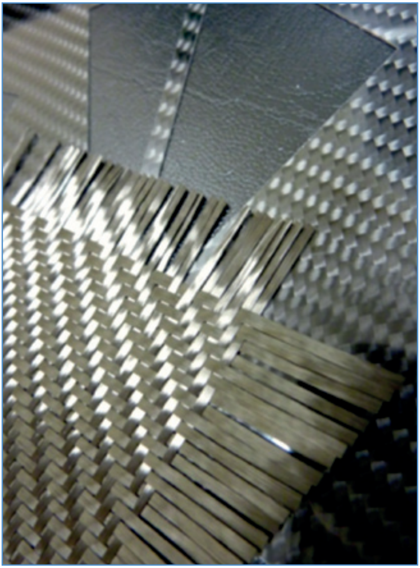
COMPOSITE MATERIALS

Fiber reinforced polymers



Major advances have been made during the past three decades in the development of organic matrix composites. This type of material consists of a polymer matrix which is reinforced with short or long, continuous or discontinuous fibers, which enable to gain a high resistance against ruptures and a high rigidity at the same time. Polymer matrix composites are usually divided into two categories:

- reinforced plastics,
- high-performance (also called advanced) composites, which contain a large volume percentage (more than 50%) of long and highly resistant fibers, such as carbon fibers, glass fibers or aramid fibers.

The aerospace industry in the US and Europe have been the predominant driver in the research of advanced composite materials because of their excellent mechanical properties and their very light weight. Weight savings lead to improved fuel efficiency and allow the construction of larger aircrafts, capable of transporting more passengers at greater speeds. A substantial research effort has therefore been achieved by the aerospace industry, as well as governmental and academic communities, in order to develop this class of materials. This means that these materials are well characterized now and given the broad spectrum of polymers and reinforced fibers available, these have been applied to other industrial sectors, such as the medical technology.

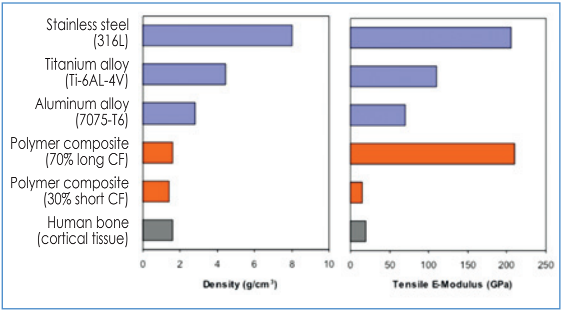


FIGURE 1: Comparison of density and mechanical stiffness between some metals and composites used in orthopedics, CF: carbon fibers

Benefits for medical devices

The composite materials used in medical applications must meet extremely stringent standards and respond perfectly to end-use requirements with regards to performance

and reliability. If these criteria are met, composite materials can become an interesting alternative to metals and metal alloys traditionally used in medical devices. In order to compete with materials like stainless steel, titanium and aluminum alloys, particular composites (mainly based on carbon fibers) have been developed specifically for surgical instruments, orthopedic products and implants. The fast progress of composite materials in the medtech field has come to a large extent from the following advantages:

- light weight, combined with mechanical properties which can be modulated,
- anisotropic behavior, allowing different properties and functionalities to be obtained in different part areas or directions,
- resistance to repeated sterilization cycles without deterioration of performance, aesthetic aspect and dimensional characteristics,
- approved biocompatibility of certain matrices and fibers, suppressing the risk of allergic reactions caused by the release of metal ions,
- x-ray transparency, thereby allowing optimal interpretation and visualization of radiographic images,

- pleasant to the touch, providing a feeling of warmth when in contact with the skin,
- visually and aesthetically appealing.

FIGURE 2: External fixation carbon ring and rods used for the osteosynthesis of fractures

Manufacturing costs

Whilst the above-mentioned advantages may be very interesting for the end user (patient or surgeon), the commercial motivation to switch from metals to composites in practice remains a critical issue. High costs are often the largest obstacle to the use of composites. It is therefore vitally important to think about strategies to reduce the manufacturing costs for parts as far as possible, early enough in the development phase.

The manufacturing costs for composites can be broken down into four main sub-elements: raw material costs, processing costs, assembly costs and inspection costs. The raw material costs for products intended for medical applications tend to be high, in particular when carbon fibers and thermoplastic matrices (like PEEK) are used. As for the processing or forming costs, these can also vary widely according to the design of the part (size and complexity), the production volume, the required tools (autoclave, press, mold, oven...) and how the process is controlled (optimization of the temperature-pressure-time parameters). Strategies to reduce processing costs include for instance introduction of agents in resins which will permit an acceleration of the polymerization reaction, or the automation of manual manufacturing steps. Automation of the process can also help reduce inspection costs by generating more reliable quality and therefore less variation. With regards to the assembly costs, these can be drastically reduced or even eliminated by a re-design of the system in order to be able to integrate several components. This has been the key to success in production processes such as injection molding and resin transfer molding (RTM), where complex-shaped parts may be fabricated in one single manufacturing step.

Property	**EP/ GF**	**EP/ CF**	**PEEK/ CF**
Material Price	↘	→	↗
Processing Temperature	→	→	↗
Sterilization Resistance	↗	↗	↗
Biocompatibility (tissue contact < 24h)	→	↗	↗
Biocompatibility (tissue contact > 24h)	↘	↘	↗
X-Ray Transparency (radiolucency)	↘	↗	↗

TABLE: Relative cost and properties of three types of composite materials, EP: epoxy, PEEK: poly(ether ether ketone), GF: glass fibers, CF: carbon fibers, ↘ : low, → : medium, ↗ : high

Risk control

Once benefits and costs have been assessed, and both technical and economic feasibility have been demonstrated, realistic and profitable implementation of composites is conceivable. However, for successful implementation, yet another important parameter needs to be considered. This parameter is the risk factor. The risk of introducing a new technology must be acknowledged, understood, assessed and perfectly managed, especially when it comes to public health. Increased product performance and quality assurance help to minimize the risk, but come at a cost premium.

Advantages, costs and risk are thus closely linked to each other and will all have to be considered, not only from a technological point of view (including mechanical performance, biocompatibility, durability, disposal after use, etc.), but also from a strategic point of view (including composite engineering skills, supply chain management, regulatory trends, etc.).

Therefore, the wish to replace a metallic component by a component made out of composite material will have wide-ranging implications. Contributions and advice from specialists involved in the development and manufacturing of composite materials are thus essential for maximizing the success of integrating these materials into medical applications.

Partner

With its ISO 13485 certification and more than 20 years of experience in the development and production of complex composite material parts, Composites Busch has emerged as a powerful OEM supplier for the manufacturing of medical devices. By adapting to the needs and requirements of customers, surgeons and patients, the company has been able to capitalize on its expertise for the development of innovative products destined for a variety of applications: external fixation elements for osteosynthesis, handles and other components for surgical and dental instruments, single-use ancillaries, patient-specific surgical guides…

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