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A Comparative Study of Transducer Array Design for Ultrasound-Assisted Thrombolysis

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Abstract

Thrombosis continues to be a major cause of global mortality, primarily due to vascular obstruction by blood clots that impede normal circulation. The available therapies used for the thrombolysis are categorized into invasive and minimally invasive. However, invasive therapies may have several side effects like incomplete clot removal, risk of stroke and systemic side effects. Whereas, minimal invasive therapy i.e. ultrasound assisted thrombolysis offers a best alternative which enhances the disruption of a clot by cavitation and acoustic pressure. The required acoustic pressure for thrombolysis is 1.2 Mega Pascal (MPa). Therefore, the aim of this paper is to design an ultrasound transducer which provides the required acoustic pressure on low voltage. Hence, **COMSOL Multiphysics 6.1** software was used to design two piezoelectric transducer array linear and rectangular were

designed having array size 24x1 and 5x5, respectively. Both transducers were investigated by keeping the identical materials and operating conditions (1-5 V and 100 kHz). Hence, the results showed that linear array produced the 0.8 MPa and rectangular array produced 1.2 MPa at 5 V. Beside the acoustic pressure the focusing capability of rectangular array was more superior as compared to linear. Moreover, the rectangular array provided enhanced cavitation and mechanical stress which is preferable for the disruption of the clot. Therefore, findings suggest that the transducer geometry and voltage play a vital role in optimizing ultrasound mediated thrombolysis. Nevertheless, the rectangular array configuration can be efficient for cardiovascular therapeutic applications.

Introduction

Thrombosis is one of the leading causes of morbidity and mortality worldwide. According to world health organization (WHO), around 19.8 million deaths are because of cardiovascular diseases (CVD) in 2022. The cardiovascular diseases include myocardial infarction, arterial thrombosis, venous thrombosis, peripheral arterial occlusion and stroke [1]. All these diseases are caused by the formation of thrombi within the vascular system. The obstruction in the blood flow vessels i.e. cerebral, coronary or peripheral arteries, due to thrombus can cause necrosis and ischemia [2]. If these both conditions are not treated timely can cause irreversible organ damage and permanent disability [3].

Thrombosis can originate due to many factors but most common factors are explained by Virchow's triad theory [4]. This theory describes that thrombosis can originate due to stasis of blood flow, hypercoagulability and endothelial injury [5]. The stasis of blood flow is caused by the abnormal blood flow in the vessels that can be due to the stagnant or turbulent flow which promotes local coagulation activation. The hypercoagulability also called thrombophilia is an abnormality of blood coagulation that increase the risk of blood clots in vessels [6]. It is due to the congenital factor also refers to inborn condition. However, the thrombosis originate by endothelial injury is due to the tissue factors or subendothelial collagen which cause fibrin deposition.

In practice, thrombotic diseases are treated clinically via medicines or intervential procedures [7]. The drugs i.e urokinase and plasminogen activator (tPA) which are used to dissolves the blood clots presents many risks [8]. The challenges include the excessive bleeding, chances of stroke, and limited fibrin specificity. However, the intervential techniques like open surgical thrombectomy, angioplasty, stenting and percutaneous mechanical thrombectomy are not always effective and may lead to death [9]. Therefore, the non-invasive technique is usually followed which not only minimizes the risk but also efficient and can provide targeted drug delivery.

Lately, the acoustic thrombolysis which is a minimal invasive procedure which uses transducer to dissolve blood clots via sound waves, provides promising results [10]. In acoustic thrombolysis, a catheter is inserted at the site of blood clot which release the drug and ultrasound is applied which emits sounds waves to enhance the targeted drug delivery by mechanical effects [11] . The mechanical effect is produced by the acoustic pressure generated on the skin due to the transducer which helps in the permeation of drug at required acoustic pressure. This acoustic pressure can interact with cavities and produce cavitation effects which cause microstreaming effects that fragment the thrombi and increase the fibrinolytic efficiency [12].

Transport of drug is based on the frequency and the acoustic pressure. Transducer operating on low frequency is capable of creating microbubbles in tissue and water [13] .

In literature it us found that the cavitation bubbles produced by low frequency ultrasound allow lipid bilayer to break down and produce channels inside the bilayers. This disruption in the lipid bilayer allows stratum corneum to enlarge the pore size which facilitates the crossing of drug with large molecular weight.
It has been widely observed that single element transducer and multi element transducer produce different acoustic pressure and intensity on a given same frequency. Whereas, the multi element transducer range from linear, rectangle, curvilinear, circular etc. shapes.
The aim of this paper is to compare the linear and rectangle piezoelectric array transducer for efficient acoustic thrombolysis. The transducer array design was simulated using COMSOL Multiphysics software by keeping same operating conditions. This paper investigates the acoustic pressure distribution on the media to confirm the efficiency of transducer in cardiovascular applications.

Mechanism of Acoustic Thrombolysis

The piezoelectric transducer can enhance the thrombus dissolution by the cavitation effect. The primary mechanism behind the acoustic thrombolysis are rooted in thermal, mechanical and cavitation effect. However, these all can work in synergy to enhance the absorption.

Thermal Effect

Another important factor involved in the transmission of ultrasound waves is attenuation. It is the loss of energy when it passes through from one medium to another i.e. from tissue to muscle [14]. The loss of energy is due to the four main causes: reflection, refraction, diffraction, and absorption. However, the absorption of sound waves into the material with a high acoustic impedance i.e. bone will convert electrical energy into heat. The temperature produced by the ultrasound is also influenced by other factors too like conduction, convection, and exposure duration. Temperature increase within the range of mechanical index can enhance the enzyme activity and accelerate the breakdown of fibrin and promote clot dissolution. Whereas, increase in temperature beyond the threshold value can cause the tissue burn.

Cavitation

Cavitation is the process by which gaseous bubbles in a liquid media form, oscillate, and then collapse when exposed to a sound wave, possibly an ultrasound, given in figure 1. It has the ability to produce violent microstreams, which raise the medications' bioavailability.
Cavitation is a process which form gaseous bubbles in a liquid media, oscillates and then collapse when exposed to sound wave [15]. It occurs due to the presence of small gaseous cavities in the skin which expands and decreses due to negative pressure cycles of ultrasound. This expansion and decrese in the cavitation may disrupt the lipid bilayer and produces aqeous channels in the skin through which the drug can permeate [16].
Cavitational effects vary inversely with frequency, as the frequency increases cavitation decreses due to the smaller wavelength the positive and negative cycle of sound wave is too short which diminish the ability of dissolved gas within the meduim to diffuse into the cavitation nuclei. Therefore, the size of the cavitation bubbles is inversely corelated with frequency applied [17]. However, the low frequency can enhance the cavitation and drug transport through lipid bilayer.

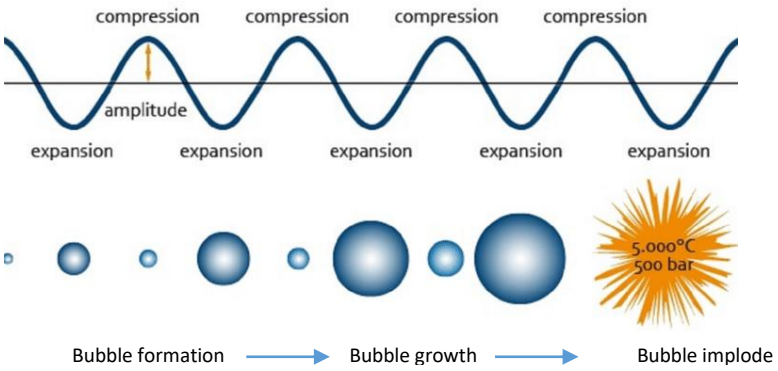

Figure 1: Cavitation due to sound wave

Mechanical Effect

The stress generated by the acoustic pressure and cavitation, stretches the vessel and deforms the fibrin network. This shear stress weakens the thrombus structure by repetative pulses. Hence, preventing the platelet aggregation and maintaining the channel for blood flow.

Influencing Factors of Acoustic Therapy

The acoustic thrombolysis depends on the piezoelectric transducer parameters and design of the transducer. The parameters includes frequency, acoustic pressure, and electric potential. However, the placement of piezoelectric elements in the transducer plays a vital role in determining acoustic pressure and creating focus beam.
The combination of frequency and acoustic pressure defines the efficiency of cavitation and mechanical action. For thrombolytic applications, frequencies typically range between 0.25 MHz and 1.05 MHz, and pressures above 1.2 MPa are required to achieve sufficient cavitation intensity [18]. Lower frequencies increase penetration depth and cavitation likelihood, making them ideal for deep-seated thrombi, whereas higher frequencies provide better focusing for superficial thrombotic lesions. The pressure must exceed the cavitation threshold but remain below the level that risks vascular rupture.

Physics of ultrasound

The piezoelectric elements present in the transducer convert electrical energy into mechanical vibrations. The vibrations produced by the transducer are transferred to the body on a predetermined path. The mechanical energy propagates into the body longitudinally in oscillations of compression and rarefaction pressure as shown in figure 1.
The produced compression and rarefaction corelates with the wavelength which is distance covered by a sound wave in one cycle from one peak point of compression to another, given in equation 1 [19].

$$\lambda = c\,f \qquad (1)$$

Where λ is the wavelength, c is the speed of sound and f is the frequency. High frequency waves have smaller wavelength. Whereas, smaller frequency's have larger wavelength which increases the cavitation in the body and penetration of drug.
Mechanical index is used to measure the acoustic power which is generated by the ultrasound. The MI can be defined as peak negative pressure divided by the square root

of the frequency of the ultrasound wave as given in equation 2 [20]. The food and drug administration reaccommodates to keep the MI below 1.9.

$$MI = P\sqrt{f} \qquad (2)$$

Where, P is peak negative pressure (MPascal) and f-frequency (Mhz).

Materials and Methods

Model Design

The transducer array simulation was carried out using COMSOL Multiphysics 6.1 software. The simulation used 3 modules namely; Electrostatics, Solid Mechanics and Acoustic Pressure in Frequency Domain (ACPR) [21]. These three modules were used to simulate piezoelectric transducer array. Among these modules, electrostatics module was used to sinusoidal input for the piezoelectric element. Meanwhile, solid mechanics was used to model backing and matching layer of the transducer to closely mimic the actual device [22], [23], [24]. The acoustic pressure in frequency domain module was used to measure the acoustic waves in the medium produced by the transducer.

Array Design

The piezoelectric transducer was designed to investigate the resultant acoustic pressure generated by linear and rectangular array configuration. The simulation was performed by keeping identical conditions in both transducer designs i.e. electric potential, operating frequency. This ensures the performance difference of the transducers are solely based on the array geometry. A transducer consists of many small elements. Each element is sandwiched between the backing and matching layer shown in figure 2. Lead zirconium titanate (PZT-5) is used as a piezoelectric element, Almunia is used as matching layer and tungsten as backing layer. PZT-5 is selected due to its thermal stability, high electromechanical coupling coefficient, and efficient energy conversion capability.

The transducer designs linear and rectangle are differed in the element placement. The linear array is designed as 24x1matrix (24 elements) with the width of 2 mm and length of 12 mm given in figure 3(a). whereas, the rectangle array is 5x5 matrix (25 elements) with width and height of 2 mm given in figure 3(b). the thickness of both designs was kept same, given in table 1. Both array designs were applied with uniform electric potential of 1-5 V (peak to peak). The selected voltage ensure the biological safe operation which lie within the range of mechanical index MI<1.9. The transducers were coupled with the skin using water gel to minimize the effects acoustic impedance mismatch and minimize reflection loss.

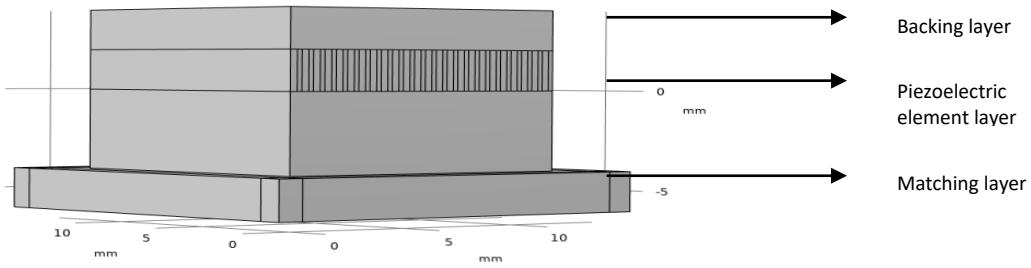

Figure 2: Transducer design (PZT elements sandwiched between backing and matching layer)

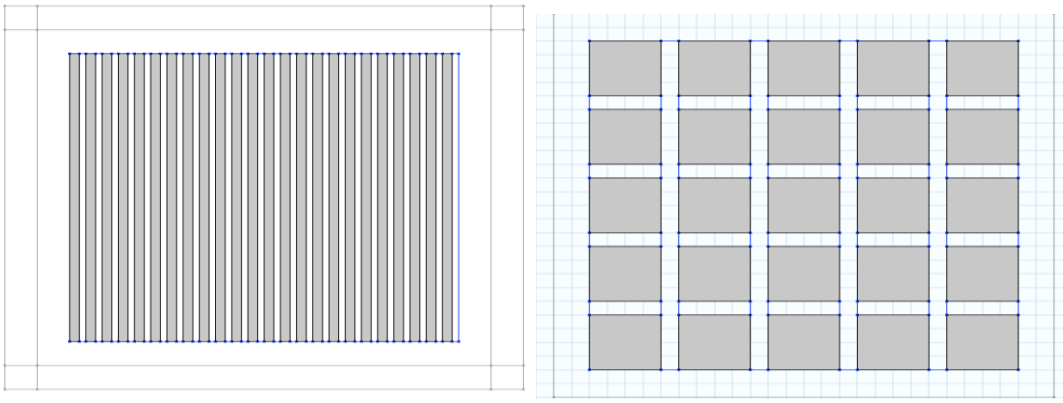

Figure 3: a) Linear array transducer (24x1) b) Rectangle array transducer (5x5)

Table 1: Array configurations and dimensions

Parameter	**Value / Description**
Linear array configuration	24 × 1
Reactangle array configuration	5x5
Element length (Reactangle) L	2 mm
Element width (W)	2 mm
Element length (Linear)	12 mm
Element thickness (T)	1 mm
Horizontal pitch (p_x)	0.1 mm
Vertical pitch (p_y)	0.1 mm
Center frequency (f)	20-100 kHz
Driving voltage (V)	1-5 V (peak-to-peak)

Material Selection Array Design

The performance of the piezoelectric transducer depends on the selection of the materials used for its elements, backing and matching layer. Each material exhibits the distinct acoustic and mechanical properties that determine signal strength, acoustic impedance etc. The material used for the piezoelectric element linear and rectangular array is PZT-5. It is widely used materials in the ultrasonic applications due to its strong electromechanical coupling coefficient, high dielectric constant and acoustic impedance. These efficient conversion of electric to mechanical energy is based on these properties which are also responsible for high acoustic pressure. The backing layer is used to dampen the propagating wave travelling backward. It reduces unwanted noise and resonance created by the soundwaves. A composite material of tungsten and epoxy is chosen for its high density and acoustic matching with the medium. It also help to strengthen the signal and ensures maximum energy transmission in forward direction. The matching layer is used to avoid the mismatch of acoustic impedance between transducer and media. Alumina maintain the structural integrity and without the matching layers, the large impedance difference between the acoustic source (about 33 Mrayls) and the target (about 1.5 Mrayls) would result in loss of transmission and receipt of acoustic energy of up to 90 percent at the interface between the source and the target. Typically, the matching layers are designed to have specific impedance values (e.g., about 15 and 3 Mrayls) and are attached to the transducer. The specification of each material is given in table 2.

Table 2. Material Specification of Piezoelectric Array Transducer

Parameter	Description	Density (ρ) (kg/m³)	Speed of Sound (c) (m/s)	Acoustic Impedance (Z = ρ × c) (MRayl)
Piezoelectric material	PZT-5	7500	4200	31.5
Matching layer	Epoxy + alumina	2600	2300	6.0
Backing layer	Epoxy + tungsten	7000	1400	9.8
Epoxy	1.5 MRayl	1200	1250	1.5

Results

The piezoelectric transducer design of both array designs showed a distinct difference in acoustic pressure distribution. It has been observed that linear array transducer produced the 0.7 Mpa when operated on 5 volts and 100 kHz frequency. Whereas, keeping the voltage and frequency same, the rectangular array produced acoustic pressure of 1.2 Mpa. The pressure distribution of linear array was less focused and more elongated which results a wider but weaker acoustic pressure. Therefore, linear array may not be suitable for the thrombolysis due to its inefficiency of producing required pressure for rapid thrombus fragmentation in deeper vascular regions.

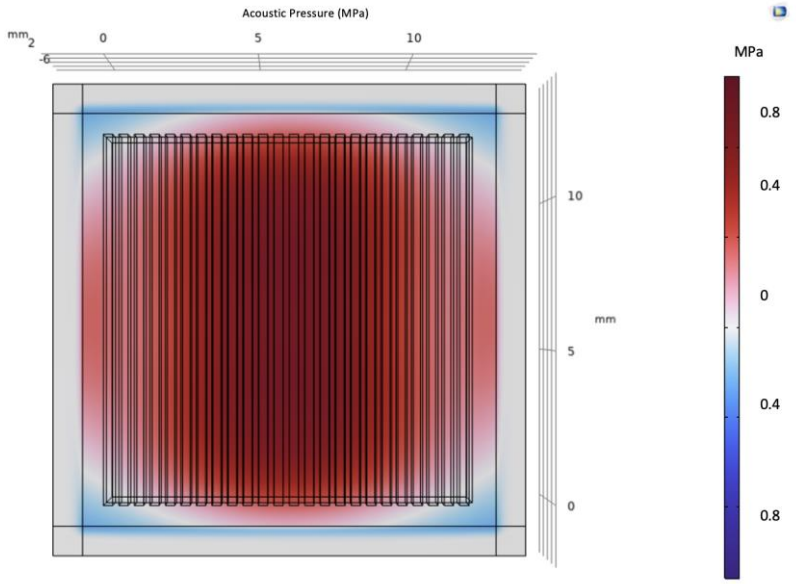

Figure 4: Acoustic Pressure achieved by Linear Array Transducer

However, the rectangular array presented a superior focusing capability as shown in figure 5. The array produced more symmetrical and on point focus at the central axis. The focus and pressure creates the likelihood of achieving required cavitation effect and disrupt the thrombolysis.

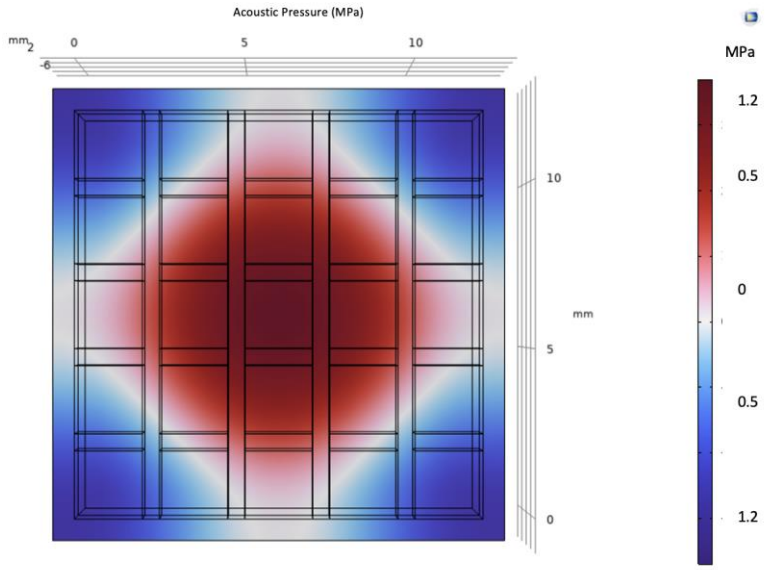

Figure 5: Acoustic Pressure achieved by Rectangular Array Transducer

The results show that acoustic pressure depend on the frequency, voltage and arrangement of the array design. As illustrated in table 3, the rectangular array is more focused and provides suitable acoustic pressure for thrombolysis.

Table 3. Comparison of Acoustic Pressure for Linear and Rectangular Array Transducers

Parameter	**Linear Array (24×1)**	**Rectangular Array (5×5)**
Operating Frequency	100 kHz	100 kHz
Applied Voltage (Vp-p)	2 V	2 V
Peak Acoustic Pressure	**0.7 MPa**	**1.2 MPa**
Acoustic Field Pattern	Elongated, less focused	Concentrated, highly focused
Cavitation Potential	Moderate	High
Suitability for Thrombolysis	Limited, for mild cavitation	Highly effective, meets 1.2 MPa threshold

For both piezoelectric transducer arrays, a direct relationship of voltage and acoustic pressure has been observed as shown in table 4. On 1 V, linear and rectangular array achieved a minimal acoustic pressure which is insufficient to generate a cavitation and disrupt the clot. Whereas, the acoustic pressure seems to be raised with the increase in voltage. on 3 V, the linear array generated the acoustic pressure of 0.5 Mpa and rectangle array 0.7 Mpa, which facilitated the cavitation. Hence, the required acoustic pressure is achieved at 5 V through rectangle array design i.e. 1.2 Mpa. Even though, the linear array on 5 V failed to achieve that pressure.

Table 4. Acoustic Pressure Generated by Linear and Rectangular Array Transducers at Different Voltages (100 kHz)

Applied Voltage (V)	**Linear Array**	**Rectangular**

	(24×1) Acoustic Pressure (MPa)	Array (5×5) Acoustic Pressure (MPa)
1 V	0.15 MPa	0.25 MPa
2 V	0.30 MPa	0.45 MPa
3 V	0.50 MPa	0.70 MPa
4 V	0.65 MPa	0.95 MPa
5 V	**0.80 MPa**	**1.20 MPa**

Figure 6, shows the comparison of rectangular and linear array on the voltage range from 1-5 volts. The linear array may achieve the required acoustic pressure with increase in voltage but that may increase the changes of burning skin due to production of heat. Therefore, rectangle array is considered as best choice for thrombolysis.

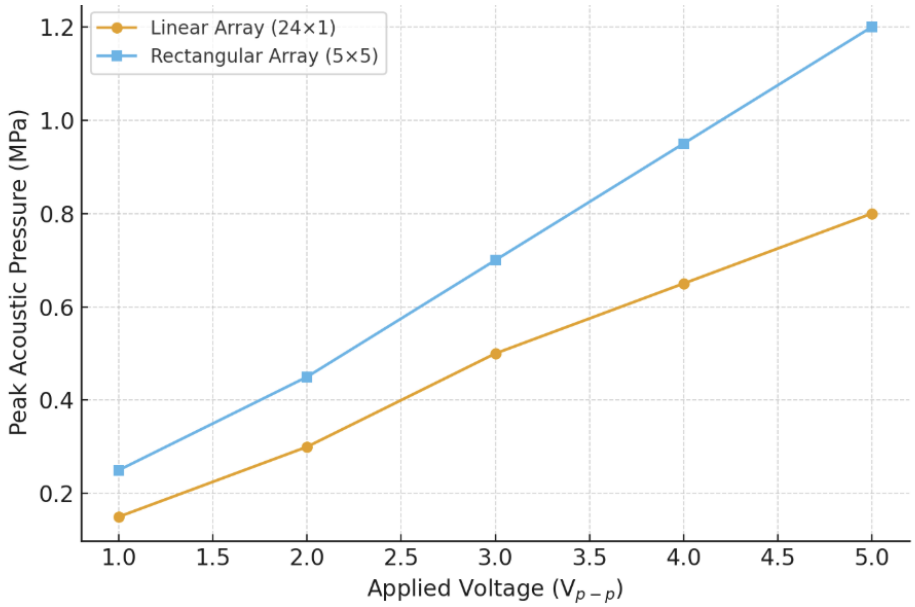

Figure 6: Comparison of Acoustic Pressure on voltage (1-5 volts)

Conclusion

This paper provides the comprehensive comparison of best suitable piezoelectric transducer array designs for cardiovascular thrombolysis. We have designed two arrays with linear and rectangular shapes consisting 24x1 and 5x5 piezoelectric elements. The transducers were simulated in COMSOL Multiphysics 6.1 software. The simulation results showed that the acoustic pressure required for the thrombolysis i.e. 1.2 MPa is achieved by rectangular array at 5 V. The achieving acoustic pressure also reduces the chances of thermal injury or collateral damage. Whereas, the linear array produced 0.8 MPa on the maximum voltage of 5 V. Hence, the rectangular array also provides the best focusing capability and also improves the fibrin disruption efficiency by minimizing the exposure to surrounding tissues. Therefore, it is concluded that rectangular array is a efficient solution for the ultrasound mediated thrombolysis. However, it was undeniable that both arrays are voltage depended, the acoustic pressure increases with the increase in voltage.

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