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In patient care in orthopaedic technology workshops, the use of fibre-plastic composites with continuous fibre reinforcement has become indispensable due to the good properties of the material. However, the use of conventional textile semi-finished products such as woven fabrics is usually associated with a large amount of material waste and high manual effort. Using generative manufacturing processes, by contrast, offers significant process- and material-specific advantages for orthotic design. In a series of joint research projects between the Leibniz-Institut für Polymerforschung Dresden e. V. and various research partners, the potential of the tailored fibre placement (TFP) process is therefore being investigated and further developed for application-oriented process chains in orthopaedic technology.

Key words: orthotics, tailored fibre placement, generative manufacturing

Introduction

In recent decades, fibre-reinforced plastic composites (FRP) have made the leap from high-performance applications, e.g. in aerospace, to applications directly related to the end user [1]. However, the full potential of the reinforcing fibres, which have so far mostly only been used in the form of textile semi-finished products such as woven or undirectional weave fabrics, is often not fully exploited. In addition, the use of these semi-finished products is mostly associated with a high level of manual manufacturing work and a large amount of material waste. On the other hand, by using the "Tailored Fiber Placement" (TFP), generative manufacturing process, process-specific and material-specific advantages for prosthesis and orthosis construction can be exploited much better. At the Leibniz-Institut für Polymerforschung Dresden e. V. (IPF) in cooperation with other project partners, the potential of the TFP process is being further developed with regard to application-oriented and novel process chains in orthopaedic technology, among other areas. The focus of the efforts is also the goal of providing smaller orthopaedic workshops with direct access to this still young technology with high application potential.

The Tailored Fibre Placement Process (TFP Process)

The Tailored Fibre Placement (TFP) process was developed in the early 1990s at the Leibniz-Institut für Polymerforschung Dresden e. V. as a process for the near-net-shape and variable-axis filing of reinforcement fibre bundles (so-called rovings) [2]. The process, which today can be counted among the generative manufacturing processes for so-called textile preforms, can not only be used for rapid prototyping applications. It is already being used for the serial production of a large number of sophisticated lightweight components: TFP-produced FRP components can already be found in the aerospace industry (e.g. on the window frame of the Airbus A350; Fig. 1a), in mechanical engineering, in the sports and leisure goods industry (prototype "Lightweight rec° 16"; Fig. 1b) and in the field of furniture construction (prototype "Lightweight stool L1"; Fig. 1c).

A key advantage over the use of dry textile semi-finished products based on woven fabrics, undirectional weaves or prepregs made from them is that the corresponding reinforcing fibres (e.g. made of carbon) can be placed more precisely in terms of position and fibre orientation, and in a repeatable manner. Offcut quantities, which typically occur when cutting fibre mats, can thus be reduced to a minimum. In addition, active yarn guidance enables the reinforcement fibres to be fixed in curved paths. On the one hand, this so-called variable-axis fibre filing enables the direct creation of complex geometric shapes; on the other hand, the anisotropic (direction-dependent) material properties of the individually deposited rovings can be optimally adapted to the mechanical stresses of an FRP component. This allows the lightweight potential of the composite material to be exploited in a unique way [3].

The TFP process itself is based on the use of modified industrial embroidery machines. By means of a CNC control (CNC = Computerised Numerical Control), complex fibre courses can be produced automatically along a lay-up pattern that was previously defined by means of Computer Aided Design (CAD). In contrast to other additive manufacturing processes, such as 3D printing with continuous fibre reinforcement, almost any type of reinforcement fibre – e.g. made of glass, basalt, carbon or polymers, dry or as thermoplastic hybrid yarn and/or thermoset towpreg (pre-impregnated roving) – can be used in different fibre

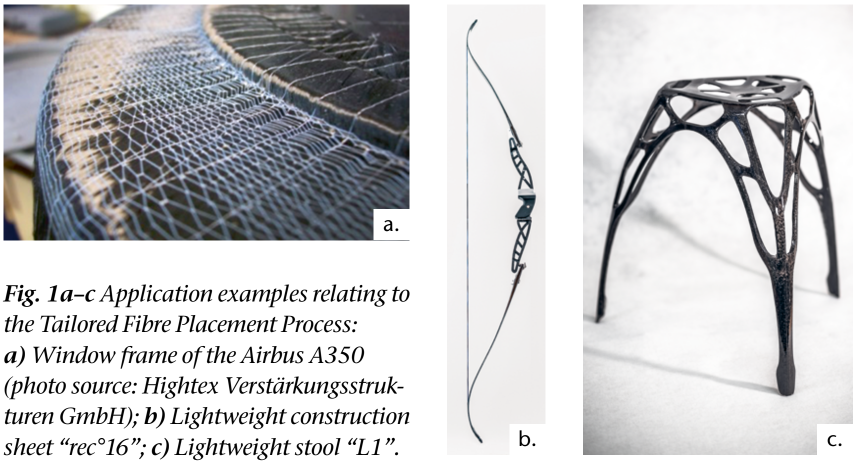

Fig. 1a–c *Application examples relating to the Tailored Fibre Placement Process:* ***a)*** *Window frame of the Airbus A350 (photo source: Hightex Verstärkungsstrukturen GmbH);* ***b)*** *Lightweight construction sheet "rec°16";* ***c)*** *Lightweight stool "L1".*

bundle thicknesses. The reinforcing fibres are sewn onto a freely selectable backing material by means of a thin upper or lower thread in a zigzag stitch (Figs. 2a and b). The use of low-thickness sewing threads ensures that the deposited fibre material is only slightly undulated and thus a reduction in the effective mechanical characteristic values is kept as low as possible. The textile weave – also in contrast to 3D printing with continuous fibre reinforcement – enables the TFP preforms to be formed without any problems and in turn, thus enables the production of sophisticated, spatially curved FRP components. This property, in conjunction with a very high productivity for generative manufacturing processes (through the use of TFP lay-up machines with multiple lay-up heads (Fig. 2c)), makes it of high interest for a variety of lightweight construction applications.

The TFP preforms, which are primarily produced using dry fibre material, can be easily infiltrated using already established vacuum infusion or injection processes and then consolidated using both cold and hot curing.

The potential of TFP technology for orthopaedic applications

In the field of orthotics, there are wide-ranging requirements for the components used, based on both the needs of the patient and the medical indications. In contrast to the application in prosthetics, where it is often a matter of creating static containers or the stable connection of modular components, orthotics has quite different demands on one and the same product. This is because, on the one hand, orthosis requires partially elastic areas that are partially and asymmetrically loaded in high load cycles and, on the other hand, rigid partial areas that have to absorb the forces that occur and thus compensate for muscular and structural instabilities. As a rule, the production of an orthopaedic component takes place by means of an individual plaster or milled PUR foam model. This can be generated either by hand or by CAD. For manufacturing an acrylic orthosis, there are various methods to choose from.

Classically, carbon fibres are used in many components due to their excellent mechanical properties in orthopaedic technology. Glass and polymer fibres, e.g. "Kevlar" and "Dyneema", only play a subordinate role, even if individual properties are particularly recommended for partial use in technical fittings. Very often, classic resin infiltration of the fibres is applied by means of gravity or vacuum support, whereby dry laid fibre mats are used. This is a technology that is universally known and used in orthopaedic workshops. In recent years, however, the prepreg process has also become increasingly established, with which very light and highly resilient components with a relatively high fibre volume content can be produced using pre-impregnated fibre mats [4].

Especially when it comes to the functional fitting of the upper limb, popular 3D printing processes such as Multi-Jet Fusion (MJF) or Selective Laser Sintering (SLS) are currently often used. Here, the advantage of an end-to-end digital workflow can be exploited, especially with regard to very filigree and multifunctional components. However, in the production of orthoses for the lower extremities, which are usually subjected to significantly greater loads, the 3D printing plastics that are used very quickly reach the limits of their mechanical load-bearing capacity. As a result, orthoses produced with this method have excessively high wall thicknesses, which has a negative impact on both patient compliance and component mass. Even with the further development of the fused deposition modelling (FDM) process with continuous fibre-reinforced thermoplastics, it is not yet possible to produce components with complex, spatially curved

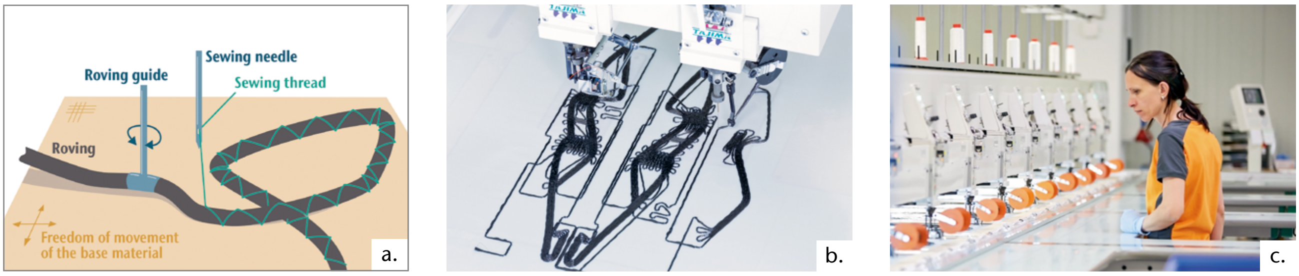

Fig. 2a–c *Tailored Fiber Placement Process (TFP):* ***a)*** *Sketch of the basic principle;* ***b)*** *real preform manufacturing;* ***c)*** *Industrial TFP plant with several laying heads (photo source: Hightex Verstärkungsstrukturen GmbH).*

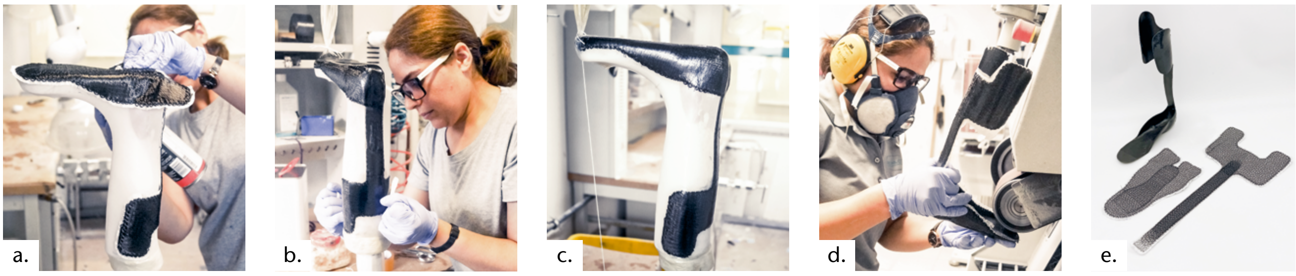

***Abb. 3a–e** Application of a TFP preform for orthosis fabrication: **a)** draping; **b)** resin casting preparation; **c)** resin infiltration; **d)** finishing; **e)** finished orthosis with TFP preform used for this purpose.*

geometries that meet the high dynamic and optical demands of patients.

Still relatively unknown, on the other hand, are the possible applications related to the tailored fibre placement process, which offers many advantages for the small scale industrial production of orthopaedic components: The ideal fibre alignment in the component is already preset during TFP preform production in such a way that no further attention needs to be paid to it during application on the infiltration model. In addition, due to near-net-shape production options, the wasting of reinforcement fibre material can be reduced to a minimum. Also, the almost unlimited shelf life of TFP preforms, once produced, enables small scale industrial companies to carry out the manufacturing process quickly and with consistent quality. Figure 3 shows the typical manufacturing steps in the application of a TFP preform for orthotic construction.

Process comparison

In comparing the previously described technologies shown in Figure 4, it becomes apparent that the TFP process offers many advantages in the field of orthopaedic device manufacturing:

- In contrast to 3D printing, the actual production remains with the orthopaedic specialist and the entire manufacturing process in the hands of the user. Here, the TFP preform is ordered as a material component and accordingly processed with the established infiltration processes (resin casting).
- MDR-compliant (MDR = Medical Device Regulation) documentation is also greatly facilitated by the use of a digital TFP lay-up plan, which reduces bureaucratic work.
- For everyday use in the orthopaedic workshop, serially produced preforms are recommended. These can be easily adapted and, if necessary, cut in the conventional way. It is possible for companies to have their own lay-up plans and cutting patterns digitised. This generates reproducible standards that improve the quality of the end product and reduce the reject rate.
- In addition, the simple application of prefabricated preforms makes it easier for less experienced users to use the technology, which is particularly advantageous in view of the current shortage of skilled workers.

Figure 5 shows the process steps from the digitised model to the finished orthosis with complex geometry.

Computer-aided design of TFP components in the field of orthopaedic technology

A major challenge for the production of TFP preforms is the efficient creation of corresponding lay-up patterns. Currently, in this context, two different approaches are being pursued for orthopaedic technology. These will be discussed in more detail below.

Creating simple TFP lay-up patterns

If the goal is to substitute orthoses that have been previously manufactured using textile semi-finished products, the use of the TFP process can significantly reduce both the amount of material used and the manual work that

	INCLUSION TECHNIQUE conventional semifinished products (dry fibre mats)	PREPREG TECHNIQUE (impregnated fibre mats)	ENDLESS FIBRE 3-D PRINTING	INCLUSION TECHNIQUE TFP Preform (dry fibre, saving)
Easy construction potential	MEDIUM	HIGH	LOW	HIGH
Use by small scale industry	HIGH	HIGH	LOW/EXTERNAL	MEDIUM
Reproducibility	MEDIUM/MANUAL	MEDIUM/MANUAL	HIGH/DIGITAL	HIGH/MANUAL
Documentation work MDR	HIGH	HIGH	LOW	LOW
Technical requirements	LOW	MEDIUM	HIGH	LOW
Storability of the material	HIGH	MEDIUM	EXTERNAL	HIGH
Material offcuts	HIGH	HIGH	MEDIUM	MEDIUM
Overall costs	LOW	MEDIUM	HIGH	MEDIUM
Remarks	• Standard technique in orthopaedic technology • Result depends greatly on the skills of the user	• Very strong and light component • Risk of residual humidity in plaster model (heat resistant model is necessary)	• Small scale industry (trade) outsourced to external supplier • No plaster model is necessary	• In the case of special production, a scan and CAD knowledge is necessary • Reproducible production standard

***Fig. 4** Comparison of different manufacturing processes for orthosis construction.*

is required for cutting as well as complicated draping steps. The layer thicknesses and fibre orientations can be adopted as far as possible from the reinforcing fibre textiles that were previously used. Repeated overstitching also makes it possible to combine several layers within a single TFP preform. At the same time, the automated lay-up process ensures that the final preform of the component always has an identical layer structure. As such, errors that happen during manual draping can be almost completely eliminated.

The actual pattern creation can be carried out using so-called punch programs, which are also used in classic embroidery technology, including "Pulse" or "EPCwin". These programs are a combination of Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) applications and, like the TFP process itself, only work in two dimensions (2D). The exported CNC data can be processed directly by the TFP machines. However, an alternative way to create the filing paths can also be via classic 2D CAD or desktop publishing programs (DTP programs) such as "DraftSight" or the free software "Inkskape". The translation of the pattern data into a CNC data format that can be read by the TFP systems can then be done, e.g. with the TFP CAM software "EDOpath" designed for this application.

All software tools for TFP pattern creation require a flat developed contour of the actual orthosis as input data. The processing can be done in two ways:

- On the one hand, it can be generated in the classical way, e.g. by means of a paper template taken from the plaster model (see Fig. 5). This is then digitised by scan or photo and scaled accordingly. With the help of the punch or CAD programs mentioned above, the contour border is then traced and used for further surface filling.
- On the other hand, it is possible to carry out virtual processing if a 3D scan of the patient can be used. Established software applications such as "Geomagic Freeform", "Rodin4D Neo" or "Vorum Canfit" are already available to most workshops for 3D data preparation. However, for the necessary 2D processing of mostly double-curved surfaces, the use of special 3D modelling programs such as "SolidWorks" is necessary, or the free software "Blender". The geometries developed in this way can then be exported with the help of the 2D CAD data format DXF and used further to create patterns.

With the help of the "EDOstructure" software, which was specially developed for the Computer Aided Engineering (CAE) of TFP components at the IPF, some of the above-mentioned development steps can be shortened. For example, imported 3D scan data can be processed directly within the program and, among other things, provided with a uniform surface filling, as shown in Figure 6.

Creating complex TFP lay-up patterns

If the full potential of TFP technology for orthoses is to be exploited on the basis of a variable-axis or stress-appropriate fibre layout, the use of simulation software based on finite element analysis (FEA) is necessary. The corresponding FEA software tools must be capable of structure simulation with anisotropic material models; among others, this is possible with "Ansys", "Abaqus" or "Nastran". In combination with the software "EDOstructure", it is possible on the one hand to generate stress-appropriate fibre curves on the basis of principal stress trajectories and export them for further editing in DXF format. In addition, it is then possible to generate realistic simulation models in a very simple way solely on the basis of the 2D-TFP sample data for the FEA applications mentioned above, and to subsequently carry out a simulation-based structural evaluation with these [5].

Example: From 3D processing to the finished TFP orthosis

As part of the "TFPPrint" ZIM project, the virtual processing of three-dimensional surfaces and returning them to a two-dimensional plane for TFP pattern production was investigated. The example of a non-articulated AFO ("ankle-foot orthosis") with a spiral-shaped lower leg is shown schematically in figure 7.

Conclusion and outlook

The versatile application possibilities of Tailored Fibre Placement technology in the field of orthopaedic technology open up the prospect of being able to adapt individual components even better to the needs of patients in the future. In doing so, the established infiltration processes can continue to be used and small-scale industrial processing methods that have already been established can be retained.

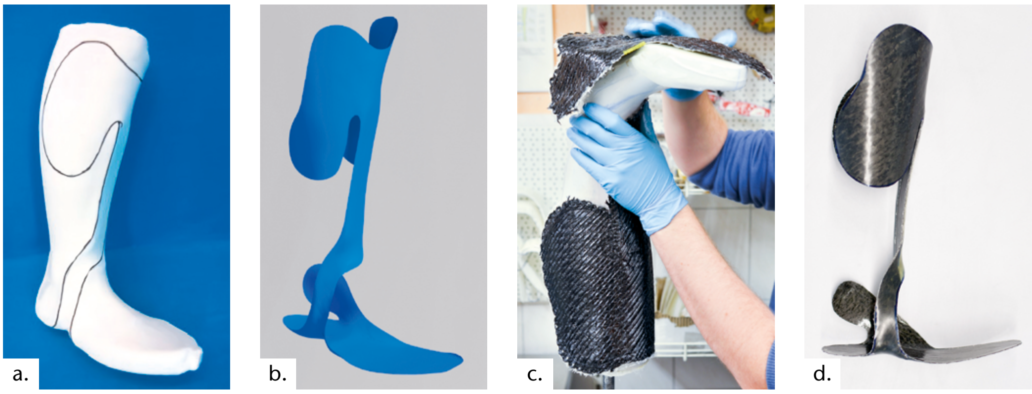

***Fig. 5a–d** Orthosis with a complex geometry – from digitised plaster model to finished component.*

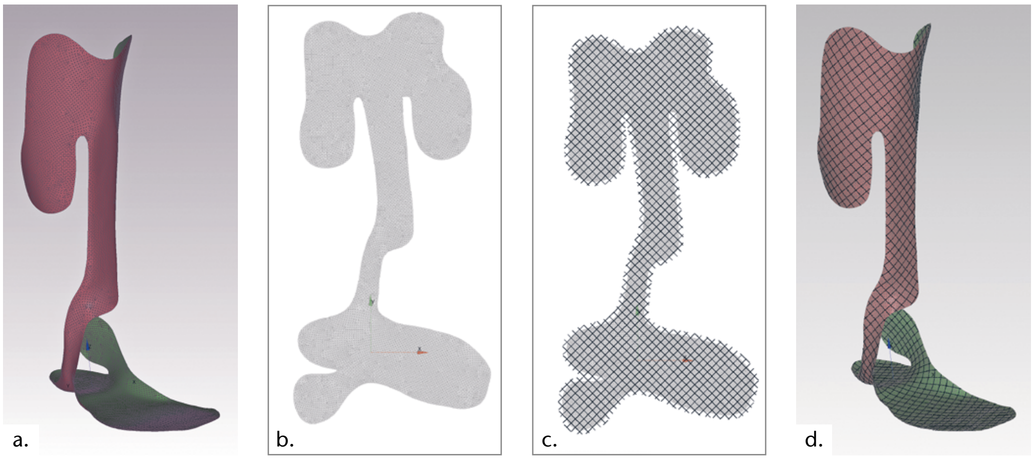

Fig. 6a–d *Digital process chain:* ***a)*** *meshed 3D model;* ***b)*** *processed geometry;* ***c)*** *automatically generated ± 45°-fibre pattern;* ***d)*** *fibre pattern on the 3D surface of the orthosis.*

In addition to the advantages already described, the TFP process also offers interesting prospects for the future due to continuous technological developments. For example, as part of the ZIM project “TFPPrint”, the TFP plant technology has been expanded to include an automated matrix print head. This makes it possible to impregnate preforms of the components to be produced locally with different plastics in a material-saving way. Through the deliberate use of a stiff and elastic plastic matrix component, both very stiff and bendable fibre-reinforced zones can be implemented in a component over a wide range of applications using the patent-pending process. For example, these can serve as solid-state joints or soft edges on orthoses or prostheses.

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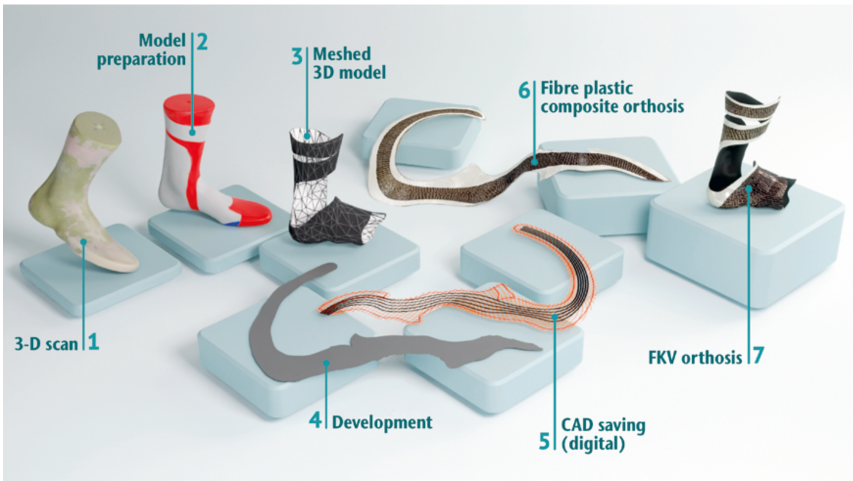

Fig. 7 *Schematic representation of the workflow from the 3D scan of the plaster model through to the TFP-FKV orthosis.*

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