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Fabrication of a piezoelectric ceramic using a spark plasma sintering technique and its application for a focused ultrasound-assisted lipolysis system

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$Pb(Zr_{0.5}Ti_{0.5})O_3$ piezoelectric ceramics have been prepared using a spark plasma sintering technique and adapted for the design of a noninvasive lipolysis system, as the traditional ultrasound-assisted lipolysis system (UALS) is extremely invasive, significantly increasing the risk of morbidity and mortality. In order to transfer high sonic energy into a certain depth of skin (subcutaneous area) with minimal damage to superficial skin, a focusing acoustic wave design was developed. The self-designed UALS device was found to be very effective in destructing the adipocytes around the focused area in animal experiments. The focusing probe with bio-applicable piezoelectric materials shows great promise for future clinical applications.

Key words: Piezoelectric ceramic, Focused ultrasound, Ultrasound-assisted lipolysis, Adipocyte.

Introduction

Although ultrasound energy has been extensively used for medical imaging, surgery, and cosmetic purposes, further attention is needed in the treatment of obesity using ultrasound energy. The externally applied ultrasound is transmitted through the skin surface and focused at subcutaneous fat tissue. The focused acoustic waves break down the adipose tissue and liquefy them by ultrasound-induced heat, and then the liquefied adipose tissue can be removed by a minimal incision and subsequent aspiration or administration of a fat-absorbing drug.

Since Zocchi introduced the use of ultrasound energy for lipoplasty in 1988 [1], Fournier successfully treated patients with medium-degree obesity using ultrasonic lipoplasty in 1991 [2], and Miwa *et al*. reported stimulation of fat mobilization through a local increase in norepinephrine secretion [3]. At that time, ultrasound-assisted liposuction was one of the most commonly performed aesthetic procedures in the world. In 2007, over 600,000 liposuction procedures were performed in the United States alone, accounting for approximately 5% of all elective surgeries in the United States [4]. It is estimated that the number of liposuction procedures will more than double every 5 years.

However, the traditional ultrasound-assisted liposuction is an extremely invasive procedure. To perform the procedure, the medical tube cannula is inserted under the skin into the adipose tissue, with a pushed-pulled method in the fat region. These traumatic piston movements may damage nerves, blood vessels, as well as fatty tissue, increasing the likelihood of complications including excessive bleeding, thereby posing a significant risk of morbidity and/or mortality. Therefore it is necessary to develop a non-invasive ultrasound-assisted lipolysis system.

External ultrasound could be used as a non-invasive way of the effective removal of fat cells by focusing acoustic waves on the target adipose tissue with minimal damage to connective tissues, muscles, and blood vessels. Acoustic waves can be focused on the target tissues by either phased array transducers or a focusing lens. The former requires multiple transducers and a series of amplifiers for the focusing of acoustic waves, but the focusing depth can be modulated with ease. The latter uses one transducer and a lens for focusing, which affordably reduces the cost of the focusing apparatus, but limits control of the focusing depth of the ultrasound. Fatty cells lie under the skin at a certain depth and individual variations of the fatty cells' depths are not great. Therefore, unlike ultrasonic imaging, a capability of controlling the focusing depth is not critical for a non-invasive ultrasound-assisted lipolysis system (UALS).

The objective of this study is to design and develop a focused UALS using a single piezoelectric ceramic transducer. The $Pb(Zr_{0.5}Ti_{0.5})O_3$ piezoelectric ceramic has been prepared using a spark plasma sintering technique. The focused UALS was designed following basic optics

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theory and its effectiveness in fat removal was tested through animal experimentation.

Experimental Procedure

Fabrication of the piezoelectric ceramics

The staring $Pb(Zr_{0.5}Ti_{0.5})O_3$ powder was prepared by a conventional solid state reaction and then loaded into a graphite die (15 mm diameter), followed by a sintering process at a temperature of 950 °C with an applied pressure of 50 MPa using a spark plasma sintering technique [5]. The sintered body exhibited a fine microstructure consisting of nanometre-sized grains with a relative density of 99%. TEM analysis confirmed that the sintered body contained a very dense domain structure, showing the nanometre-sized domains even with small grains below 100 nm. Piezoelectric properties such as the electromechanical coupling factor (Kp) and mechanical quality factor(Qm) were also evaluated to be the superior to those of a conventionally sintered specimen, showing 0.53 and 560, respectively. This is attributed to the fine microstructure of the sintered body.

Design of UALS

The UALS is comprised of a probe containing a piezoelectric transducer and a focusing lens, and a peripheral electronics device to generate a high frequency sinusoidal voltage fed to the transducer. A schematic drawing of the probe is shown in Fig. 1 where three layers of the probe, piezoelectric transducer, a focusing layer lens, and a transfer layer are shown. Each layer serves a distinctive purpose. The piezoelectric layer generates vibrations transmitted through the skin and the focusing layer focuses the vibrations generated at a certain depth under the skin. The transfer layer enables the vibrations generated to be transmitted efficiently into the body, a form of impedance matching.

Performance of the UALS hinges on the effectiveness of focusing the acoustic energy generated by the piezoelectric transducer of the probe at a desired location called the focal point under the skin. The geometrical parameters of the probe affecting the focal length (D) of the probe include the width of the probe (L), the thickness of the transfer layer (h), and the radius of the circular lens (R) as shown in Fig. 2. The thickness of the focusing layer (d) has no effect on the focal length, which will be discussed later.

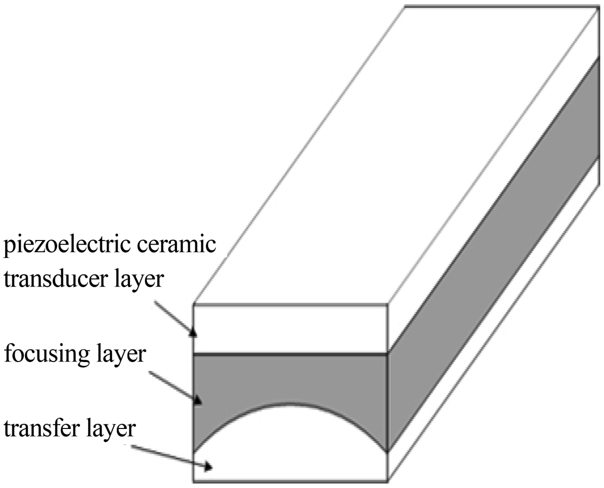

Fig. 1. Schematic concept drawing of the probe.

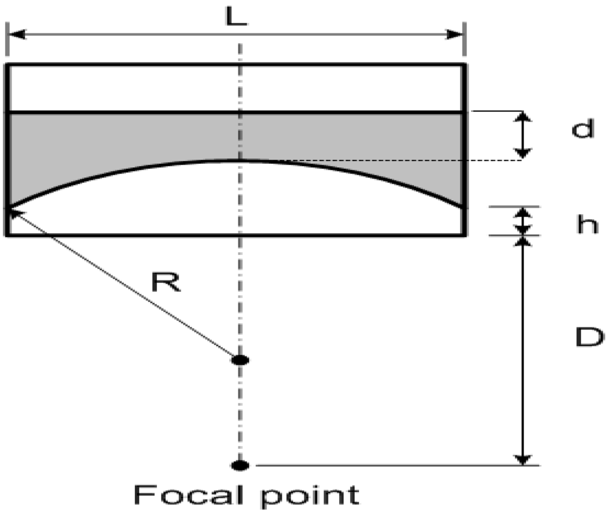

Fig. 2. The results of calculation of the equation of the sonic probe.

The ultrasonic waves transmitted from the piezoelectric transducer are longitudinal waves. Therefore, focusing of the ultrasonic waves can be achieved following the procedures commonly used in the design of optical lenses where circular lenses are employed to focus rays of light at a focal point.

The geometrical parameters of the probe can be readily obtained by applying Snell's law sequentially along the wave path P_1-P_2-P_3, as illustrated in Fig. 3.

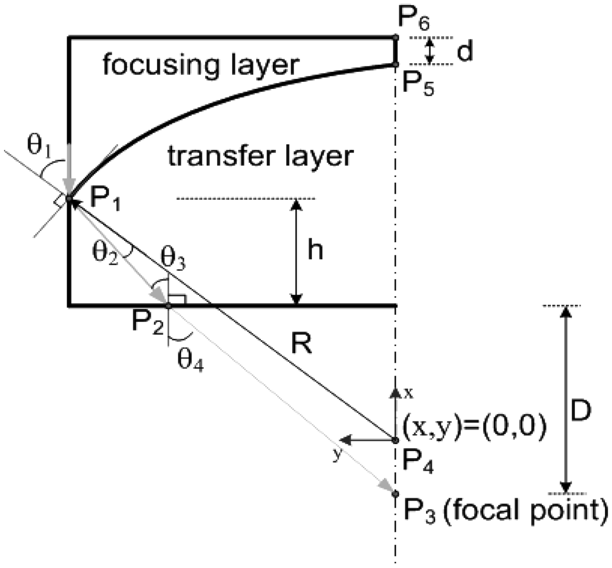

Fig. 3. Geometrical parameters of the probe by applying Snell's law.

The detailed calculation procedures of the geometrical parameters of the probe are as follows. Eq. 1 can be obtained by applying Snell's law at a point P_1 where the focusing layer interfaces with the transfer layer:

$$\frac{\sin\theta_1}{\sin\theta_2}=\frac{v_1}{v_2} \tag{1}$$

where θ_1 : the angle of incidence at P_1, θ_2 : the angle of refraction P_1, v_1 : the velocity of wave in the focusing layer, and v_2 : the velocity of wave in the transfer layer.

Based on the geometry of the probe, Eq.2 is obtained as below:

$$\sin\theta_1 = \frac{L}{2R} \tag{2}$$

Combining Eqs.(1) and (2) gives:

$$\theta_2 = \sin^{-1}\left(\frac{v_2}{v_1}\frac{L}{2R}\right) \tag{3}$$

Using trigonometry, the angle of incidence at P_2, θ_1 can be obtained as below:

$$\theta_3 = \theta_1 - \theta_2 = \sin^{-1}\left(\frac{L}{2R}\right) - \sin^{-1}\left(\left(\frac{v_2}{v_1}\frac{L}{2R}\right)\right) \tag{4}$$

Applying Snell's law at P_2 gives:

$$\theta_4 = \sin^{-1} = \left(\left(\frac{v_3}{v_2}\right)\sin\left(\sin^{-1}\left(\frac{L}{2R}\right) - \sin^{-1}\left(\frac{v_2}{v_1}\frac{L}{2R}\right)\right)\right) \tag{5}$$

where θ_4 is the angle of refraction P_2, v_3 is the velocity of the wave in the transfer layer, and v_4 is the velocity of the wave in the skin.

Let the x coordinate of the point P_1 be $x(P_1)$ and the y coordinate of the point P_1 be $y(P_1)$.

Then:

$$x(P_1) = R\cos\left[\sin^{-1}\left(\frac{L}{2R}\right)\right] \tag{6}$$

$$y(P_1) = \frac{L}{2} \tag{7}$$

Similarly:

$$x(P_2) = x(P_1) - h = R\cos\left[\sin^{-1}\left(\frac{L}{2R}\right)\right] - h \tag{8}$$

$$y(P_2) = y(P\text{-}) - h\tan\theta_3 \tag{9}$$

Therefore, the focal length of the probe under the skin, D can be obtained as below:

$$D = \frac{y(P_2)}{\tan\theta_4} = \frac{y(P_1) - h\tan\theta_3}{\tan\left[\sin^{-1}\left(\left(\frac{v_3}{v_2}\right)\sin\left(\sin^{-1}\left(\frac{L}{2R}\right) - \sin^{-1}\left(\frac{v_2}{v_1}\frac{L}{2R}\right)\right)\right)\right]} \tag{10}$$

It is noted from Eq.(10) that the focal length D is not a function of the thickness of the focusing layer d. After evaluating the physical characteristics of probe materials, the sonic probe was designed as illustrated in Table 1.

Animal experiment

An obese Zucker rat (fa/fa), 20 weeks of age and with a weight of 490 gram, was prepared for the experiment. Before the experiment the Zucker rat was administered pentothal sodium anesthesia and the dorsum of the Zucker rat was shaved. Then, the Zucker rat was fixed to the bench for the appropriate sonic apparatus attachment. (Fig. 4)

The sonic apparatus was applied for 1 hour at an excitation frequency of 850 kHz with an acoustic intensity of 0.4 W/cm^2. During the sonic irradiation, the focused target site received up to 6 times more concentrated sonic energy than non-concentrated irradiation. Immediately after the sonification, a biopsy was drawn from the subcutaneous tissue and processed for histological examination.

Results and Discussion

Through ultrasonics, we can transfer the appropriate energy from the skin down into a certain region of the human body for probing or treatment. We have already stated the purpose and importance of the focusing. Without ultrasonics, it would be difficult to send the same amount of energy into a specific region of the inner body. For example, microwaves are directly absorbed by the water content of the body, which is hazardous, light beams are reflected by the skin surface, leaving no energy for the subskin tissue, and X-ray and NMR cannot carry the energy for the body structure. Ultrasonics pose an effective technique for energy transfer to cells.

There are many different structures which appear within the skin tissues of the human body, however, we are concerned only in fat cell disruption. If the ultrasonic beam is irradiated into the human body without focusing,

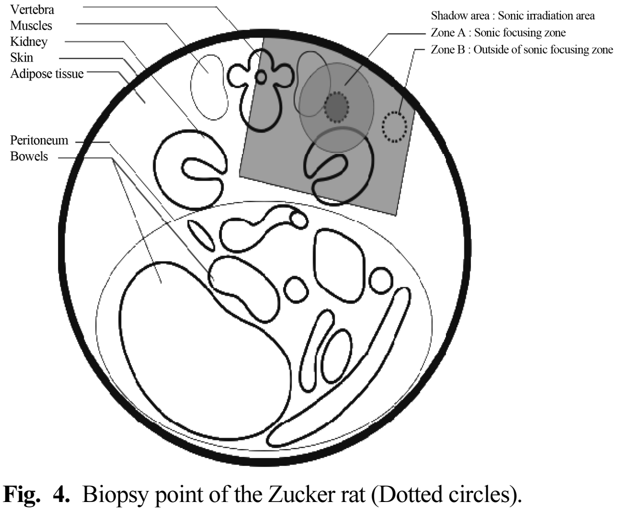

Fig. 4. Biopsy point of the Zucker rat (Dotted circles).

the major incident ultrasonic energy will be absorbed by the skin surface and the underlying tissue structure, causing permanent damage such as burnout on the skin structure, while reduced energy will arrive at the fat cells below the skin. In order to transfer the majority of energy directly into the fat cells, we need to focus the ultrasonic beam just onto the fat cells. The ultrasonic energy density depends inversely on the divergence area if we neglect the absorbance, therefore, the major portion of the incident ultrasonic energy will be onto fat cells, while a small amout of energy will be absorbed by the body structure.

Thus, we can use an ultrasonic system with moderate total energy disruption by linear focusing of the beam, where the areal energy intensity is at a safe level to use the system.

In this experiment, after sonic irradiation of tissues from 2 sites (Zones A, B Fig. 4) were obtained, a histological examination was performed. The tissue from focusing area in zone A showed massive destruction of adipocytes in the whole microscopic field. Small vessels were coagulated and adipocyte membranes were also ruptured and defragmented, as revealed with a light microscope. (Fig. 5)

On the other hand, adipose tissue from zone B showed a variable size of adipocytes with intact interstitial tissues and well preserved cell membranes, with the exception of slightly increased extracellular fluid. Zone B is the outer side of the focusing area adipocytes, expected to be exposed to weak sonic irradiation. (Fig. 6)

During the last several decades, body reshaping and re-contouring techniques have significantly advanced. The most predominant of these techniques include radio-frequency systems, laser-assisted lipolysis, and ultrasound-assisted liposuction in the case of cosmetic patients. However, traditional ultrasonic-assisted liposuction showed traumatic injury to skin, vessels, and nerves. Therefore, it is not uncommon to witness patients with fat embolism, extensive bleeding, and paresthesia, all of which increase morbidity and mortality after liposuction.

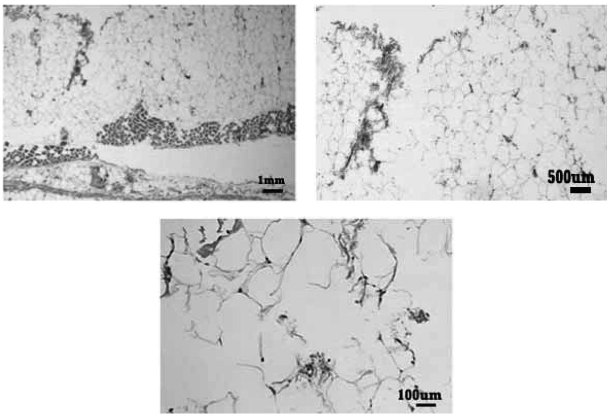

Fig. 5. Histologic images of focusing zone (Fig. 4; Zone A). Treated tissue shows massive membrane destructuin, defragmentation observed.

Table 1. Design of the Material of the Sonic Probe [6,7]

Parts	Materials	Density	Sonic Velocity (kms^{-1})
Focusing Layer	Aluminum	2.70	6.32
Transfer Layer	Acryl	1.18	2.73
Body Surface	Soft Tissue	1.08	1.54
	Fat		1.44
	Muscle		1.64

*Result of the calculation; L = 5 cm, d = 0.5 cm, R = 3.0 cm, h = 3.0 cm, D = 0.98 cm.

In addition, the international guidelines for sonic energy application limitations should be considered in the case of human application. The recommended spatial peak temporal average intensity (ISPTA) is 720 (1500) mW/cm^2 [8]. Therefore, focused UALS methods have the benefit of focusing ultrasound energy from a location external to the skin to rupture adipose cells within a subcutaneous tissue region This may minimize damage caused by invasive surgical procedures [9, 10]. Focusing sonic irradiation prevents unintentional damage of superficial skin tissue such as collagen and elastic fibers with low penetration energy. Compared to the target region, the skin surface was exposed to only one-sixth of the applied energy.

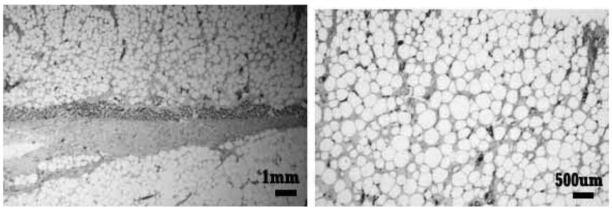

Fig. 6. Histologic images of most outer side of focusing zone (Fig. 4; Zone B). Adipocyte membranes are preserved well.

In this study, it has been shown that when concentrated near a target tissue region, focused acoustic waves effectively transfer energy to the target region, providing a safer and more effective method of destroying fat tissues than conventional methods.

Conclusion

$Pb(Zr_{0.5}Ti_{0.5})O_3$ piezoelectric ceramics have been prepared using a spark plasma sintering technique and adapted for the design of a noninvasive lipolysis system. The feasibility of the focused sonic irradiation procedure was examined in an animal experimental model. Microscopic observations of experimental results revealed that the ultrasound can destroy subcutaneous fat cells and that adipocytes are destroyed within a subcutaneous tissue region using a focused transducer disposed externally adjacent to skin. The focused transducer emits acoustic energy that is focused at a linear focal zone within the tissue region. The acoustic energy having sufficient intensity ruptures fatty cells within the focal zone while minimizing injury to adjacent areas.

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