Objective:

For interventional Magnetic Resonance Imaging (iMRI) dedicated MR-conditional or even MR-safe instruments are required. The guidewire is a key device for intravascular interventions. Mechanical stability and stiffness are required for navigation, while good visibility during real-time imaging is needed for optimal guidance. In addition to these demands, RF-safety is mandatory for any clinical use. We developed a passively MR-visualized guidewire (MR-GW) consisting of fiber glass compound with X-ray radiopaque jacket and hydrophilic coating. Mechanical properties of the MR-GW and resulting handling and operability in different interventional scenarios, sliding properties and visibility in both MR and X-ray were evaluated in a swine model.

Methods:

The core of the evaluated MR-GW (Fig. 1) consists of an MR-safe fiber-compound developed and produced using micro-pultrusion [1,2]. In this process, glass fibers and resin matrix material are pulled through a shaping tool where traction, lateral pressure, and heat are applied. This leads to a compound fiber with excellent flexural and torsional stiffness and improved kinking properties as compared to PEEK-based guidewires proposed previously [3](Fig. 2). At the distal part of the MR-GW a 100mm long cone-shaped Nitinol wire is attached to provide higher flexibility and to allow shaping of the tip (Fig. 1a). To improve MR-visibility, the matrix of the compound material was doped with iron at a concentration of 1% of the effective matrix mass. Additional tiny iron splints (size 50µm diameter 2mm length) are affixed along the distal 10cm of the MR-GW every 2cm, and every 5cm in the following 30cm. For protection and stabilization, a polyurethane jacket covers both, the fiber compound core and the Nitinol tip. Tungsten powder embedded within the adhesive layer and jacket is used to render the MR-GW visible under X-ray fluoroscopy while RF-safety is preserved (Fig. 1b). A biocompatible hydrophilic coating covers the jacket to reduce blood clotting and to ensure proper gliding within catheters and vessels. Overall, the diameter of the MR-GW measures 0.032'' with a length of 200 cm.

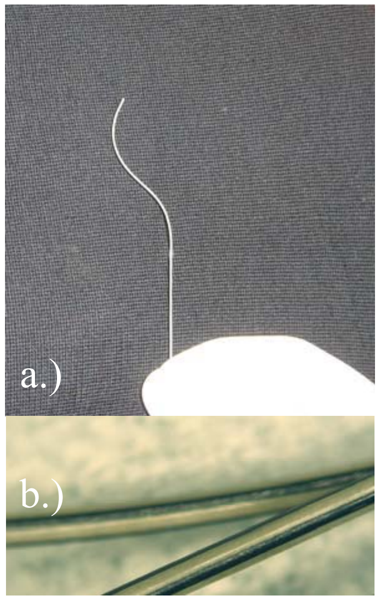

Fig. 1: a.) The MR guidewire with shapable tip section and b.)

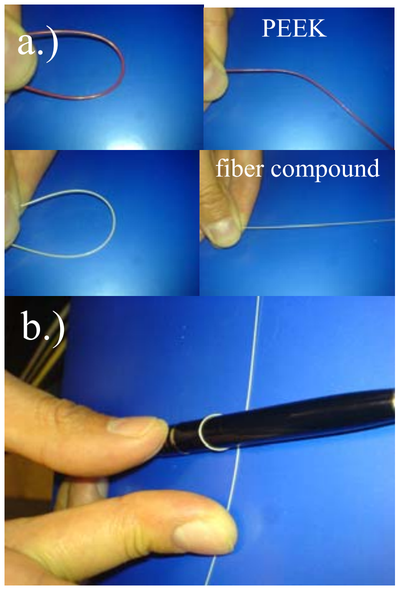

Fig. 2: a.) Kink resistance of unreinforced polymer (PEEK) vs. fiber compound material of the MR-GW. b.) 4mm radius fracture test for fiber compound material of the MR-GW.

Various interventions were conducted in 5 pigs at a 1.5 Tesla whole body MRI scanner (Achieva, Philips Healthcare, Best, The Netherlands) using a 5 element surface coil. All interventional procedures were guided using a real-time balanced-SSFP sequence (TR=2.8ms, TE=1.41ms, flip-angle=40°, Matrix 112, Field of View 320 mm, sliding window-technique 5 images per second). Arterial approach was established via an inguinal artery sheath (8 F). The MR-GW was repeatedly placed in the renal (n=30), carotid (n=10) arteries, in the left cardiac ventricle and with the aid of an ACN1 angiography catheter (Cook Inc., USA) in the contra lateral inguinal artery (n=20). The time required for each vessel and the visibility of the MR-GW were assessed.

From inguinal approach, a self-expanding Nitinol stent (Jostent SelfX, Abbott Vascular Devices, The Netherlands; 8 mm diameter, 32 mm length) was deployed into an iliac artery. Catheters were inserted over the wire into both renal arteries. Subsequently, the guidewire was removed and a small amount of contrast medium was injected through the catheter (Magnevist, Schering, Germany, 0.25 mmol in 5 ml saline). In addition, a balloon catheter was advanced into the right renal artery and filled with a MR contrast medium. A 6F Cobra angiographic catheter (Terumo, Japan) was advanced over the MR-GW into a renal segment artery. Via a coaxially introduced 3F micro catheter 0.5 ml butylcyanoacrylate (Histoacryl, B. Braun, Germany) were applied for embolization of the segment. To verify successful embolization, intravenously contrast enhanced MR-angiography was performed. Two experienced interventionalists conducted the iMRI procedures and evaluated the handling subjectively.

For the approval, RF-safety (RF heating) and mechanical tests (flexing, fracture) following corresponding norms and standards were performed.

Results:

Real time MRI enabled distinct visualization of the MR-GW by susceptibility artifacts. The induced artifacts by the iron markers (Fig. 3 left) as well as the doped core material (Fig. 3 right) of the GW could clearly be differentiated. On real time MR images, the artifacts measured approximately 2 and 5 mm. This was sufficient for depiction of the GW without precluding the orientation within the vessels and allowed accurate navigation of the MR-GW. The MR-GW was placed in the renal arteries within averagely 16 sec, in the carotid arteries within 5 sec, in the contra lateral inguinal artery within 46 sec and was successfully introduced into the left ventricle. The MR-GW allowed fast guidance of a catheter into the renal artery. After injecting CM arterially, a broad loss of signal within the kidney on real time MR images proofed the location of the catheter. After inserting the balloon catheter and expanding the balloon with a contrast agent a signal void was visible in the renal artery. A stent was deployed precisely at the pre-selected position in the inguinal artery. Embolization of segment arteries was successfully performed after catheterization of the renal artery with the MR-GW and a cobra catheter and coaxial introduction of a 3F catheter into a segment artery. The subsequent MR angiograms showed the accurate outcome of this treatment. All interventionalists assessed handling of the GW to be nearly equal in terms of stiffness, flexibility and guidance compared with a standard Nitinol guidewire (Radifocus 0.032'', Terumo, Japan).

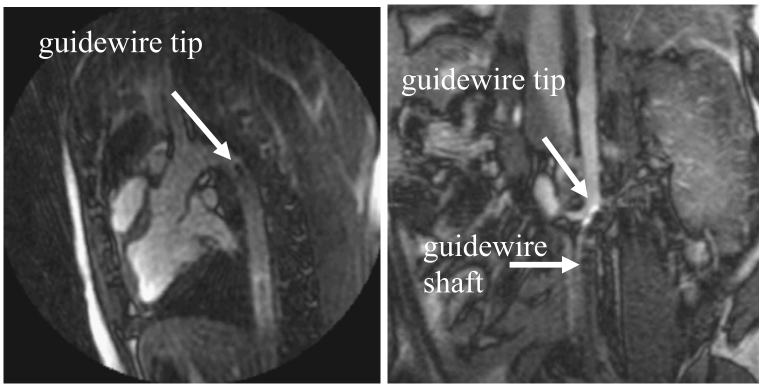

Fig. 3: On real-time MRI, the artifacts induced by the iron markings (arrowheads) are clearly visible. Additionally, the artifacts induced by the iron doped core material can be delineated.

During the RF-safety tests no RF heating was observed. The MR-GW passed the flexing and fracture tests.

Conclusion & Outlook:

The introduced MR-guidewire proved to be maneuverable and allowed for catheterization of the target vessels in all described interventions. The GW was well-visualized on real-time MRI. Moreover, it permits excellent handling characteristics that facilitate a precise and safe MR-guided positioning.

RF-safety and mechanical tests following corresponding norms and standards have been completed successfully. All remaining tests required for the approval, e.g. biocompatibility (cyto-toxicological effects, hemocompatibility) and sterilization have been initiated and results are still pending.

[1] Krueger S. et al, Proc. 6th iMRI Symp., 2006
[2] Krueger S. et al, Proc. ISMRM, (15), p291; 2007.
[3] Mekle R. et al., JMRI, 23:145–155, 2006