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● *Original Contribution*

PRECLINICAL TESTING OF FREQUENCY-TUNABLE CAPACITIVE MICROMACHINED ULTRASONIC TRANSDUCER PROBE PROTOTYPES

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Abstract—In intracardiac echocardiography (ICE) it may be beneficial to generate ultrasound images acquired at multiple frequencies, having the possibility of high penetration or high-resolution imaging in a single device. The objective of the presented work is to test two frequency-tunable probe prototypes in a preclinical setting: a rigid probe having a diameter of 11 mm and a new flexible and steerable 12-Fr ICE catheter. Both probes feature a forward-looking 32-element capacitive micromachined ultrasonic transducer array (aperture of 2×2 mm^2) operated in collapse mode, which allows for frequency tuning in the 6-MHz–18-MHz range. The rigid probe prototype is tested *ex vivo* in a passive heart platform. Images of an aortic valve acquired in high-penetration (6 MHz), generic (12 MHz) and high-resolution (18 MHz) mode combine satisfying image quality and penetration depth between 2.5 cm and 10 cm. The ICE catheter prototype is tested *in vivo* using a porcine animal model. Images of an aortic valve are acquired in the 3 imaging modes with the ICE catheter placed in an ascending aorta at multiple depths. It was found that the combination of the forward-looking design and frequency-tuning capability allows visualizing intracardiac structures of various sizes at different distances relative to the catheter tip, providing both wide overviews and detailed close-ups. (E-mail: martin.pekar@philips.com) © 2017 World Federation for Ultrasound in Medicine & Biology.

Key Words: **Medical imaging, Intracardiac echocardiography, Capacitive micromachined ultrasonic transducer, Collapse mode, Frequency tunability.**

INTRODUCTION

Cardiovascular deaths represent 31% of all global deaths in the past few years, claiming more lives than all forms of cancer combined (Mozaffarian et al. 2016). Minimally invasive procedures have proven to be effective in improving the patient outcome while minimizing trauma and complexity of cardiac interventions. Intracardiac echocardiography (ICE) is an established guidance tool for device closure of interatrial communications and electrophysiological ablation procedures (Earing et al. 2004; Reddy et al. 2010). The exploitation of ICE for navigation during other cardiac interventions and, more importantly, its use as a diagnostic tool is currently limited by its imaging performance at a distance (Vitulano et al. 2015, p. 233, Fig. 3c) and the restricted view it typically provides (Bartel et al. 2014). Our goal is to design a steerable forward-looking catheter that can change its imaging frequency between 6 MHz and 18 MHz, allowing for high-penetration or high-resolution imaging within a single device. The forward-looking design will offer complementary views to the conventional side-looking ICE concept. The frequency tunability combined with the catheter maneuverability will allow for both navigation and detailed close-up imaging.

While the clinical review reports demonstrate the unmet need for a frequency-tunable forward-looking ICE catheter, only one description of a forward-looking ultrasound transducer array that can change its operating frequency has been published (Yeh et al. 2006). This design utilized a capacitive micromachined ultrasonic transducer (CMUT) ring array operated at 8 MHz and 19 MHz in conventional and collapse mode, respectively. The array could generate 3-D images of a wire phantom

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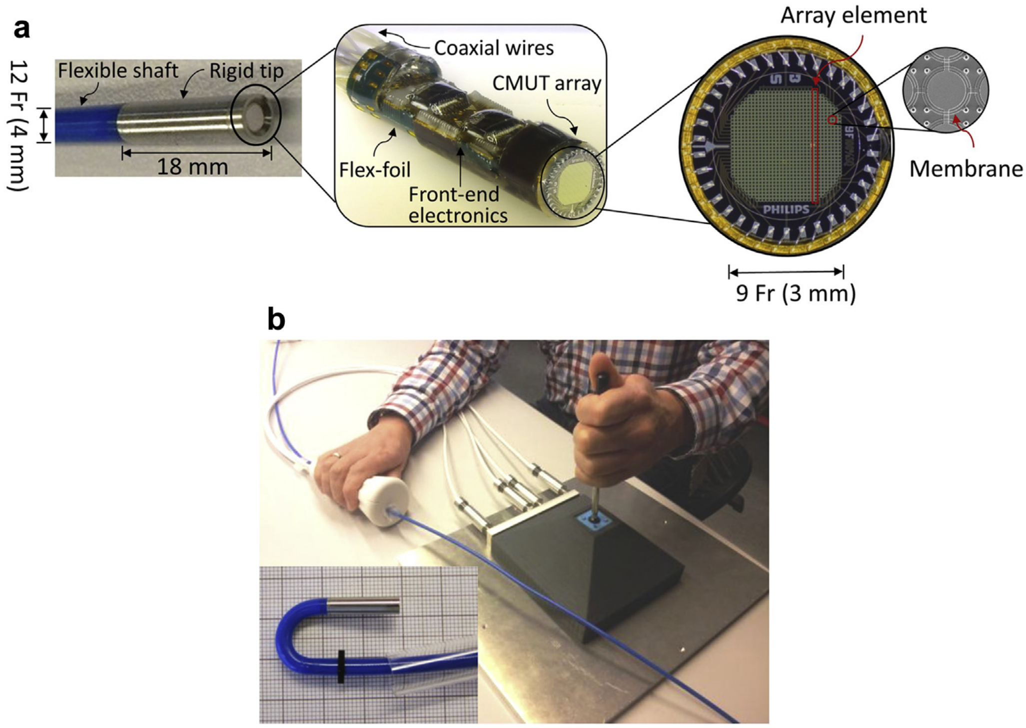

Fig. 1. (a) Assembled forward-looking catheter tip with integrated capacitive micromachined ultrasonic transducer array and front-end electronics; (b) Steerability of the catheter tip by a mechanical joystick.

in oil; however, its integration in a steerable catheter shaft and its preclinical imaging capability remains to be demonstrated.

Our design utilizes a single-type CMUT operated solely in collapse mode, which has an extra feature that allows changing its operating frequency. This behaviour is referred to as "frequency tunability" throughout a continuous range of frequencies (Pekař et al. 2017) as opposed to a discrete change between conventional and collapse mode. The frequency tunability is investigated in this preclinical study for forward-looking ICE imaging, addressing the requirement of having the possibility of high penetration (zoom out) or high resolution (zoom in).

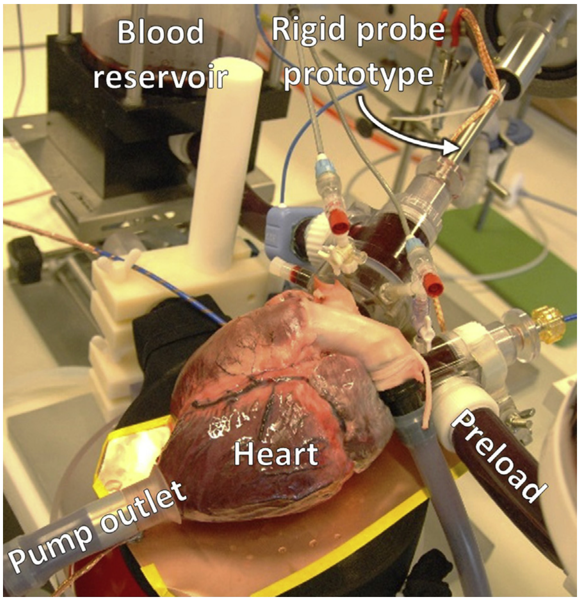

Fig. 2. Photograph of the *ex vivo* testing of the rigid probe prototype using a passive heart platform.

The principal objective of the present work is to test two frequency-tunable forward-looking probe prototypes in a preclinical setting: a rigid probe having a diameter of 11 mm and a new flexible and steerable 12-Fr catheter. The acoustic characterization of the rigid probe has been published earlier (Pekař et al., 2016). The following section introduces the development of the new 12-Fr catheter. The concept of frequency tunability is first demonstrated on 2-D images of an aortic valve in a controlled *ex vivo* setting using the rigid probe. Zoom in and zoom out capability of the developed catheter is presented in *in vivo* imaging of the aortic valve in a live animal model.

MATERIALS AND METHODS

Transducer technology

Our design utilizes a 32-element CMUT phased array operated in collapse mode Klootwijk et al. (2011), having a 9-Fr active aperture of an octagonal shape as