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Development of a miniaturized low-frequency transducer for accurate placement of screw implants in the spine

Peiyang Li[1,2], Weiwei Shao[2], Tingyi Jiang[2], Zhangjian Li[2], Suoyuan Li[3], Junjie Fan[3], Liming Cai[2] , Yaoyao Cui[2*]and Jun Shen[3*]

[1]Academy for Engineering & Technology, Fudan University, Shanghai, China
[2]Suzhou Institute of Biomedical Engineering and Technology (SIBET), Chinese Academy of Science, Suzhou, China
[3]The affiliated Suzhou Hospital of Nanjing Medical University, Suzhou Municipal Hospital, Suzhou, China

Corresponding email: szshenjun@yeah.net, cuiyy@sibet.ac.cn

Abstract—**Many spinal fusion procedures require the insertion of screws through the pedicles into the vertebral bodies. The existing methods (C-arm fluoroscopy, CT imaging navigation, O-arm navigation) imaged the pedicle from the outside, which are always interfered by environmental and equipment factors. Ultrasound navigation in channel may be a potential method to avoid improper pedicle screw placement. It is reported in the literature that low-frequency (1-3MHz) ultrasound can achieve sufficient penetration depth and resolution in the bone, but the elements were too large to fit into the pedicle's bore hole. The purpose of the study was to develop a miniaturized low-frequency transducer for accurate placement of pedicle screws in the spine, and two designed methods for low frequency miniaturized transducer were modeled, fabricated, characterized and evaluated.**

Keywords—spinal fusion, pedicle screw, ultrasound navigation, low-frequency (1-3MHz) ultrasound, miniaturize, bone sonography

I. INTRODUCTION

Pedicle screw internal fixation[1] is a surgical technique widely used to operative treatment of spinal trauma, degeneration, tumor and deformity. Approximately 303,374 spinal fusion operations were performed in the U.S. in 2004 and the number increased to 800,000 in 2012— a 260% increase in the 8-year period[2, 3]. However, it is reported in the literature that the intraoperative screw misplacement rate during surgery is up to 14%-39.8% [3-5]due to the complexity of the spine morphology, limited visibility of the spine, and continuous intraoperative bleeding. The pedicle is adjacent to many vital vascular and neural structures, once the screw penetrates the pedicle to stimulate or damage these peripheral tissues, it may lead to complications such as dysesthesia, hemorrhage, neurological injury, and aortic perforation.

In order to reduce the risk of complications caused by misplaced pedicle screws and improve the success rate of surgery, various image-guided screw placement methods [6, 7](C-arm fluoroscopy, CT imaging navigation, O-arm navigation) have been widely used clinically imaging the pedicle from the outside, which are always interfered by environmental and equipment factors. Moreover, radiation exposure produced by these equipment is detrimental to the surgeon and patient's health. Ultrasound navigation[8, 9] detecting through internal trabecular of pedicle may be an potential method to avoid pedicle screw misplacement and harmful ionizing radiation. The micro-ultrasound probe is placed into the internal bone holes drilled through the pedicles imaging the peripheral walls of pedicles from inside. The integrity of pedicle screw path is real-time detected and proper orientation adjustment could be taken before screw final placement.

However, it is difficult to observe the High-frequency ultrasound through the bone due to the high attenuation in bones and the large acoustic impedance mismatch between bone and soft issue[10]. Many studies on bone sonography have shown that low-frequency (1-3MHz)[11, 12]ultrasound can achieve sufficient penetration depth and resolution in the bone, but the elements were too large to fit into the pedicle's bore hole. It is well known that the size of the high-frequency ultrasonic probe can be made relatively small, but as the frequency of the ultrasonic probe decreases, the size of the probe will gradually increase. According to the traditional transducer design theory, the ultrasonic probe with a center frequency between 1-3MHz has a size range of 3-4mm which is not include the package structure size. It is a big challenge to develop a miniaturized low-frequency transducer that can be fit into the pedicle.

As we know, Piezoelectric materials have different frequency constants under different vibration modes, for instance, the 3203HD (CTS Corp. USA) have the thickness mode frequency constant of 2.02 MHz • mm and contour-extensional mode frequency constant of 1.5 MHz • mm. The transducer working at different vibration models was analyzed by Finite Element Method (FEM). After considering the demand for miniaturization of low-frequency ultrasound transducer for spinal fusion surgery navigation, two designs of piezocomposite and ceramic transducer with different piezoelectric material, dimensions, structure and matching layers were proposed. The transducer mode of design I was initially designed based on piezoelectric material 3203HD of PZT-5H with software COMSOL Multiphysics5.4 in Fig.1.

II. Design of the Miniaturized Transducers

A. Simulation Analysis and Transducer Manufacturing

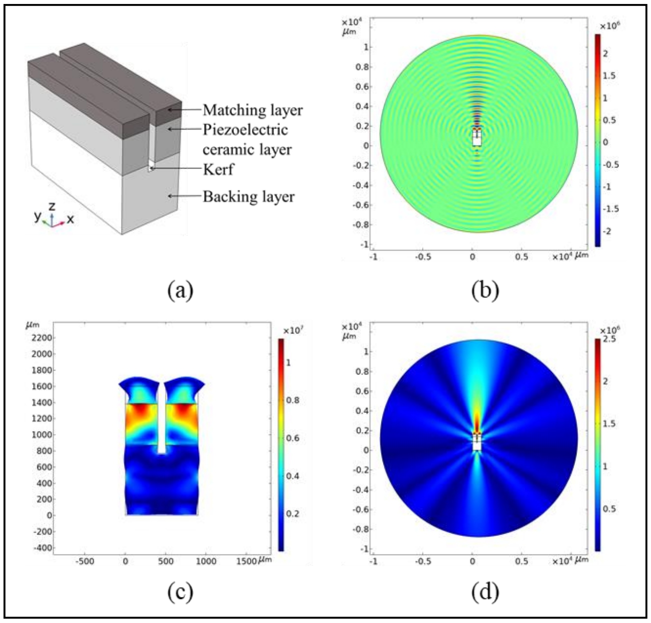

Fig. 1. Simulation moddel and analysis results: (a) Piezoelectric transducer model, (b) Total acoustic pressure field, (c) Von Mises stress, (d) Absolute pressure.

The transducer mode working at different vibration models was analyzed, and a 3MHz transducer mode was designed in Fig.1(a). The dimensions of matching layer, piezoelectric layer, and backing layer are 220μm, 510μm , 830μm respectively, the final dimension of the mode is 2 mm × 0.9mm × 1.6mm and with a kerf (wide 100μm , deep 830μm) in the middle of transducer mode. The total acoustic pressure field, von Mises stress and absolute pressure at the resonant frequency of 2MHz are showing in Fig.1(b), Fig.1(c) and Fig.1(d), respectively. The simulated analysis result revealed that their performance were mainly governed by the coupled vibration of thickness and contour-extensional vibration modes.

B. Transducer Performance

Designs I and II of transducers were fabricated using PZT5H and 1-3 Piezocomposite, respectively (see Fig. 2). Matching layer of PZT5H transducer was designed based on a one-dimensional KLM model. Composite transducer has no matching layers. Both designs had the same backing layer (12μm tungsten powder filled E-solder 3022, 1:5 by WT %) which possess high acoustic attenuation so as to eliminate the back-wall reflections and reduce the ring-down time of the transducer. The ceramic transducer (Design I) works at fusion vibration mode, center frequency 3MHz, final dimension 2 mm × 0.9mm × 1.6mm, -6 dB bandwidth of 48.26%. The composite transducer (Design II) had a center frequency 2.52 MHz, final dimension 5 mm × 2mm × 2.5mm, -6 dB bandwidth of 50.08%.

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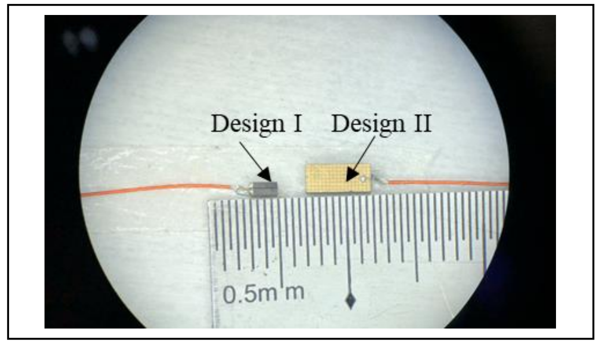

Fig. 2. Prototype photos of the two designs of ultrasound transducers

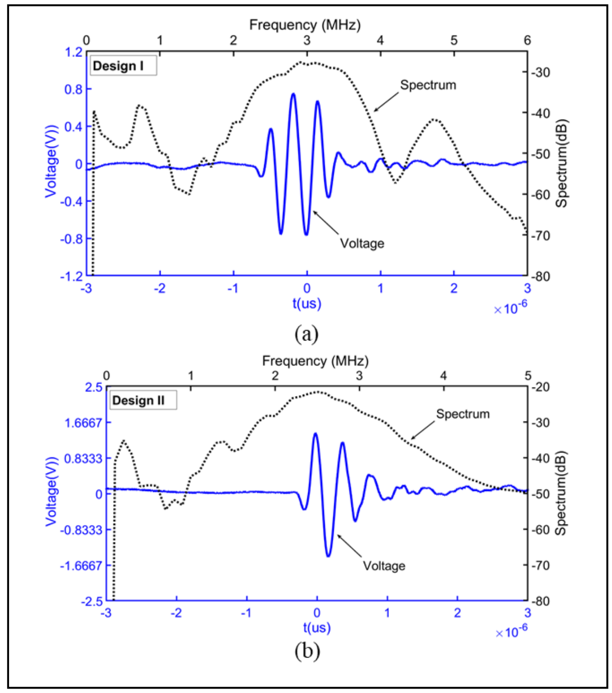

Fig. 3. Spectral and time domain analysis of pulse echo response of the two designed ultrasonic transducer.

The performance of Designs I and II of transducers were characterized by spectral and time domain analysis of pulse echo response (see Fig. 3). The pulse echo responses of both designs were measured by JSR DPR500. Experimental result of Design I (see Fig. 3(a))revealed that it's responses were mainly governed by contour-extensional mode which has the frequency constant of 1.5 MHz • mm, and the resonant frequency of piezoelectric ceramic with thickness of 510μm will be 3MHz in this vibration mode. The spectral response of design I also have the frequency components of 4MHz, i.e., the overall response of the transducer design I was also affected by the thickness mode. The design of two elements of piezoelectric ceramic will benefit higher energy output which will achieve sufficient sensitivity under the miniaturized dimensions of transducer. It is feasible to realize the miniaturization design of ultrasonic transducer by using the low frequency constant vibration mode of piezoelectric ceramic and the fusion vibration mode. The design II 1-3 Piezocomposite transducer which possess large electromechanical coupling coefficient, high sensitivity and high signal-to-noise ratio achieved excellent performance in both spectral and time domain analysis (see Fig. 3(b)). However, its final dimension needs to be further reduced for the detection in the pedicle of the spine.

III. Experiment Setup And Result

A. *Experiment Setup*

In order to verify the application of low-frequency ultrasound transducers in orthopedic surgery navigation, we initially conducted an experiment in vitro animal bone with the homemade low-frequency ultrasound transducers. In our experiments, we selected the femoral head of the swine to fabricate various bone samples. The experiment setup as the Fig.4 shows.

A circular hole with a diameter of 10mm was created on the bone model with hand-held electric drill BOSCH GBM340 (BOSCH Corp. GERMANY). In order to facilitate the experiment, the aperture of the bone model in the experiment is much larger than the diameter of the pedicle screw in the clinical spinal fusion surgery. The single-element transducer could be motor-driven to achieve 360° radial data with the motorized rotation stage (ZOLIX INSTRUMENTS CO.,LTD. CHINA), and the data acquisition system is Vantage 64 LE (VERASONICS, USA).

B. *Experiment Result*

Based on the experiment setup, we initially conducted an experiment in vitro swine bone with the homemade transducers of design I and design II. The experimental results are shown in Fig.5. The cross sectional ultrasound image of both designs can clearly image the hole drilled in cancellous bone.

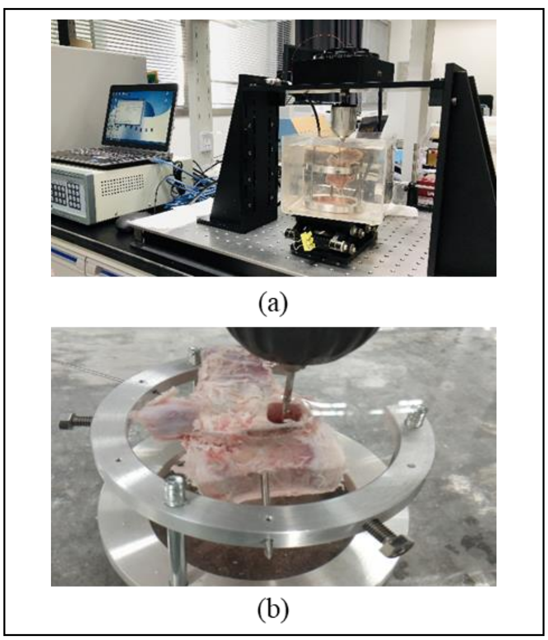

Fig. 4. Prototype photos of the two designs of ultrasound transducers

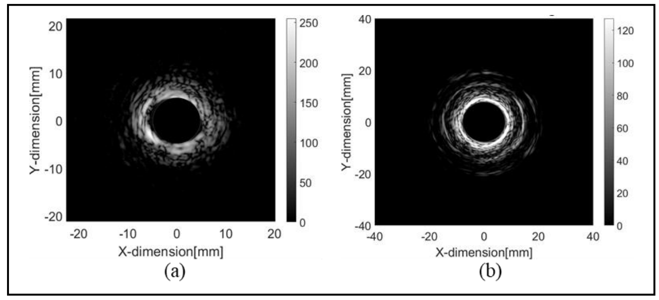

Fig. 5. Cross sectional ultrasound image of bone model in-vitro: (a) The experiment result of piezoelectric ceramic transducers, (b) The experiment result of 1-3 piezocomposite transducer.

IV. Conclution

The performances of two miniaturized low-frequency transducer were compared in simulations and experiments. Piezoelectric ceramic transducers can be miniaturized by introducing other vibration modes which have a lower frequency constant, it will facilitates the detection of small spaces, but it also brings some problems, such as the performance of the transducer is degraded, the efficiency is reduced, etc. To some extent, the design of two elements of piezoelectric ceramic will benefit higher energy output which will achieve sufficient sensitivity under the miniaturized dimensions of transducer. The composite transducer may be more suitable for bone sonography, but its final dimension needs to be further reduced. In vitro experiment, both the composite piezoelectric transducer and piezoelectric transducer can clearly image the cancellous bone, and the ultrasound images also contain some deep information of cancellous bone which needs to be further analyzed combining with CT scan results. The Piezoelectric ceramic transducers with different vibration mode will be further studied, and the dimension of composite transducer will be further reduced to fit into the smallest cervical pedicle in our future work.

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