Evaluation of an MR-compatible guidewire made in a novel micro-pultrusion process

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Objective: MR-guided interventional procedures are gaining more attention as MR-compatible devices become available. Nitinol is the gold standard material for various interventional instruments and devices. However, nitinol is a conductor, which results in RF safety problems especially for long guidewires [1]. This work shows the usage of a 0.019" RF-safe guidewire based on a glass fiber reinforced plastics (GFRP) material made in a process referred to as micro-pultrusion.

Material and Methods: A 0.019" guidewire was produced using a novel micro-pultrusion technique (pultrusion = "pulled extrusion") using glass-fiber reinforced plastics (GFRP) materials. Recently, a carbon fiber material based on micro-pultrusion was proposed as an MR-compatible material for biopsy needles [2]. This process has been further miniaturized and optimized for using quartz fibers in an infinite process.

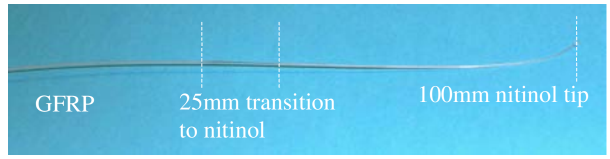

Fig.1: Tip section of the MR-compatible guidewire.

To achieve the proven mechanical properties for the tip of the guidewire, a 100mm long nitinol section was attached to the GFRP material. The two materials were joined over a shafted section of 25mm. The mechanical properties of the GFRP material were determined and compared with alternative RF-safe materials [3,4] and standard nitinol guidewires.

The GFRP matrix holding the fibers was doped with iron powder for passive visualization during real-time MR imaging using the susceptibility artifact. Additionally, discrete susceptibility markers were positioned at regular distances starting at the tip of the guidewire.

Real-time MR-guidance was performed on a 1.5T whole body scanner (Achieva, Philips Medical Systems, Best, The Netherlands) during catheterization of the renal arteries using the MR-safe guidewire and a straight 6F RF-safe actively tracked catheter [5]. The instrument handling was assessed by determining the procedure duration of ten subsequent catheterization attempts. An actively tracked catheter was chosen in order to have better visual control during catheter advancement.

Results and Discussion:

The flexural modulus of the material was measured as 20GPa, thus being 10 times stiffer than PEEK (<u>P</u>oly<u>e</u>ther<u>e</u>ther<u>k</u>etone). The shafted section provided a high stability and a smooth mechanical transition.

The average procedure duration of ten subsequent left renal artery catheterizations (guidewire placement and catheter advancement, branching angle at aorta = 63°) was determined as 39s (±7). Fig.2 (a, b) shows real-time MR images of the guidewire in its final position inside the kidney and the advancement of the straight RF-safe active catheter. Fig. 2c shows the signal gain due to administration of gadolinium contrast agent.

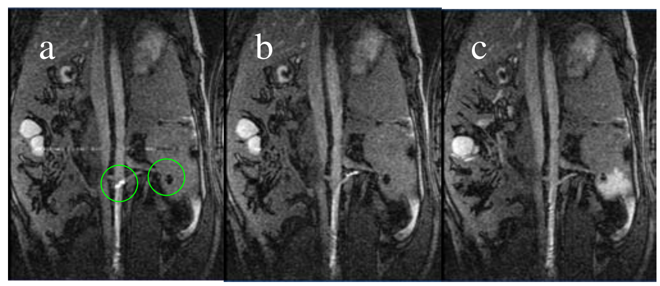

Fig.2: a.)b.) Catheterization of the left renal artery. The green circles indicate the position of the tip coil of the active catheter and the position of the guidewire tip artifact. c.) Administration of gadolinium contrast agent.

The guidewire maintained its mechanical properties and its straight shape and showed no obvious differences in handling after residing inside the animal for more than 30min, which proves the thermo-set characteristics of the material. The shafted transition section to the nitinol tip did not show any signs of damage after more than one hour of intravascular manipulation.

Catheterization of the right renal artery (branching angle = 82°) without an appropriate guiding catheter was not successful.

Conclusion and Outlook: An MR-safe guidewire was used successfully in a pig study for renal artery catheterization. The performance of the instrument relies strongly on the mechanical properties of the GFRP pultrusion material, which provides a high stiffness at body temperature. The material may have the potential to serve as a mechanical basis for a variety of RF-safe interventional instruments. Currently, an RF-safe snare is under development (Fig. 3) and will be tested in future animal studies. Other applications of the material may reside in an MR-compatible braiding to control the stiffness of catheters or MR-compatible pull wires for steerable devices.

Different thermo-set matrix materials to further improve the mechanical properties and the stability of the micro-pultrusion process are currently under investigation.

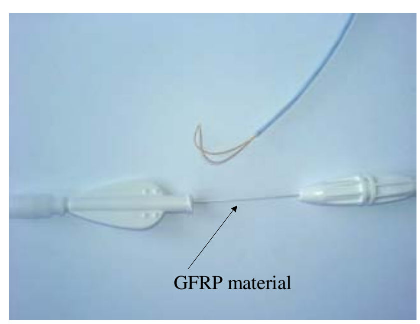

Fig.3: MR-compatible snare using a GFRP control wire.

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