MICRO-PULLWINDING – AN AUTOMATED PRODUCTION TECHNOLOGY FOR MEDICAL DEVICES

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Abstract
This paper shows the development of an automated production technology for MRI-safe medical devices made from fiber-reinforced plastics. To meet the requirements for minimal invasive medical devices, the new micro-pullwinding technology has been developed. This technology allows the adjustment of tensile, bending and torsional stiffness and strength of miniaturized fiber-reinforced profiles independent from each other. It allows to vary the stiffness along the length of the profile without interrupting the process. This manufacturing technology was developed, built up and tested by the Fraunhofer Institute for Production Technology IPT in Aachen, Germany. A guide wire based on a profile made with the micro-pullwinding technology was developed in cooperation with industrial partners and medical experts. The performance of the guide wire regarding the mechanical properties, visibility in MRI and usability was successfully investigated.

1 Background
Fiber-reinforced plastics (FRP) cannot only be used for lightweight production, but are also perfectly suitable for medical applications because of their anisotropic material properties and the wide range of available fiber and matrix materials.

Out of the various applications of FRP for medical devices there are some examples that use the advantages of fiber-reinforced plastics in particular. Prosthetic implants like total hip replacements are typically made of metallic or titanium alloys. But the high difference in the stiffness of bone and the implant leads to a reduction of the bone density around the implant. Because of Wolff’s law healthy bone will remodel in response to the applied loads. Therefore, if the load on a bone decreases, the bone will become less dense and weaker because there is no stimulus for continued remodeling that is required to maintain bone mass. The effect is called “stress shielding” and leads to a loosening of the prosthesis and weakening of the bone structure.

When fiber-reinforced plastics are used for the design of an implant, the inner structure and the mechanical properties can be precisely adjusted. Therefore stiffness and load transmission properties are much more similar to the bone than metal alloys or other isotropic materials. It has been shown, that with hip prostheses made of FRP high loads can be taken and stress shielding effects can be avoided.

The same advantages can be used for the surgical treatment of bone fractures. Trauma implants like nailing or plating systems made of FRP are lightweight, can take high loads and show good damping properties. Furthermore, fiber-reinforced plastics cause no artifacts in medical imaging like CT or MRI, so these materials are even more suitable for the use in implants [1]. The advantage of artifact-free imaging make FRP products to a superior material choice for medical products used in minimal invasive surgical interventions.

This form of surgical interventions has been established in the last twenty years and is today widely used for all kinds of interventions. Unlike open surgery, which requires a long incision, minimal invasive procedures are performed through
one or more small incisions. For most patients, this leads to significantly less postoperative pain, a shorter hospital stay, faster recovery and, in some cases, a better overall outcome. Minimal invasive surgery may also allow more people, some of whom might not be candidates for open surgery, to undergo surgical repair.

Minimal invasive interventions can be performed to treat a wide range of diseases: Vascular extensions (e.g. of the coronary arteries or kidney arteries), the placement of stents, tumor related embolization of the kidney arteries and many other surgeries. For all of these interventions imaging techniques are required to navigate the instruments through the body.

The imaging techniques used for such interventions are currently based on X-rays. But for many procedures Magnetic Resonance Imaging (MRI) provides far better images, due to the more detailed representation of soft tissues than with X-Ray based imaging methods like digital radiography or CT. Additionally, there is no harmful radiation exposure to patients and medical staff. This is of particular importance for the treatment of pregnant women and children and has already provided pediatricians with new therapeutic options.

As the basic principle of MRI imaging is based on strong magnetic fields, metallic materials cause image distortions in MRI, may become hot or even get attracted towards the magnet field. Many state-of-the-art instruments for minimal invasive surgery consist of metallic components and are therefore not suitable for the use in MRI.

As can be seen in the example in figure 1, a conventional steel needle creates an artifact in MRI imaging that distorts the image around the needle and makes it impossible to navigate properly. This artifact, known as susceptibility artifact, occurs as the result of gradients in the magnetic field strength occurring near the interfaces of substances of different magnetic susceptibility. The imaging result is a bright and dark area with a spatial distortion of the surrounding anatomy.

When a non-metallic instruments is used while MRI imaging, such as a carbon fiber reinforced (CFRP) puncture needle, no susceptibility artifact or any other distortion is visible, which makes the instrument perfectly to navigate.

To use MRI imaging during minimal invasive interventions the development of new MR-safe surgical instruments is required [3].

![Fig. 1. Comparison of a conventional metallic puncture needle and a CFRP puncture needle under MRI imaging [2].](image)

Fiber-reinforced plastics are suitable for designing minimal invasive medical devices because they combine high specific mechanical stiffness and strength, defined chemical, electrical, and magnetic properties, as well as biocompatibility and full compatibility for all imaging methods including MRI.

For the manufacturing of such miniaturized medical devices made of fiber-reinforced plastics, Fraunhofer IPT has developed a continuous and automated production process, the micro-pultrusion technology.

Whereas the dimensions for profiles manufactured with state-of-the-art pultrusion machines are between a few mm up to several cm, Fraunhofer IPT focuses on the pultrusion of miniaturized profiles. Diameters down to 200 micrometers can be manufactured using the equipment at Fraunhofer IPT. Especially for minimal invasive medical devices low diameters are necessary [4, 5]. Examples for these devices are puncture needles, catheters or guide wires used in MR-guided interventions. Figure 2 shows the cross-section of a glass fiber reinforced profile made by micro pultrusion used as body material for a guide wire.
Due to the hexagonal packing density the highest possible fiber volume content using the pultrusion technique is ca. 90% (see figure 2). The fiber volume content that can be reached with the micro-pultrusion process is more than 80% and thus nearly as high as possible (see figure 3).

By reducing the diameter of the micro-pultruded profiles, a totally new set of challenges emerges, requiring the development of a substantially new process technology. The process forces of the micro-pultrusion process are mostly generated by the friction of the profile surface in the die. As the cross-section is a function of the square of the radius and the surface is a function of the radius, the ratio of the cross-section to the surface area decreases with decreasing diameter. Therefore the number of filaments in the profile that have to bear the surface friction forces is significantly lower than in standard pultrusion processes (see figure 4). The optimization of the process parameters for micro-pultrusion is even more important compared to state of the art pultrusion [4].

Fig. 3. Cross-section of a micro-pultruded glass fiber reinforced profile

Several medical devices for minimal invasive interventions have been developed at Fraunhofer IPT using this technology. Among other devices, a glass fiber reinforced guide wire has been designed, manufactured and tested in preclinical and first-in-man studies [6]. Guide wires (see figure 5) are used as a guide for subsequent insertion of stiffer or bulkier instruments like catheters into a confined or tortuous space.

Fig. 4. Relation of profile diameter to surface of a micro-pultruded profile

Fig. 5. Glass fiber reinforced guide wire

To allow an optimal guiding through the body, the guide wire has to show different mechanical properties over its complete length. The distal tip has to be soft and flexible to avoid perforations of the vessels, but the proximal end has to be stiff to allow a precise guiding and to take up the forces that are applied by the user. Because profiles manufactured with the pultrusion technique cannot have different mechanical properties along the length, the FRP guide wire made by micro-pultrusion faces these requirements by connecting a stiff FRP profile with a flexible tip made from nitinol [7].
2 Methods

Because guide wires are used as disposables, a more automated manufacturing process is required. The manual assembly of the stiff FRP profile with the nitinol tip is not cost-effective enough to gain a benefit over commonly used products. The mechanical properties of the developed guide wire were sufficient, but not superior to state-of-the-art products. Due to the manufacturing process that only allows one direction of the fiber orientation, there were certain limitations in the design of the body.

To manufacture the body of the guide wire in one process with the possibility to adjust different mechanical properties along the length (i.e. to avoid a second assembly step), a new manufacturing technology based on micro-pultrusion, the micro-pullwinding technology was developed by Fraunhofer IPT.

The pullwinding process is a combination of the pultrusion and filament winding technique. Fibers are pulled from a roving unit through a resin bath and a die comparable to the pultrusion process. The pultruded profile is then wrapped and consolidated with additional layers of fibers in winding units. By the additional layers the mechanical properties of the profile can be enhanced significantly to profiles produced using the micro-pultrusion process [8]. Figure 6 shows the principle of the pullwinding process.

There are two main advantages of the pullwinding technology in general:
First, the possibility to adjust the mechanical properties of the profile by variation of the fiber orientation within the different layers.
Second, the possibility of changing the layer structure during the continuous manufacturing process. When the rotation of the winding units is continuously accelerated and the pulling speed remains constant, the angle of the wound fibers becomes higher. Therefore it is possible to produce a profile with changing winding angles and changing the mechanical properties in a continuous process.

For the manufacturing of minimal invasive devices a new micro-pullwinding system was built up at Fraunhofer IPT (see figure 7). According to the miniaturizing of the pultrusion process the same challenges had to be considered for the development of the micro-pullwinding system. A precise force measurement for each of the tools is integrated to optimize the process. With the developed system multidirectional reinforced micro-profiles with diameters down to 500 µm with a line speed of up to 2.3 m/min can be manufactured fully automated.

As the system is designed to produce profiles for medical devices, some additional features are required. The pullwinding system is therefore
equipped with a laminar flow system, which establishes cleanroom conditions with the help of a laminar air flow from the top of the system. A database which records all the process parameters is required for a consistent documentation of the manufacturing process.

3 Results

The Fraunhofer IPT is developing an innovative MRI-safe guide wire using this micro-pullwinding technology. The possibility to adjust tensile, bending and torsional stiffness independent from each other and to vary the stiffness along the axial length of the profile, allows the design of a guide wire with optimized mechanical properties. The avoidance of ferromagnetic material qualifies the guide wire for MRI, ultrasound and X-ray imaging.

Figure 8 shows the design of the guide wire. The pultruded core (1) provides the minimal bending stiffness along the complete length. The wound layers (2 and 3) provide the torsional stiffness as well as additional bending stiffness. Furthermore the breaking strength is significantly improved by these layers as well. To provide the same high torsional stiffness in both rotational directions, which is necessary for a proper steering of the wire through the body, two layers with inverted winding angles are wound around the core.

The required medium bending stiffness and high torsional stiffness along the wire is in this set-up achieved with winding angles of ca. +45° / -45° around the pultruded core. At the distal tip of the wire a low bending stiffness is required, so the wire can be navigated at junctions of vessels with a reduced risk of perforation. The so called “floppy tip” is achieved by a high winding angle to adjust the lowest bending and torsional stiffness and hence the required flexibility for a navigation without any trauma.

During the development of the guide wire the processing of different fiber materials such as carbon fiber, glass fiber or aramid fiber as well as different winding angles have been investigated. Figure 9 shows the combination of different fiber materials and winding angles. Carbon fiber (core material in left picture) is electroconductive and cannot be used in MRI-guided interventions due to alternating magnetic fields which could heat up the material. The middle picture shows the profile with core and wound layers made from aramid fibers, which provides a very good flexibility but not the required bending stiffness. Using a combination of glass fibers for the core and aramid fibers for the wound layer leads to the best mechanical properties: The high tensile strength of the glass fiber provides a high basic stiffness of the profile. The ductility of the aramid fiber allows to wind very small diameters and provides the required high torsional stiffness of the profile. As glass fibers are very susceptible to buckling, the wound layers also provide a protection in the case of accidental breakage of the core.
To investigate the influence of the winding angle on the mechanical properties, bending and torsion tests were performed. The test results (see figure 10) show the significant increase of the shear modulus and the decrease of the tensile stiffness when the winding angle is increased.

![Graph showing the dependency of tensile and shear modulus on the winding angle.](image)

Fig. 10. Dependency of tensile and shear modulus on the winding angle

Figure 11 shows different segments of the same guide wire, where the different winding angles can be seen. The winding angle at the distal end is around 60° (upper picture), which is the highest possible angle for this set-up. The maximum winding angle depends on diameter and used roving types. The winding angle at the proximal end of the wire is around 45° for the highest torsional stiffness (bottom picture).

![Image showing different wound segments of a guide wire.](image)

Fig. 11. Body material of the guide wire with different winding angles

As the basic fiber-reinforced polymer is not visible in MRI, special markers are applied on the guide wire to control the visualization characteristics during the imaging (see figure 12). Superparamagnetic iron oxide nanoparticles are applied on the body material and show small susceptibility artifacts, which are used to locate the position of the guide wire. Those markers have to be applied in defined intervals and different concentrations to identify both the shaft and the tip of the wire. It is crucial that the artifacts of the markers don’t overlap the surrounding tissue but are also visible at all times.

The markers are currently tested in real-time MRI, ultrasonography and X-ray.

![MRI image of guide wires with different markers.](image)

Fig. 12. MRI-image of guide wires with different markers

The basic material of the guide wire with the applied markers is treated with a hydrophilic and biocompatible coating for low-friction navigation through the catheter and the vessels.

4 Interpretation

With the transfer of the advantages of state-of-the-art pullwinding technology to a miniaturized pullwinding system a new production technology for minimally invasive medical devices has been developed. As an example for the use of this technology in medical applications a MRI-safe guide wire with tailored mechanical properties has been developed. Different types of this guide wire were manufactured and are currently reviewed by clinical experts and shall also be tested in animal experiments.
The results of mechanical tests of the guide wires manufactured by micro-pullwinding show, that the developed technology allows not only to increase the tensile modulus of miniaturized FRP profiles significantly, but also allows the variation of torsional stiffness and strength independent from the bending properties by varying the winding angles. The exact influence of the winding angle variation on the bending stiffness has to be investigated further, but the test results already show the possibility to achieve the desired low bending stiffness at the distal tip of the guide wire. Further investigations for the adjustment of the characteristics of the guide wire are currently performed.

Process investigations have shown that there are still challenges in the precise adjustment of the winding angle. Deviations from the adjusted angle during the process have been found. A possible reason for these deviations could be slip effects in the pulling unit. The pulling speed is not constant and therefore the winding angle varying. With the integration of a line speed measurement system the rotational speed of the winding units could be controlled by this measurement output and the deviation could be reduced. Also the tolerances for the cutting unit at the end of the pullwinding system could be improved.

During the investigations of different winding angles it has been found, that the surface of the wire is smoother the higher the winding angle is adjusted. When the highest possible winding angle is set, a very smooth surface with a tight circular runout tolerance is achieved (see figure 11, upper picture). When the winding angle is reduced to 45° or lower, gaps between the wound fibers appear due to the limited number of rovings that can be placed into the winding units. By increasing the number of rovings that are placed into the winding units to the maximum, the width of the gaps could be reduced. In addition to that, first test has been shown, that a second impregnating process following the regular production process improve the surface quality, as gaps are filled with resin and small roundness deviations are equalized.

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References