Design of Multi-Element Piezoelectric Emitters for Shock Wave Therapy Devices

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Abstract : *In medical practice, not only devices using ultrasound for diagnostics and treatment have become widespread, but also shock wave therapy devices for short-term exposure to tissues with acoustic impulses. The most important part of shock wave therapy devices (hereinafter referred to as "SWTD") is the applicator is a device that forms a shock wave and ensures its passage to the target area. Focusing the shock wave is important to avoid exposure to areas of the body that are not subject to therapy. The article discusses the requirements and limitations that arise in the design of a piezoelectric shock wave former (applicator), which is a component of the SWTD. The aim of this work is to formulate reasonable requirements for the main structural elements of the SWTD focusing applicator, built based on piezoelectric emitters (piezo elements) and allowing control of the geometric parameters of the shock wave focus - size, shape, and position in space. To solve this problem, the considered design of the SWTD applicator uses the following methods: the use of water as a propagation medium inside the applicator; the use of a silicone membrane to ensure the passage of the shock wave to the target area; the use of piezoelectric elements for converting the energy of an electric pulse into the energy of a shock wave in a propagation medium; control of piezoelectric elements during the formation of a shock wave as elements of a phased array to ensure the possibility of controlling the geometric parameters of the focus of the shock wave. The results of the work are substantiated requirements for the design of the SWTD piezoelectric applicator, built on the principle of a phased array, and allowing controlling the geometric parameters of the focus of the shock wave. The considered method of installing piezoelectric elements provides for the possibility of their simple replacement as they wear out to increase the resource of the applicator as a whole. For piezoelectric SWDT with the ability to control the geometrical parameters of the focus of the shock wave, the applicator should be built on the principle of a phased array with a significant number of elements. In this case, it should be possible to easily replace individual piezoelectric elements.*

Keywords — *applicator, focusing, phased array, piezoelectric element, shock wave therapy.*

I. INTRODUCTION

Ultrasound is widely used in medical practice [1]. Against this background, in the last 15 years, there has been a rapid development of methods of shock wave therapy (SWT), through the impact on the therapy zone of a shock wave, leading to a local effect that causes some biological and disorganizing effects. This method is currently successfully used in many fields of medicine.

Various types of transducers can be used to generate ultrasound, such as electro-hydraulic, pneumatic, electromagnetic, piezoelectric, etc. [2].

The main working element of the SWT device (SWTD) is a shock wave shaper - an applicator. Applicators of modern piezoelectric SWTD have up to several hundred piezo elements fixed on a spherical or parabolic surface that sets the direction for focusing wave fronts or the focus area. As a result, it becomes possible to create a peak pressure of about 100 MPa in the focus region [3], [4] using relatively low-power elementary emitters. To solve the problem of controlling the focal spot of a shock wave, in our opinion, it is most appropriate to use a multi-element piezoelectric applicator built on the principle of a phased array. In this case, it is possible to realize the most flexible control of the shock wave parameters by controlling each elementary radiator or groups of several radiators. Such devices, operating in the frequency range from 200 kHz to 10 MHz with an acoustic power in the range of 10-30 W/cm2, show the best results in the adjacent direction of high intensity focused sound (High Intensity Focused Ultrasound, HIFU) used not for therapeutic purposes, but for the destruction of tumors [1], [5], [6], [7]. On the other hand, calculations [8] show that to obtain a shock wave with the required amplitude using small emitters (with an aperture of ~ 200 mm), the frequency range is 1–3 MHz.

The purpose of this paper is in formulating the requirements for the design of the applicator, suitable for use in the practical development of SWTD, which has the ability to control the focusing spot of the shock wave energy.

II. LITERATURE REVIEW

In clinical practice, high-intensity ultrasound or high-energy single shock waves have long been used [5], [9]. In this case, the energy of the shock wave must be delivered to the target without a serious impact on the tissues located in the path of wave propagation, which requires the use of means of focusing the shock wave in the target area of influence. In clinical practice, high-intensity ultrasound or high-energy single shock waves have long been used [5], [9]. In this case, the energy of the shock wave must be delivered to the target without a serious impact on the tissues located in the path of wave propagation, which requires the use of means of focusing the shock wave in the target area of influence.

Applicators of therapeutic SWTD, built based on lenses, reflectors, and forming focused shock waves, in addition to obvious advantages have significant disadvantages, the main one of which is the lack of the possibility of operational control of the characteristics of the shock wave. Usually, a change in the shape and location of the focus requires the replacement of structural elements or the use of rather complex mechanical devices that control the geometry of the structural elements of the applicator, ensuring the formation of the focus [5], [10].

SWTD used in clinical practice, have different principles of shock wave formation: electromagnetic, electrohydraulic, piezoelectric, pneumatic, and others [11]. Of the listed principles of shock wave formation, only piezoelectric corresponds to the set task, since other options do not provide the ability to electrically control the size, shape, and location of the shock wave focal spot.

The piezoelectric elements of the applicator use the inverse piezoelectric effect, which consists of the mechanical deformation of the medium under the influence of an external electric field. Currently, a composite material has been developed and is used [12], consisting of rods of lead zirconate-titanate inside a polymer of low density. For the emission of short acoustic pulses at the output of a piezoelectric emitter, it is possible [13] to use an RL chain with specially selected parameters. It is connected in parallel or in series with piezoelectric ceramics. The use of a chain allows reducing the duration of the emitted pulse to 3 periods, but at the same time, it leads to a slight decrease in the power transmission coefficient of the piezoelectric emitter.

One of the difficulties associated with the use of piezo ceramic emitters is due to the high value of their acoustic impedance. It was noted [14] that when the impedances differ by a factor of 14, the radiation power drops by 12 dB. To overcome these difficulties, a quarter-wave matching layer is applied to the ceramic surface. It is possible to use two antireflection layers at once. It should be noted that powerful radiation leads to heating of the ceramics; therefore, it is necessary to provide a system for its cooling.

Another difficulty [14] is the need to provide a good transmission capacity at the contacts of the wires supplying electric current to the ceramic. The ability to carry large instantaneous currents is usually achieved using low-temperature soldering.

SWTD, used in clinical practice, must focus radiation to be able to supply shock wave energy to the target without affecting the tissues located in the path of wave propagation. Acoustic lenses can be used to solve this problem, but this is not the most efficient way, since about 40% of the energy [5] is absorbed in the lens. Overheating and damage to lenses are especially noticeable at high frequencies and intensities of ultrasound. Sound aberrations on the lens also interfere with focusing on radiation.

The second type of emitters is a device containing a piezoelectric element in the form of a parabolic plate, the radiation of which is already focused [5]. In this design, the distance from the focus to the cutoff of the cone can be changed by moving the piezoelectric emitter inside the device.

The way the piezoelectric elements are arranged affects the range of change in the focus position without an unacceptable decrease in amplitude in it and without the formation of side foci. Quasi-random and deterministic arrangements are possible [15]. As shown in [16], when considering a lattice of elements in the form of disks, located at random on an aperture of increased diameter, as well as lattices of square elements, the centers of which are located on the Archimedean spiral. The use of a grating with a spiral configuration allows a significant gain in maximum intensity in focus. In this case, the size of the scanning area for such gratings is somewhat smaller than for gratings with a random arrangement of round elements.

III. METHODS

For an informed choice of design solutions, the methods described below were used. The choice of the principle of the formation of the shock wave - the method of comparative analysis of the characteristics achieved in the existing SWTD and the analysis of fundamentally achievable results for structures based on the considered principles were used. Electromagnetic, electrohydraulic, piezoelectric, pneumatic, and others are considered [11]. The design solutions of Piezowave by Richard Wolf, Duolith SD-1 by Storz Medical, Dermagold (Urogold, Orthogold, Orthowave) 100/180/280 by MTS, Dolorclast by Swiss were adopted as standard.

The wave propagation medium in the applicator body was selected through the comparative analysis of the performance properties of the SWTD applicator using water and silicone.

The choice of the shape of the emitting surface - the method of analysis of the geometry of the emitter was used in relation to the required focusing of the shock wave, taking into account the influence of the directivity of elementary emitters and the shape of the base on the energy of the shock wave in focus.

The choice of a method for attaching piezoelectric elements to a common base - the method of analyzing the manufacturability of the applicator design as a whole was used, at both the manufacturing stage and taking into account the replacement of individual piezo elements during operation.

The choice of the principle of the arrangement of piezoelectric elements on the surface of the base - the method of comparative analysis of fundamentally achievable characteristics for various location options, taking into account the manufacturability of the resulting design and the features of piezoelectric elements available for use in the experimental sample, was used.

The choice of the principle of control of piezoelectric elements - the method of forming a diagram of a phased array located on a spherical surface was used by controlling the relative phase delays of the control action for elementary emitters.

A. Problem statement (Necessary requirements and restrictions

For the therapeutic use of ultrasound, both pressure waves and shock waves are used. The use of shock waves for therapeutic purposes requires an increased, in comparison with pressure waves, attention to the localization of the area of influence. In order to prevent the impact on the tissue adjacent to the treated area, a sufficient concentration of energy in the area of the focal spot of the shock wave is required for a short period without the formation of secondary foci. The geometric shape of the focus area is close to spherical with a characteristic size of 1-10 mm.

Acoustic lenses can be used as focusing devices, but their use is impractical, because in this case, the energy loss in the focusing system can be up to 40% [5], and the position of the focus area is controlled by changing the lenses.

The focus position can be controlled by mechanically moving the piezo emitters, including pre-focused emitters [17]. The main disadvantage of this approach is the high complexity of manufacturing a mechanical applicator system capable of providing acceptable characteristics in terms of reliability and resource.

The most promising focusing method seems to be the use of a plurality of independent elementary emitters that form a phased array on a common base. The preferred base shape is spherical. In this case, by controlling the electrical characteristics of the control pulses of elementary emitters (phase and amplitude), it is possible to change the position and size of the focus area without changing the geometry of the applicator.

For use in the applicator, piezoelectric elements must be selected that can operate at frequencies below 1 MHz, because at frequencies less than 1 MHz, it is difficult to implement a shock-wave irradiation regime for a radiator with a diameter of about 200 mm.

SWTD should have a power of up to 40 W/cm2 [18], therefore, to reduce the power of elementary emitters, one should strive for the maximum possible number of emitters in the applicator and the minimum required technological gaps. According to the results of calculations in the adjacent field of ultrasound [8], for successful neurosurgical operations, it is possible to use gratings with an operating frequency of 1 MHz, an aperture D = 200 mm and a fill factor of more than 80%. At lower density values, the efficiency of the emitter sharply decreased. In addition, with an increase in the number of elementary emitters, the accuracy of controlling the parameters of the focus area increases.

For effective control of the geometric characteristics of the focus area, it is necessary to set the phase with accuracy from units to tens of nanoseconds, therefore, the mutual influence of elementary emitters located on a common base should be minimized. The use of individual grounds is impractical because leads either to an unacceptable increase in weight and dimensions or to an unacceptable complication of the applicator design.

B. SWTD emitter design. Placement of piezoelectric elements

From the point of view of manufacturability in manufacturing and flexibility in controlling the position of the focus area, the preferred shape of the base is a flat plate, but in the case under consideration, a spherical shape was chosen as providing a better concentration of shock wave energy and convenience of preliminary focusing, as compared to a flat plate, although it has a minus in relatively limited volume for possible control of the focal spot.

The size of the emitter is chosen from a compromise between usability and the number of elementary emitters. The diameter of the base with the mounting area is 152 mm, the diameter of the emitter itself is 123 mm. Because cylindrical piezoelectric elements with the required characteristics are not available for ordering, rectangular elements of 5x5x2.7 mm in size were manufactured for the emitter.

On the selected base, 288 elementary emitters are placed, while the fill factor of the emitter is 0.61, the minimum size of the insulating gaps between individual piezoelectric elements is about 0.5 mm. The layout of the elements is shown in Fig. 1.

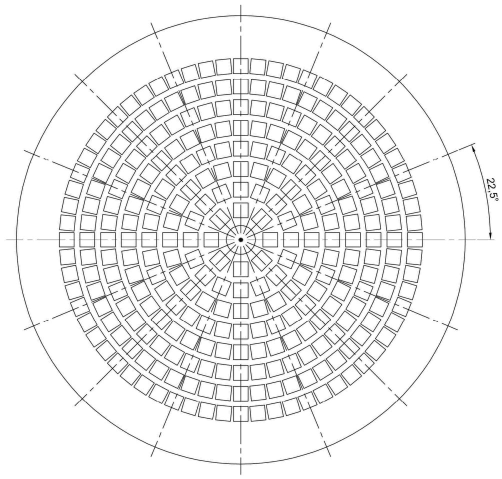

Fig. 1: Layout of emitter's elements

Piezo elements are placed with several axes of symmetry to simplify the organization of control of groups of elements, which allows them to simplify the control system.

C. Fastening and connection of piezoelectric elements

Because during the design study one of the tasks is to ensure maintainability, it was decided to mount piezoelectric elements without the use of soldering, which greatly simplifies the replacement of piezoelectric elements if necessary. The principle of fastening piezoelectric elements on the base is shown in Fig. 2.

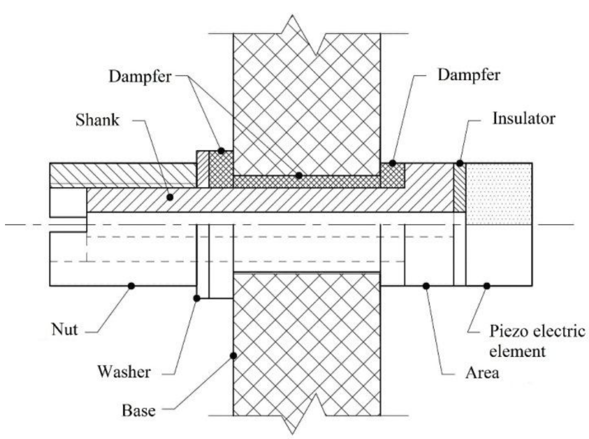

Fig 2: Mounting the piezoelectric element

The piezoelectric element is glued through an insulating gasket (insulator) to a platform with a brass shank. The shank of this assembly goes through a hole in the base and is tightened with a cylindrical nut with a flat metal washer. The nut has a slot for a figured screwdriver. To weaken the mutual influence of piezoelectric elements through a common base, a damper is used, which consists of three parts: a rectangular gasket with a hole under the platform, a tubular insert in the hole in the base and a circular damper washer under a metal washer. All parts of the damper are made of silicone.

The piezoelectric elements are connected with insulated wires soldered to the contact pads located on the side surfaces of the piezoelectric elements. The wires go through the slots of the pad and the hole in the shank as shown in Fig. 3.

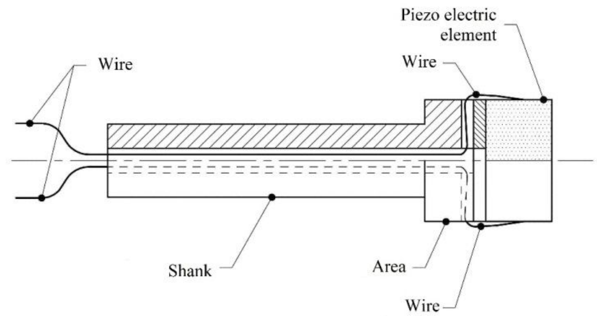

Fig. 3: Connecting a piezoelectric element

The wire passages through the slots of the platform are sealed with glue, sealed with glue, with which the insulator is glued to the platform (see Fig. 2).

D. Emitter with water

Water was chosen as the main medium for wave propagation within the applicator. The choice is because the use of water allows you to control the area of contact between the applicator membrane and the body. Water should not completely fill the applicator body, so the wet volume must be separated from the dry one.

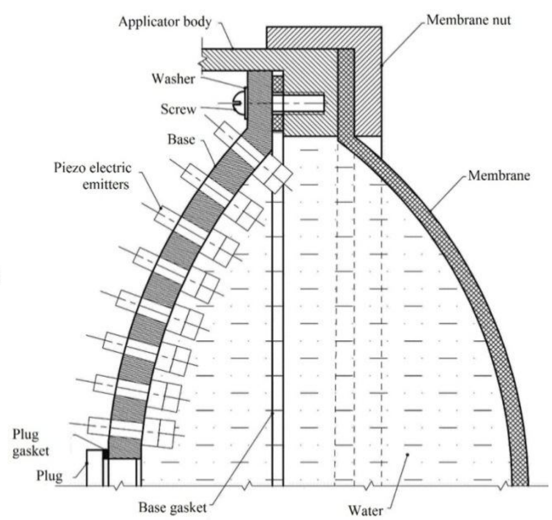

Fig. 4: Sealing the applicator

There is water between the outer surface of the base with piezo elements placed on it and the applicator membrane that provides contact with the patient's body. Water pressure depends on the conditions of the use of SWTD and can significantly exceed atmospheric pressure. Behind the rear surface of the base (from the side of connecting the piezoelectric elements), there are nodes for the formation of control pulses (printed circuit boards and power components), which should not get water. The principle of dividing the internal volumes of the applicator is shown in Fig. 4. Separation of volumes is achieved by the sealed installation of piezoelectric elements (see Figs. 3 and 4), using a threaded plug with a gasket for the centre hole (currently the centre hole of the base is not used, reserved for the sensor) and a base gasket. The base is pulled to the applicator body by a screw and washer through the base silicone gasket.

The decision to use water as a medium for the propagation of a shock wave inside the applicator body was taken as the main option at the stage of development of the experimental sample as providing the greatest flexibility of use since with this approach; it is possible to control the size of the contact patch with the patient's body. An increase in the size of the contact spot makes it possible to reduce energy losses and, accordingly, improve the energy in the focal area.

The solution with water is universal from the point of view of the SWTD performance, but it is not free from drawbacks: a hydraulic system is needed that provides a given water pressure in the applicator during exposure, which complicates the device, increases its price and, possibly, operating costs. In addition, the conditions of use do not always allow the use of the largest possible contact patch area. There may be restrictions on the conditions of use from the side of the anatomy and treatment method.

E. Emitter with silicone

The use of silicone as a medium for the propagation of a shock wave inside the applicator body allows the cost of SWTD to be reduced. In this case, replaceable silicone inserts are used instead of water, an example of such a solution is shown in Fig. 10.

The silicone solution is tested on an experimental sample with the hydraulic system disconnected and the silicone membrane replaced with an insert. In this case, reliable contact of the working surfaces of the piezoelectric elements with silicone is ensured by using a specialized gel.

Advantages of silicone: cost reduction, simplification of SWTD.

Disadvantages: the need to use replaceable inserts in the work, the inability to smoothly adjust the size of the contact patch

F. Emitter focusing and piezoelectric control

The design of the applicator under consideration uses a pre-focused emitter, i.e. in the absence of control of the phases (delays) of the control pulses; the center of the focus area is in the middle position, which is ensured by the spherical shape of the base. The base has a complex shape, a spherical shape, in this case, means a segment of a virtual sphere touching the centers of the radiating planes of all piezoelectric elements.

The main geometric characteristics of the emitter with an indication of the location of the pre-focusing point are shown in Fig. 5. During operation, the focal point can be shifted relative to the initial position by selecting the delays of the control pulses.

At the stage of working with an experimental sample, the possibility of independent control of each piezoelectric element is provided to obtain the maximum possible control flexibility in the process of experimental tests. In the future, based on the results of working out control algorithms, an attempt will be made to combine elements into groups with a single control to reduce the size and weight of the key control unit, as well as reduce the price of SWTD as a whole.

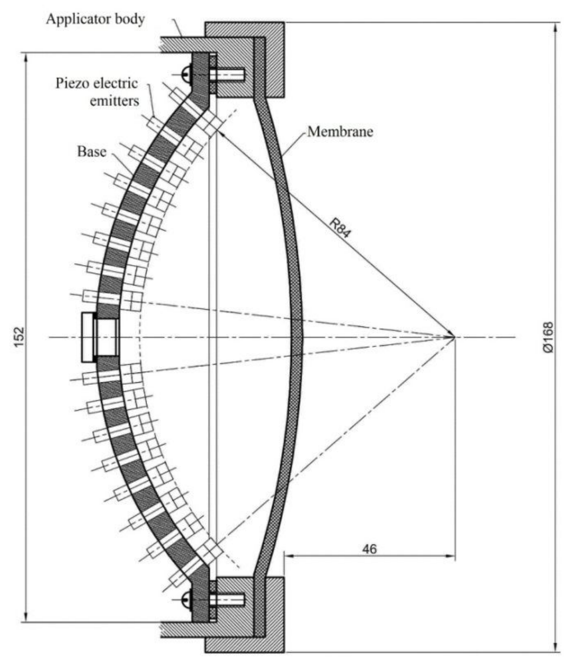

Fig. 5: Pre-focusing

Between the pulses, the piezoelectric elements are in a prestressed state: they are not at zero potential, the voltage at their terminals has the opposite polarity compared to the control pulse, and its value is approximately equal to the amplitude of the control pulse. This solution allows for almost doubling the efficiency of piezoelectric elements.

The shape of the base surface is determined not by a sphere, but by a set of broken lines (segments of cones), which makes it possible to improve the fit of the seals of piezoelectric elements and to simplify the requirements for manufacturing technology. As an example, Fig. 6 shows an enlarged view of the installation site of the sixth ring piezoelectric emitters.

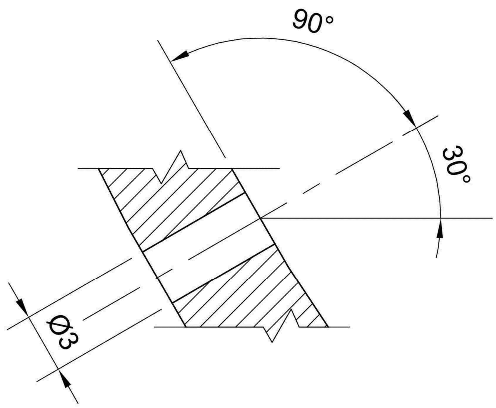

Fig. 6: Surface shape under the sixth ring of piezoelectric elements.

The angles of inclination of the surface are chosen so that the centers of the radiating planes of the piezoelectric elements are on the surface of a virtual sphere common for all piezoelectric elements (see Fig. 5).

G. Emitter assembly

The design of the SWTD emitter assembly from the inner side and from the side of the emitters is shown in Figs. 7 and 8 respectively.

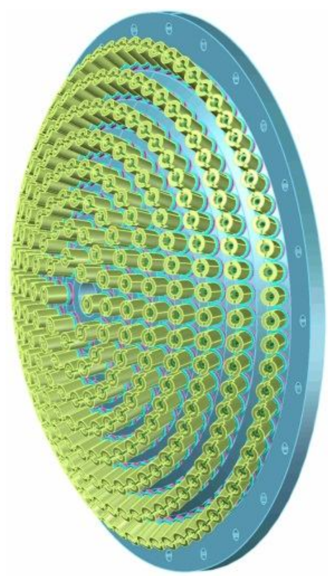

Fig. 7: SWTD emitter from the inside.

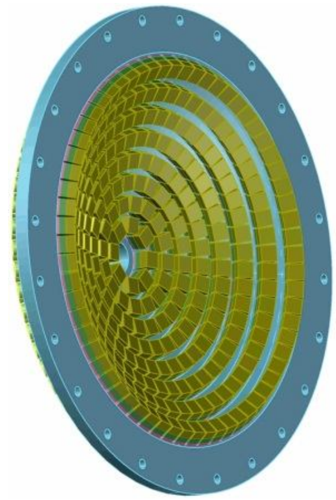

Fig. 8: SWTD emitter from the side of the piezo emitters.

H. Comparison with known solutions

When making a radiator, they are usually fixed to the inside of a common base by soldering as shown in Fig. 9 for the Richard Wolf's Piezowave applicator.

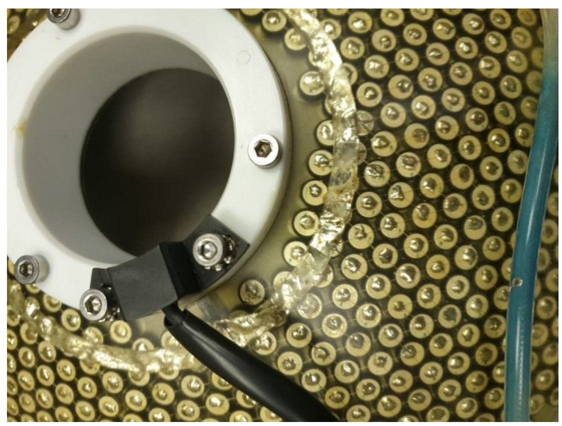

Fig. 9: Piezo emitters soldered to the base.

The piezoelectric elements are soldered to the inside of the common base. The base has a small thickness; therefore, with the simultaneous supply of a control electric pulse, it works as a single shock wave shaper (see Fig. 10).

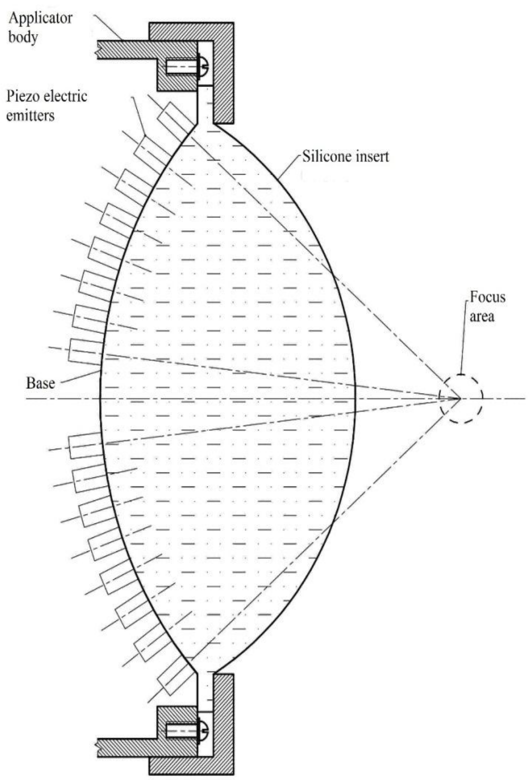

Fig. 10: Base as a single shaper.

The advantages of this design are that it is easy to manufacture, allows you to place piezoelectric elements with an acceptable density, has sufficient mechanical strength, piezoelectric elements are well protected from the influence of the propagation medium inside the applicator (if such a design is used with water and a silicone membrane, and not solid silicone). At the same time, according to the authors, this design has disadvantages that can become decisive when choosing an approach to designing an SWTD applicator for use in a clinic:

Insufficient maintainability - it is extremely difficult to extend the life of the applicator by replacing damaged or worn out piezoelectric elements because it is difficult to replace a damaged piezoelectric element without displacing adjacent ones.

Piezoelectric elements do not have a rigid base on the side of the conductor connection, which leads to a significant loss of energy during the formation of a shock wave.

There is practically no possibility of controlling the geometric characteristics of the focus area - the emitting surface is the base on which the piezoelectric elements are mounted, therefore, changing the parameters of the control electrical pulses for elements or groups of elements does not allow controlling the position in the focus space of the emitter as a whole.

IV. RESULTS

Based on the results of the work, substantiated requirements were formulated for the main structural elements of the SWTD focusing applicator, built based on piezoelectric emitters (piezo elements) and allowing control of the geometric parameters of the shock wave focus - size, shape, and position in space.

The expediency of constructing an SWTD applicator with the ability to control the geometrical parameters of the focus of the shock wave based on piezoelectric elements forming a phased array has been confirmed.

The only way to change the geometrical parameters of the shock wave focus without replacing or mechanically moving the elements of the applicator structure is to control the relative delays of the control electrical impulses applied to the piezoelectric elements.

The spherical shape of the base was determined as the most effective for working with piezoelectric elements available for use in the experimental SWTD sample.

There are two options for the material of the shock wave propagation medium inside the applicator body: water and silicone. There is no final decision for choosing one of them since both options have merits and demerits. It seems reasonable to implement two versions of SWTD: a cheap one with limited functionality on silicone and a more expensive one with a hydraulic system. The final choice of the option should be made taking into account the conditions of use.

The design of the applicator should provide for the possibility of simple replacement of individual piezoelectric elements to reduce the cost of operating the SWTD during operation - this task has been worked out within the framework of the considered design.

The considered design of the SWTD emitter is capable of solving the assigned tasks both in the version with water and in the version with silicone as a medium for the propagation of a shock wave inside the applicator body.

V. DISCUSSION

A. Why are there so many piezoelectric elements?

For two reasons:

1. The piezo emitter of the applicator is a highly specialized, but full-fledged phased array; therefore, an increase in the number of elementary emitters makes it possible to increase the accuracy of control of the focus geometry.

2. An increase in the number of elementary emitters makes it possible to reduce the requirements for the output of each of them; this is useful for increasing the life of piezoelectric elements.

B. Why consider the manufacture of two versions of the applicator: with water and silicone? Isn't it better to dwell on the most promising?

Both options have both advantages and disadvantages. The applicator with water is more versatile, potentially able to provide increased energy compared to silicone, but more expensive. Depending on the conditions of use, its advantages may not be required, and additional, in comparison with silicone, costs are not justified.

C. Why is a spherical rather than a parabolic base used?

According to the initial conditions, it was required to obtain the shape of the focus area close to spherical. This is easier to do with a spherical base. The use of a parabolic base leads to the formation of an elongated focus for preliminary focusing and, accordingly, additional energy costs for approaching a spherical focus.

D. What prevents from using a flat base? It is more technologically advanced and the size of the applicator may be smaller.

There are no formal obstacles to this; moreover, the flexibility of controlling the focus geometry is higher precisely with a flat base. Nevertheless, the energy is significantly better when using a spherical base. At the stage of working with an experimental sample, this consideration became decisive, which does not negate a more detailed consideration of a flat base in the future.

E. Why is quasi-random or spiral placement of piezoelectric elements not used as potentially more efficient?

Radial placement of piezoelectric elements is a forced solution due to the design features of piezoelectric elements available for use in the experimental SWTD sample. Changing the placement of piezoelectric elements is one of the promising tasks.

VI. CONCLUSIONS

Based on the results of considering various options, constructive solutions have been selected that are expedient for constructing an SWTD piezoelectric applicator with focusing a shock wave in the target area and the ability to control the geometric characteristics of the focus area. The most expedient is the use of piezoelectric elements, which are elementary emitters of a phased array and fixed on a common spherical metal base.

Both water and silicone can be used as the medium for the propagation of the shock wave inside the applicator body - both options have their advantages and disadvantages, the final choice depends on the tasks to be solved and the conditions of use.

For the effective formation of a shock wave, the piezoelectric applicator of an SWT device must have a large number of elementary emitters, located rather tightly. In the considered design, the total area of elementary emitters is 61%, which is due to the shape and size of the used piezoelectric elements, the need to provide technological gaps for electrical insulation and lateral connection of conductors. In the future, taking into account the development of the technology of 3D printing of piezoelectric ceramic materials [19], [20], it is necessary to work out the issue of increasing the fill factor to 0.8 with the quasi-random placement of piezoelectric emitters and using piezoelectric elements of complex shape, which will improve the quality of control over the focus area of the shock wave [21].

It seems expedient to conduct a study of the effect of the directional pattern of elementary emitters, placed both on a spherical and on a flat base, on the geometric characteristics and energy of the shock wave in the focus area.

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