts testing the implant for which the microcontroller controls the electronic key with a compressor and increases the fluid pressure that comes to the implant inlet. Feedback is provided by a microelectromechanical pressure sen-

sor that continuously records the pressure level at 50 Hz and transmits data to the microcontroller, the second feedback provided by the fluid detector, registers the passage of fluid through the implant.

The pressure in the above system continually increases until the implant starts to withdraw the fluid, and recorded by the fluid sensor. At the moment the fluid passes through the implant, the system determines the pressure level at which the implant starts to remove the test fluid, after the operation of the fluid detector, the system registers the pressure of the opening of the implant and stops the fluid supply point (1a, 1b, 1c) in Figure 2.

Open valves smoothly reduce the system's pressure level until it is completely closed (points 2a, 2b, 2c). The process of testing the valves depends on the quality of these products, different levels of hardness.

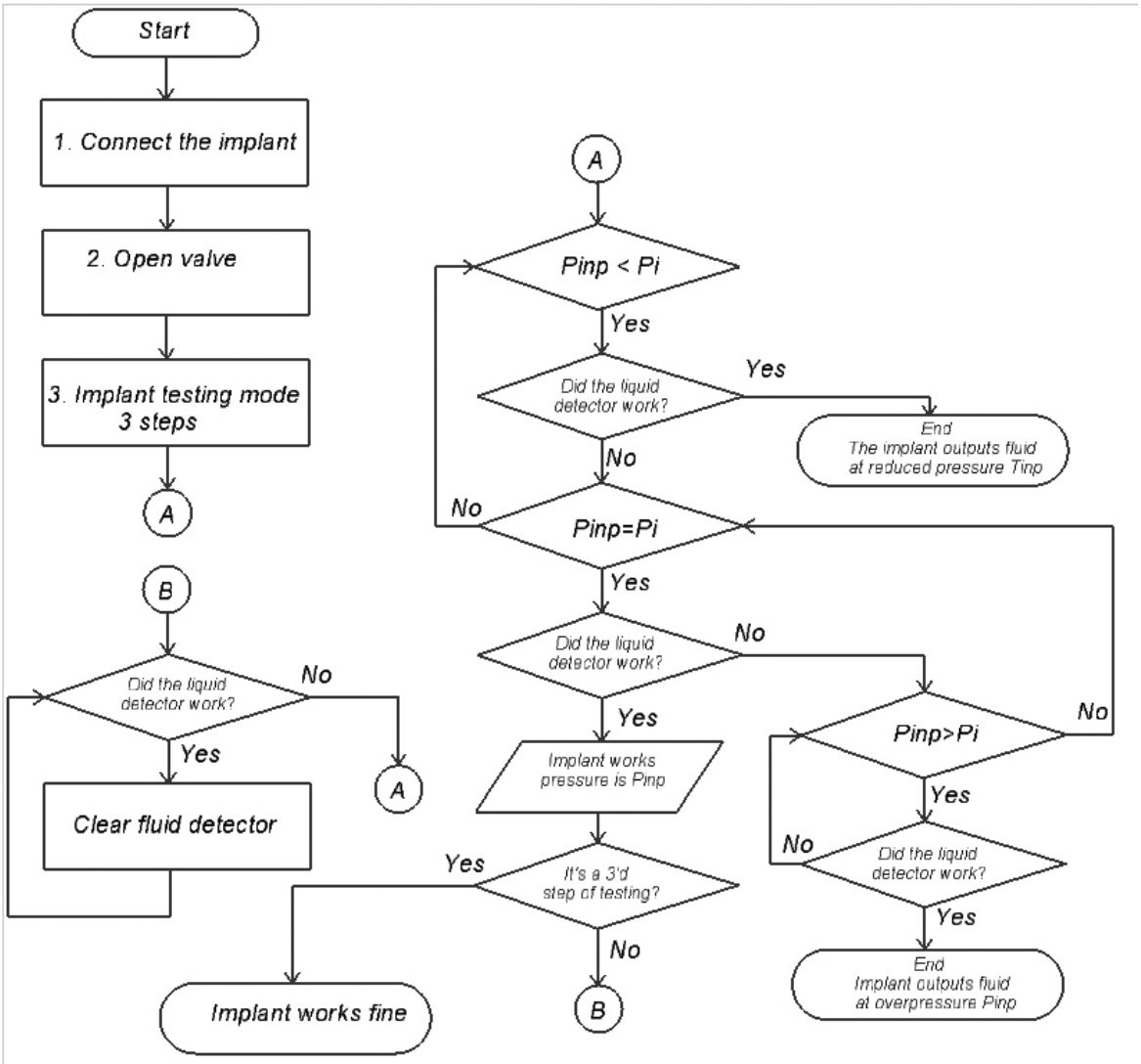

Fig. 2. Algorithm of the implant testing system for the regulation of intraocular pressure

Results

During the testing process, the system checks the parameters and conditions that are important for further ensuring the implants' quality, and there are three options for the obtained result. Fig. 3 shows the graphs of checking the pressure parameters for three implants of different hardness levels, marked by the symbols a, b, and c.

First implant a (Fig. 3) has a reduced level of hardness and characterized by pressure changes from 8 mm Hg. (valve opening point 1a) to 5 mm Hg. (closing point 2a). The testing cycle of such an implant lasts within 30 - 40 seconds. Activation of the liquid detector at this stage is a sign of the implant failure with the risk of hypotension for the patient's eyes, and such a valve is not suitable for use.

The second implant, marked with the symbol b, has a higher hardness and therefore opens at a higher pressure level and increases the test time to 65 seconds.

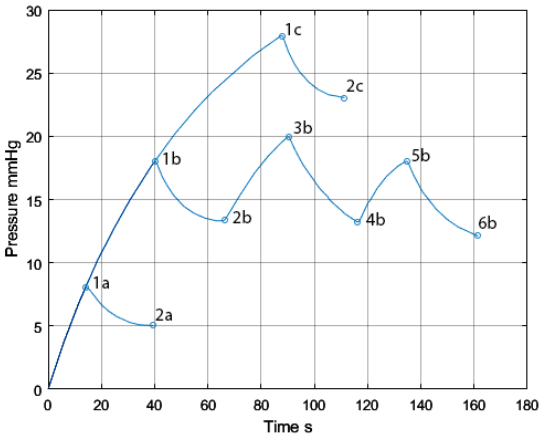

Fig. 3. Test pressure diagrams of implants of different valve hardness: a, c – defective implants, b – functional implant

The change of the pressure parameters of the second implant (Fig. 3) of the points 1b and 2b is within the normal range of 18-13 mm Hg. Activation of the fluid sensor indicates that the implant works within the normalized intraocular pressure range of 9-21 mm Hg. After determining the implant, which meets the normative requirements, the reproducibility of parameters checked by the method of multiple repeated pressure increases. For this purpose, the operator removes the fluid from the fluid detector indicator plate and switches on the system of pressure increase again up to the moment of the fluid detector actuation, fixes the moment of the implant reopening in the point 3b. The detector's signal stops the compressor, after which the open valve pressure is reduced and stabilized at point 4b. This step repeated (points 5b and 6b). Due to triple testing in repeatability, the valve is recognized as a quality valve and used for surgical treatment of a patient with glaucoma.

The third implant c (Fig. 3) characterized by high hardness (stiffness) and change of actuation pressure within the range of 28-23 mm Hg at points 1c and 2c, which exceeds the normal range of intraocular pressure. Activation of the liquid detector at this pressure indicates a complete malfunction of the implant. The use of such an implant indicates the risk of hypertension in the patient's eye.

The realization of an automated system for testing existing implants before the surgical intervention was carried out using the following elements of microsystems technology.

Microcompressor WHALEB-100 with 1.5 V supply voltage was used to create the required pressure variation range from 0 to 30-40 mm Hg. As a microcontroller used the STM32F103RET6 chip to provide automated modes of system operation. An essential element of the system is a pressure sensor – it is one of the functional units, which provides the possibility of automation of the verification process and the corresponding accuracy of implant testing. The ST Microelectronics LPS33HW microelectromechanical pressure sensor satisfies these requirements. The sensor has an integrated filter, a pressure reading frequency from 1 to 75 Hz, the microcontroller reads the data from the sensor via the SPI interface, and provides communication with a computer. The accuracy of the pressure measurement is 0.075 mmHg or 0.25% at the maximum pressure in the LPS33HW. WAVGAT MH RD resistive liquid detector with 4 cm x 5 cm sensor part size, with ADC based on LM393 comparator, 5V supply voltage, and comparator response speed of 1.3 μs was used as a liquid detector. The conversion characteristic for the analog output of such a detector is a discrete function of the presence of liquid on the sensor plate of the detector w and looks:

$$\begin{cases} y = 0, \ at - w = 0, \\ y = 1, \ at - w \neq 0. \end{cases} \quad (3)$$

As follows from (3) on the digital output 0 or 1 is formed, in the absence or presence of liquid on the sensor, the required response sensitivity adjusts by changing the potentiometer's resistance.

Conclusions

The proposed system provides:

1. Simplification of the scheme with the possibility to automate the process of preoperative verification of implants of different types.

2. Allow getting higher sensitivity, measurement accuracy, and objectivity of implant parameters determination.

3. Determining their suitability for use in medical-surgical practice by the parameters of fluid withdrawal, namely opening pressure, closing pressure, and reproducibility of the characteristics at repeated operation will contribute to the efficiency of the performed operations

4. Shortened implant testing time, which is limited to 2-3 minutes, can save and store parameter information, both electronically and in paper form.

The system developed by the authors is a promising one and can be used not only for checking known types of valves but also for testing implanted radiofrequency chip [2,3], which are currently only undergoing experimental testing.

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[1)]О. П. Яненко, [2)]А. А. Ткачук, [2)]Р. А. Ткачук

[1)]Національний технічний університет України «Київський політехнічний інститут імені Ігоря Сікорського», Київ, Україна

[2)]Тернопільський національний технічний університет ім. І. Пулюя, Тернопіль, Україна

АВТОМАТИЗИЗОВАНА СИСТЕМА ВИПРОБУВАНЬ ІМПЛАНТАТОВ ДЛЯ РЕГУЛЮВАННЯ ВНУТРІШНЬООЧНОГО ТИСКУ

Мета роботи. Імплантація дренажних пристроїв при глаукомі зазвичай виконується після попередніх невдалих процедур і є останнім шансом пацієнта зберегти зір. у статті описаний пристрій, що дає змогу автоматизувати процес передопераційної перевірки імплантатів різних типів, що використовуються для виведення внутрішньоочної рідини при глаукомі. такий прилад допоможе підвищити успішність операції та допоможе зберегти зір пацієнтам із глаукомою, завдяки попередній перевірці імплантатів на справність та параметри виведення внутрішньоочної рідини.

Методика. Для реалізації поставленої мети авторами на базі елементів мікросистемної техніки розроблена структурна схема автоматизованої системи для вимірювання та контролю параметрів імплантатів регулювання внутрішньоочного тиску.

Результати. Залежно від матеріалу та ступеню твердості імплантату можливі три випадки, коли імплантат відкривається раніше, водночас виникає ризик гіпотонії для ока пацієнта, пізніше – ризик гіпертонії й коли імплантант працює в зоні встановленого тиску. Авторами приводяться графіки тестування трьох імплантатів різного ступеню твердості, а також графік відтворюваності характеристики не дефектного імплантату.

Наукова новизна. Запропоновано метод перевірки параметрів імплантатів шляхом апаратного створення надлишкового тиску, з можливістю автоматизованого контролю параметрів передопераційної перевірки імплантатів.

Практична значимість. Розроблена автоматизована система для передопераційного тестування імплантатів, яка забезпечує: спрощення схеми з одночасною можливістю автоматизації процесу передопераційної перевірки імплантатів різних типів; дає змогу здобути підвищення чутливості, точності вимірювання та об'єктивності визначення параметрів імплантаті; визначення їхньої придатності для використання в медичній хірургічній практиці за параметрами виведення рідини, а саме тиску відкриття, закриття та відтворюваності характеристики під час повторного спрацювання, що сприятиме підвищенню ефективності проведених операцій; скорочення часу перевірки імплантату, який обмежується 2–3 хвилинами, і можливістю збереження інформації про параметрів, як в електронному (на комп'ютері), так і в паперовому вигляді.

Ключові слова: глаукома; внутрішньоочний тиск; імплантат; вимірювання тиску; тестування; автоматизація процесу; мікросистемна техніка.

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[1)]А. Ф. Яненко, [2)]А. А. Ткачук, [2)]Р. А. Ткачук

[1)]Национальный технический университет Украины «Киевский политехнический институт имени Игоря Сикорского», Киев, Украина

[2)]Тернопольський национальный технический университет им. И. Пулюя, Тернополь, Украина

АВТОМАТИЗИРОВАННАЯ СИСТЕМА ИСПЫТАНИЙ ИМПЛАНТАТОВ ДЛЯ РЕГУЛИРОВАНИЯ ВНУТРИГЛАЗНОГО ДАВЛЕНИЯ

Цель работы. Имплантация дренажных устройств при глаукоме часто выполняется после предыдущих неудачных процедур и является последним шансом пациента сохранить зрение. В статье описано устройство, автоматизирующее процесс предоперационной проверки имплантатов разных производителей, используемых для вывода внутриглазной жидкости при глаукоме. Такой прибор поможет повысить успешность операции и поможет сохранить зрение пациентам с глаукомой, благодаря предварительной проверке имплантатов на исправность и параметры вывода внутриглазной жидкости.

Методика. Для достижения поставленной цели авторами на базе элементов микросистемной техники разработана структурная схема автоматизированной системы для измерения и контроля параметров имплантатов регулирования внутриглазного давления.

Результаты. В зависимости от типа материала и степени твердости имплантата возможны три случая, когда имплантат открывается раньше, одновременно возникает риск гипотонии глаза пациента, позже – риск гипертонии и когда имплантант работает в зоне установленного нормального уровня давления. Авторами приводятся графики тестирования трех имплантатов разной степени твердости, а также график воспроизводимости характеристики не дефектного имплантата.

Научная новизна. Предложен метод проверки параметров имплантатов путем аппаратного создания избыточного давления, с автоматизированым контролем параметров предоперационной проверки имплантатов.

Практическая значимость. Разработана автоматизированная система для предоперационного тестирования имплантатов, которая обеспечивает: упрощение схемы с одновременной автоматизацией процесса предоперационной проверки имплантатов различных типов; позволяет получить повышение чувствительности, точности измерения и объективности определения параметров имплантатов; определение их пригодности для использования в медицинской хирургической практике по параметрам вывода жидкости, а именно давления открытия, закрытия и воспроизводимости характеристики при повторном срабатывания, что будет способствовать повышению эффективности проводимых операций; сокращение времени проверки имплантата, который ограничивается 2-3 минутами, и возможностью сохранения информации о параметрах, как в электронном (на компьютере), так и в бумажном виде.

Ключевые слова: глаукома; внутриглазное давление; имплантат; измерения давления; тестирование; автоматизация процесса; микросистемная техника.

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