Development of a stiff MR-compatible and MR-safe catheter guidewire

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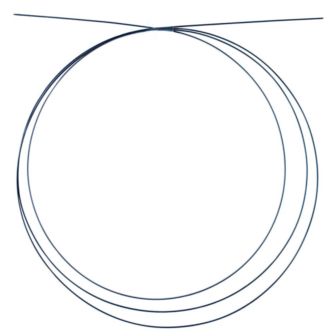
Introduction

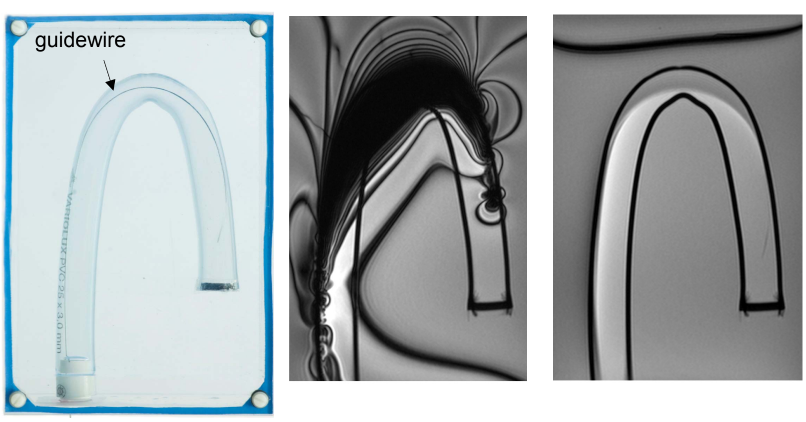
MR-guidance of minimally invasive procedures such as Transluminal Aortic Valve Implantation (TAVI) or implantation of aortic stent-grafts has relevant advantages compared to conventional x-ray based imaging. Implementation is still limited due to the absence of stiff MR-compatible and MR-safe guidewires. Available guidewires with necessary stiffness have an electrically conducting steel core and are at high risk of heating up tremendously due to RF resonance. The investigation shows an approach to develop a completely metal free (MR-compatible) and non conducting (MR-safe) guidewire with 0,89 mm (0,035“) in diameter and mechanical characteristics comparable to a reference guidewire with a stiff stainless steel core.

Development

To provide sufficient stiffness, structures made of carbon fiber reinforced plastics (CFRP) are an option to substitute metallic materials. Different wire structures of CFRPs were investigated to find a compromise between maximum stiffness and kink resistance. A structure was developed having 85% of a 0,035“ steel guidewire`s bending stiffness and even higher resistance to plastic deformation. Within ideal elasticity a minimal bending radius of 25 mm was achieved while the steel guidewire began plastic deformation already at 40 mm radius. However, although investigated carbon fibers have a 30 times lower electrical conductivity than stainless steel, an RF-resonance provoking phantom test setup at 1,5 T showed relevant heating of the CFRP-prototype-wire. Even sparks at the tip were observed, leaving the first prototype to be no safety improvement compared to the steel guidewire which showed similar effects under identical conditions. Modification of the carbon fiber alignment within the structure, however, eliminated the precondition for RF-resonance and therefore the root cause for heating. Testing of a modified wire structure under identical parameters showed no heating anymore and no sparks at the wire tip. To enable safe advancement in vessels a flexible atraumatic and metal free guidewire tip was developed and integrated. Further, a PTFE-coating was applied to minimize friction in the vessel and to ensure biocompatiblity. Phantom tests at 1,5 T in a NaCl-solution-filled model of an aortic arch in NaCl-gel proofed easy advancement of the developed guidewire through the arch aswell as great improvement in considerably reduced susceptibility artefacts.



Prototype of CFRP-guidewire, ∅0,85mm



Phantom tests with a NaCl-filled model (left) of an aortic arch. A conventional steel guidewire (middle) and the devolped CFRP-guidewire prototype (right) were advanced separately through the arch. The steel guidewire provokes strong artefacts whereas the newly developed guidewire is nearly artefact free. Both wires were investigated under identical parameters.

Conclusion

This investigation demonstrates the feasibility to design a metal free MR-compatible and MR-safe catheter guidewire with a high bending stiffness approximating (85%) a conventional stiff stainless steel guidewire. Further optimization of materials and methods is expected to raise stiffness even more.

Thus, this approach to design a guidewire could be suitable to enable sophisticated procedures such as TAVI and several other procedures in need of voluminous catheters to be safely performed under MR-guidance.