A Catheter-Based Ultrasound Device for Treating Vascular Occlusions

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Background, Motivation and Objective

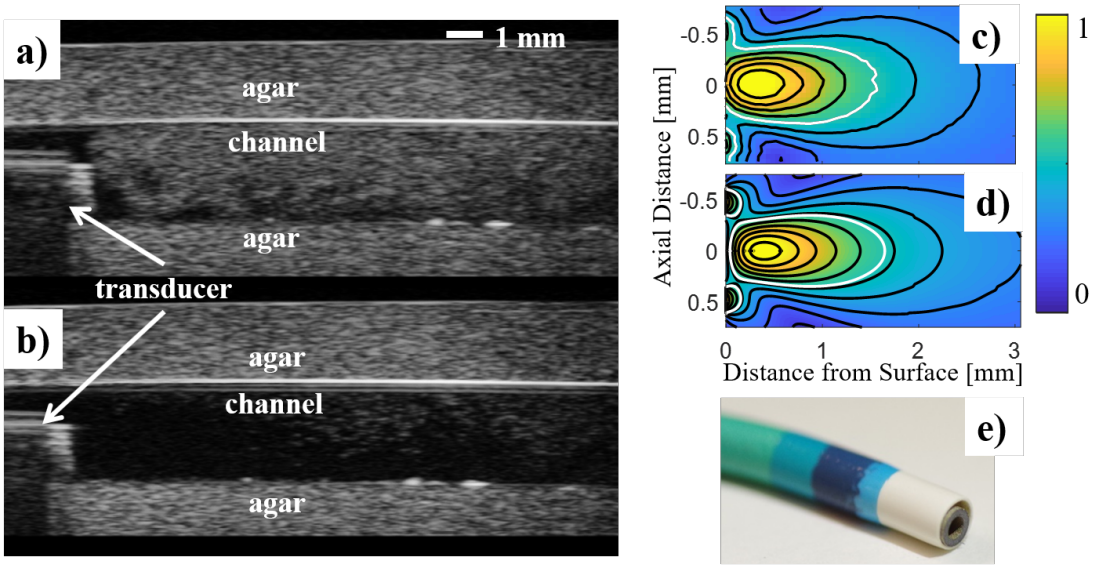
Chronic total occlusions (CTO) are thrombotic obstructions that can develop collagen rich proximal fibrous caps (PFC). Minimally invasive percutaneous (PCI) CTO revascularization is frequently unsuccessful due to the presence of stiff PFCs. The injection of collagenase softens CTO PFCs, and has recently shown favourable clinical trial results. The addition of ultrasound-stimulated microbubbles (MBs) has also shown improved performance in animals. A catheter-based transducer allowing for the delivery of collagenase, MBs and forward-looking therapeutic ultrasound has the potential to improve patient outcomes and enable procedures to be carried out in a single PCI session.

Statement of Contribution/Methods

We present a novel design that centers upon a radially polarized hollow cylindrical PZT transducer (1.2/0.8 mm outer/inner diameter, 3 mm length) situated at the catheter tip. A thin-walled metal sheath connects the electrode on the inner surface. The inner hole accommodates a guide wire to situate the tip adjacent to an occlusion, and the lumen allows for MB and enzyme delivery. Stimulation at length or radial-mode frequencies directs sub-MHz to MHz pressure in a forward-looking direction. PZFlex™ simulations assessed the effects of transducer geometry and materials on resulting acoustic fields. Prototype transducers in combination with a variable matching circuit were characterized with hydrophone scans. In vitro experiments include anthropomorphic vessel phantoms formed in agarose with collagen based occlusions. The developed experimental system combines simultaneous optical and ultrasound imaging with passive cavitation detection using an external hydrophone. A MATLAB control loop synchronizes a syringe pump and microcontroller-based pulse generator for the repeated injection of MBs followed by sonication for long-duration treatments.

Results/Discussion

Hydrophone measured pressures closely matched simulations. By exploiting higher frequency modes of vibration compared to traditional length-mode excitation, higher pressures were achieved. Peak pressures over 2.5 MPa were attainable 0.5mm from the face. Lower frequency modes showed internal cavitation behaviour limiting pressure output. Phantom experiments demonstrated the ability to introduce MBs into the vessel and then induce cavitation and destruction.



Left: Vessel phantom channel cast in doped agarose (a) after injection of MBs and (b) subsequent MB destruction after sonication (1 second duration, 0.1% duty cycle, 1.85 MHz, 56 $V_{pk\text{-}pk}$)
Right: Hydrophone (c) and simulated (d) pressure maps showing pressure distribution, (e) photo of transducer situated within catheter