MR-guided trans apical delivery of a self expanding heart valve prosthesis equipped with a resonant circuit: initial experiences in a porcine model

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Introduction: Current aortic valve prosthesis comprise either glutaraledhyde preserved porcine valves that are sewed to a polyester fabric frame or mechanical valves comprising a metal ring and synthetic valve mechanisms. Percutaenous valve repair [1] makes use of balloon expanding stents with a bovine jugular vein valves for repair of the pulmonary artery [2] or self expanding (CoreValve) and balloon expanding stents with polymer valves [3]. During x-ray guided placement the positioning of the valve in the correct orientation and secure anchoring is difficult to achieve due to the lack of soft tissue contrast. The metal leads to susceptibility artifacts and RF shielding of the valves compromising diagnostic value of MRI. The purpose of this study was to improve visualization of a percutaneously implantable heart valve under MRI trough the use of a resonant circuit [4].

Material and methods: As the bioprosthetic valves show the best long-term clinical results we have selected these valves and a self expanding stent frame for the basic design. A porcine heart valve was dissected and sewed in to 24 mm x 40 mm. Nitinol stent (Memothem, Bard Angiomed Karlsruhe, Germany) with 4-0 Prolene (Ethicon). A resonant circuit was designed comprising a meandered helical coil as inductive component (8,18 µH) and a non-magnetic 30pF SMD (Surface Mounted Device) as capacitive component. The resonator was tuned to the frequency of 63.8 MHz and the wire insulated with a polyamide tube to provide an appropriate quality factor and to facilitate fixation. It was sewn with a polyfilament 2-0 polyester thread to the stent struts in a wave form to achieve controlled compression and expansion whereby the resonator functions remains. This stent valve was tested in 1.5 T Siemens Sonata and Espree. The MR tests were performed in 1 liter distilled water with 0.9% NaCl at 21° Celsius ambient pressure in a Tupper ware container (113mm x 113mm x 55mm). The container was placed in the standard head coil.

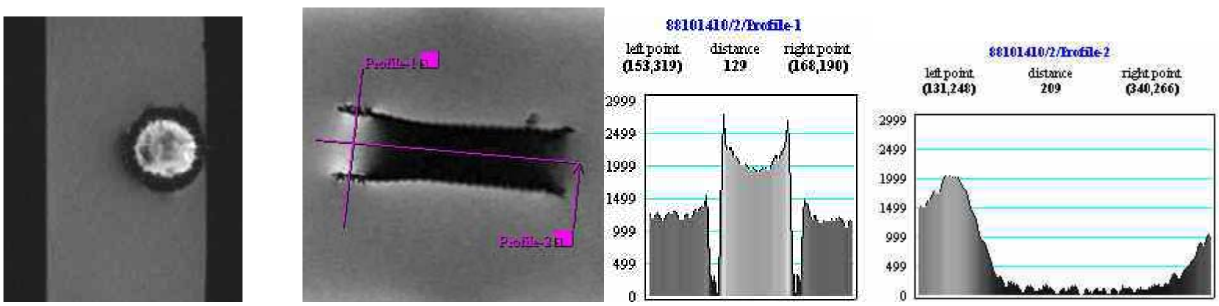

Fig 1. a-d) a transverse and b coronal MRI image (1.5 Tesla Siemens Sonata, True Fisp, TR=150ms, TE=12ms, FA=20°, FOV 180) of porcine heart valve Nitinol stent equipped with a resonant circuit (63, 8 MHz), (c and d) signal intensity profiles view through the resonant section.

The heart valve was introduced into a 13mm (inner diameter) delivery tube that was attached to a disposable MRI compatible plastic trocar sleeve used for laparoscopic surgery, Versaport Plus, Tyco. Saddle coil like resonators (tuned to 64 MHz) have been mounted to the distal end and 50 mm proximal to achieve adequate visualization in the MRI images and improve orientation in the slice plane.

The animal trial was approved by the Animal Care and Use Committee of the NIH. The valve was delivered in 80-85 kg female mini pigs under general anesthesia. The pig has been monitored via standard ECG and detection of blood oxygenation and CO2 level. Transapical approach was accomplished via minimally invasive subxiphoid midline incision. The apex of the heart was exposed and stabilized with a pericardial cradle. Two concentric purse strings of pledged 0 Prolene suture (Ethicon) were used to secure a 12 mm trocar (US Surgical)that was placed under direct vision through the apex into the left ventricle. Intracardial position was assured via realtime MRI imaging, with the operator viewing the device and heart on a projection monitor in front of the scanner. Simultaneous imaging and display of multiple planes was used to position the valve in the aorta. The real-time imaging sequence was SSFP, TR=3.4ms, TE=1.7,tip angle=45, bandwidth=800Hz/pixel, 192 x 108 matrix, even/odd view sharing, slice=7mm. During insertion three planes were imaged: coronal oblique with aortic valve in plane, sagittal and transverse oblique through the apical access site and aortic valve.

Results and Discussion:

The aortic valve could be approached with the delivery system and the expansion of the heart valve could be visualized with real-time MRI. There was a two-fold increase in signal of the resonant part of the stent. The RF shielding of the Nitinol stent could be overcome so that the substrate could be visualized using a flip angle of 20°. The signal increase facilitated MRI guided positioning. The results demonstrate that the use of a resonant structure on the stent based heart valve could minimize or avoid the negative shielding effects of the stent structure.

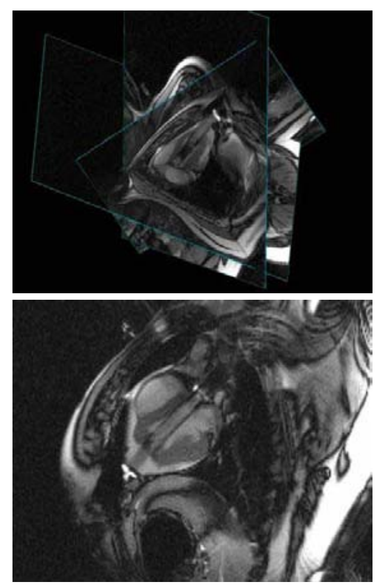

Fig 2. a, b) Realtime MRI guided trans apical aortic valve implantation.

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