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Development of an artifact-free aneurysm clip

Concept and approach for the development of an aneurysm clip entirely made from fiber-reinforced plastic materials

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Abstract: For the treatment of intracranial aneurysms with aneurysm clips, usually a follow-up inspection in MRI is required. To avoid any artifacts, which can make a proper diagnosis difficult, a new approach for the manufacturing of an aneurysm clip entirely made from fiber-reinforced plastics has been developed. In this paper the concept for the design of the clip, the development of a new manufacturing technology for the fiber-reinforced components as well as first results from the examination of the components in phantom MRI testing is shown.

Keywords: aneurysm clip; artifact-free; CFRP; fiber-reinforced plastics; intracranial aneurysm; PEEK; pultrusion.

1 Introduction

Intracranial aneurysms are congenital or acquired bulges of cerebral arteries, presumably caused by local defects at the branching of basal cerebral arteries [1]. The surgical management of such aneurysms by the application of aneurysm clips is a well-established procedure in neurosurgery. With those clips the aneurysm gets clamped off in order to exclude them from bloodstream and thereby avoid life-threatening cerebral bleedings. The aim of this procedure is to totally occlude the aneurysm, while preserving flow in the involved vessels. Postoperative diagnostic is mandatory to detect possible objectionable results such as incomplete occlusions or neck remnants [2]. Materials in conventional clips, e.g. titanium, cause artifacts in Magnetic resonance imaging (MRI). Those artifacts considerably exacerbate the diagnosis of the aneurysm and the surrounding tissue. Therefore, in postoperative diagnosis often invasive examinations with catheters or examinations which go along with radiation exposure as in X-ray computed tomography (CT) have to be performed instead.

In order to allow for an artifact-free imaging and at the same time meet the mechanical requirements of the clip, innovative materials are required. Fiber-reinforced plastics (FRP) face these requirements by the combination of different fiber and matrix materials, so that highly customized components can be designed especially for the intended usage. For the precise and patient-friendly diagnosis using MRI imaging, fiber-reinforced plastics are unrivaled to other materials, as they show no spurious artefacts, show excellent mechanical properties and have good biocompatibility characteristics [3]. First attempts with hybrid solutions containing metal based springs and carbon fiber reinforced yaws did not find their way into clinical application [4].

However, the biggest challenge and obstacle up to now to actually use fiber-reinforced plastics in implants like aneurysm clips is the development and manufacturing of miniaturized, biocompatible and high strength fiber-reinforced profiles at the required level of complexity.

2 Material and methods

There are several types of aneurysm clips on the market, which have been analyzed according to the possibility to substitute the used metallic materials by fiber-reinforced plastics. The type of clip shown in Figure 1 was selected, as it shows both advantages for the manufacturing and for the application during surgery. The differential design of the clip offers the possibility to use different processes for the manufacturing of the spring and the jaws.

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Figure 1: A state-of-the-art aneurysm clip made from titanium by Peter Lazic GmbH, Tuttlingen.

Also, the exploitation of the load-optimized fiber-reinforcement can be increased by a part-wise manufacturing of the clip.

In terms of the application, this type of clip allows a better sight into the surgical field by an opening from the inside out. Also, the opening of the clips is very wide in comparison with other types of aneurysm clips [5].

Figure 2 shows the concept for the design of the clip and the used manufacturing processes for the components. A continuous fiber-reinforcement has to be used for the spring, to achieve the required spring tension. For the jaws, reinforcement with short carbon-fibers is used to enable the manufacturing of complex structures such as the brackets for the forceps or the atraumatic structuring of the jaws. In addition, different types of jaws can be easily manufactured without changing the general design.

Following this concept, a small, unidirectional fiber-reinforced rod is manufactured, which is subsequently formed to a helical torsion spring. The forming step requires a thermoplastic polymer, as only this class of polymers allows the subsequent melting and re-shaping. The jaws are manufactured in an injection molding process using short carbon-fiber reinforced plastic. The assembly of the clip is done by plastic welding.

The material for both the spring and the jaws was chosen to be carbon-fiber reinforced PEEK, because of its very high mechanical forces, especially in terms of bending stiffness and strength and the possibility of a subsequent forming. It also shows no artifact in MRI and the biocompatibility for implants is proven [6].

3 Approach

The approach for the manufacturing of the spring is the use of the micro-pultrusion technology. Pultrusion is a process for the continuous and automated production of unidirectional fiber-reinforced profiles. It has been miniaturized at Fraunhofer IPT for manufacturing diameters down to 200 µm and has been successfully applied for the manufacturing of medical devices, such as fiber-reinforced puncture needles, catheters and guide wires [7].

Pultrusion allows the highest possible mechanical properties in terms of bending stiffness and strength by a consistent alignment of the fibers in axial direction only and a very high fiber-volume content of up to 80%. As the load case in a helical torsion spring induces mainly bending forces on the profile, pultrusion is an applicable manufacturing process for the wire. However, only thermoset polymers are currently suitable for miniaturized pultrusion processes, which have the major drawback for the use in the clip, as they cannot be melted and re-shaped after curing. Also, only a few thermoset polymers suitable for FRP are certified for biocompatibility standards [8].

The biggest challenge of processing thermoplastic polymers such as PEEK in the micro-pultrusion process is

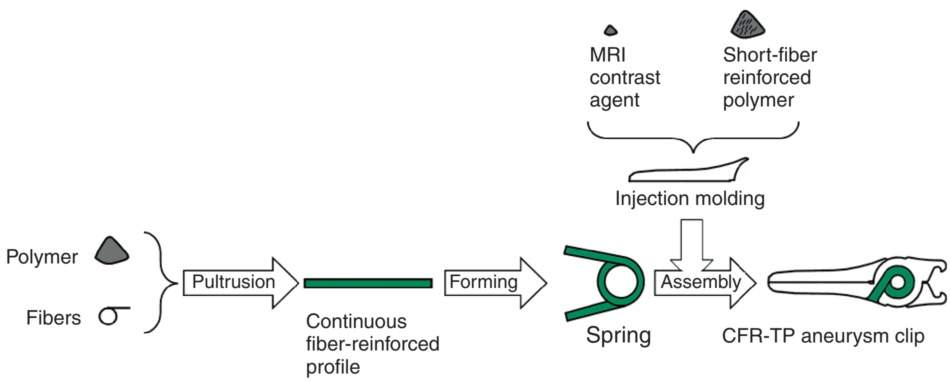

Figure 2: Concept of manufacturing an aneurysm clip using only thermoplastic fiber-reinforced components.

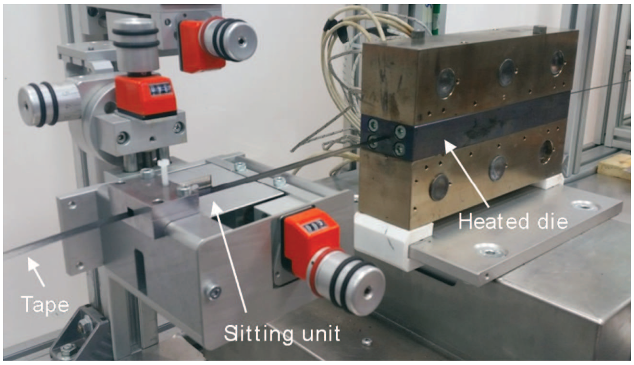

Figure 3: Pultrusion unit for the manufacturing of the FRP rod.

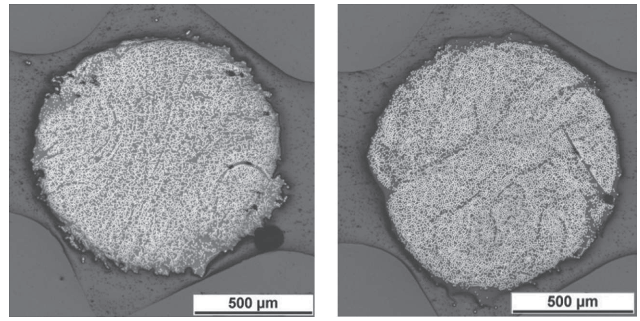

Figure 4: Pultruded micro-profiles made from PEEK/CF (left) and PA12/CF (right).

Figure 5: Helical torsion spring made from unidirectional reinforced PA12/CF.

the high melt viscosity of the matrix material, which makes a proper impregnation of the fibers difficult and requires high processing temperatures and pressures. The chosen approach is the processing of pre-impregnated materials, so called prepregs or tapes, instead of separated fiber and matrix materials. Using this principle, the impregnation and consolidation step is done already by the tape manufacturer and does not have to be realized within the used equipment. One drawback of using tapes for pultrusion is the very high costs for the materials compared to the prices of the raw materials [9]. As only small amounts of material are processed for the production of the spring element, this disadvantage can be neglected.

Figure 3 shows the machine setup, which was developed and built up during the project. Tapes with a rectangular cross-section are slitted to the correct dimension and pulled through a heated forming die, where they perform a continuous forming process to realize the desired geometry.

After the manufacturing of a FRP rod, a thermoforming step is required. For this, a small test rig was built up to investigate the feasibility of the process.

4 Results

Using FEM-simulations it could be shown that the bending stiffness to achieve the required clipping force can be achieved by using a micro-profile made from carbon-fiber reinforced plastic with a diameter of around 1.1 mm. At the same time, the opening of the jaws can be realized by the use of a helical torsion spring with a multiple number of turns.

In first trials, small rods with a diameter of 1.1 mm were manufactured, using tape material of PA12 and PEEK, continuously reinforced with 55 vol.-% carbon fibers. The analysis of the manufactured profiles showed a homogenous fiber distribution and high fiber volume content. The mechanical properties were in the same range as the used tape material. Figure 4 shows microscopic images of the cross-section of the pultruded profiles.

In further trials the forming of the profiles was investigated. For a first analysis of the feasibility, a heated pin was used, where the pre-heated profiles were bent around manually. The result of this manual winding of a PA12/CF rod can be seen in Figure 5. A winding diameter of 3 mm using a rod with a diameter of 1.1 mm could be achieved with a satisfying quality of the profile.

Spring samples made from PA12/CF were tested in water solution via three Tesla MRI (Skyra, Siemens, Germany). MRI was performed including the following sequences: T2 in the axial plane [repetition time (TR) of 7.300, echo time (TE) of 88, slice thickness of 2 mm] and coronar plane (TR of 8.600, TE of 91, slice thickness of 1.5 mm), T1 in the coronar plane (TR of 600, TE of 12, slice thickness of 0.7 mm).

The evaluation of the MRI images showed only minor artifacts caused by small air bubbles at the sample surface (Figure 6). No difference in image quality between the different number of windings was seen in the MRI. Overall a clear delineation of the profile to the surrounding water was possible.

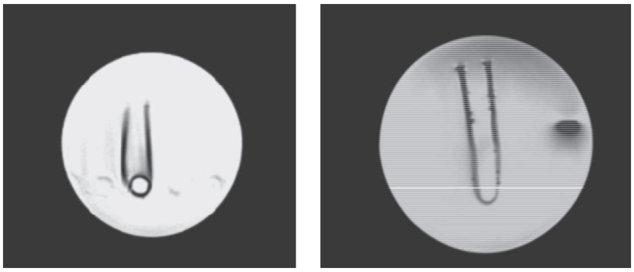

Figure 6: T2 images of PA12/CF springs with different winding numbers.

5 Discussion

For the development of an artifact-free aneurysm clip entirely made from fiber-reinforced plastics, a concept has been developed, which allows the manufacturing of the components using different and especially designed production processes. The concept takes all the different requirements for the clip into account, such as mechanical forces, small size, wide opening of the jaws, biocompatibility and visibility in MRI.

A new process for the continuous manufacturing of miniaturized rods made from thermoplastic FRP using pre-impregnated tape material could be established. The required system technology has been developed, built up and put into operation. Sample rods using carbon-fiber reinforced PA12 and PEEK show the possibilities of the process. Based on the results of the manufacturing process, all kinds of thermoplastic polymers, that are available as tape material, can be processed with the developed technology. Also, the diameter of the profiles can be further reduced.

The feasibility of a thermoforming of the profile in the required dimensions could be shown. The forming of PA12 profiles has shown decent results, whereas the forming of PEEK profiles requires some deeper investigations of the process. The assembly of the clip using plastic welding was not investigated yet.

The MRI investigation revealed the required absence of artefacts as expected. *In vivo* investigations for more detailed analyses including breathing artefacts and contrast agent enhanced imaging are currently in progress.

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Author's Statement

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