PERFECT ALIGNMENT

3DP composite surgical aiming arm is made with greater properties and at less cost than aluminum alloy or composite block

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A feasibility study conducted by 9T Labs AG of Zürich, Switzerland, considered the challenges and opportunities of converting a surgical device from machined metals or composite block to 3D-printed (3DP) carbon fiber-reinforced thermoplastic composite (CFRTP) with positive results.

The component selected was a surgical aiming arm used to align surgical tools, pins and bolts with holes in a bone plate to repair shattered bones while speeding healing and restoring mobility. Functionally, parts see relatively low loads in use, but must maintain high dimensional accuracy while resisting wear, hydrolysis and dimensional changes due to temperature and humidity cycling during repeated autoclave sterilization. They also must be X-ray translucent to permit in situ position verification of the entire bone-fixation system during surgery.

Hybrid 3D Printing Technology

9T Labs' hybrid technology platform produces precision structural CFRTP parts in small to medium size (printer build envelope: 350 x 270 x 250 millimeters /13.8 x 10.6 x 9.84 inches) for low to medium volume production (100 to 10,000 parts/year). What's different is the technology combines 3DP, accomplished in a layup/preform machine called the Build Module, with a compact compression press fitted with matched-metal dies called the Fusion Module, which consolidates preforms, then shapes them into final parts—and provides 100 percent traceability.

The company's additive fusion technology (AFT) uses both neat filaments of 1.75 millimeters (0.07 inches) and unidirectional (UD) carbon fiber-reinforced thermoplastic tapes that are slit, then roll-formed into filaments 0.1 to 0.2 millimeters (0.004 to 0.008 inches) thick in either polyetherketoneketone (PEKK) or polyamide 12 (PA 12), materials that are reliable, established and globally available. The system reportedly works with other off-the-shelf thermoplastic tapes and filaments. Rolled filaments provide fine printing resolution, up to 60 percent fiber volume fractions (FVF), and fiber positioning of nearly any angle in X, Y and Z axes. Unreinforced filaments lower global FVF and cost where higher mechanicals aren't required. Layers fuse since the same matrix is used for filaments and tapes.

The system reportedly provides greater part complexity, design freedom and fiber-orientation control than other continuous-fiber composite processes. Little to no scrap is produced since parts are printed to (near) net shape. Because thermoplastic matrices are exclusively used, cycle times are fast, scrap is recyclable, smaller parts can be welded into larger modules and hardware can be inserted after consolidating but before forming. Consolidating and forming in metal molds ensures excellent surfaces, low voids and high repeatability and reproducibility. 9T Labs says the system permits cost-competitive manufacturing at a size and production range that are typically difficult to achieve affordably in structural carbon composites.

Materials and Fiber Layup Options

The 9T Labs team looked at design opportunities to reduce cost and optimize geometry for the surgical aiming arm. Given the high heat and humidity of autoclave sterilization, they chose PEKK over PA 12 owing to higher thermal performance and better hydrolysis resistance. Basic properties of

Final design of a 3D-printed surgical aiming arm in carbon fiber/PEKK. Images and data courtesy of 9T Labs AG filaments and tapes are shown on on the left.

Basing their design on commercial parts but optimizing it for 3DP and demolding, the team next used the company's Fibrify design suite to import CAD files from leading structural-analysis programs to optimize fiber layups for the AFT process. Those designs were then exported back into structural-analysis packages to verify that parts met performance requirements.

Given how critical position and dimensional stability of aiming arm holes were for positioning surgical tools, these locations were locally reinforced with aligned fibers (UD tapes). To further reinforce the part against in-plane flexure, tapes were used along predicted load paths. Additional reinforcement was added along the external perimeter to reinforce through-thickness resistance to out-of-plane flexure. And to ensure robust exterior surfaces for post-print deburring, polishing and engraving, stiff face skins were used, creating a sandwich structure surrounding the bulk volume of the part, which was filled with unreinforced PEKK. With the basic structure defined, researchers applied additional fibers to reinforce aiming arm holes, so they didn't shift due to linear displacement or in-plane shear loads.

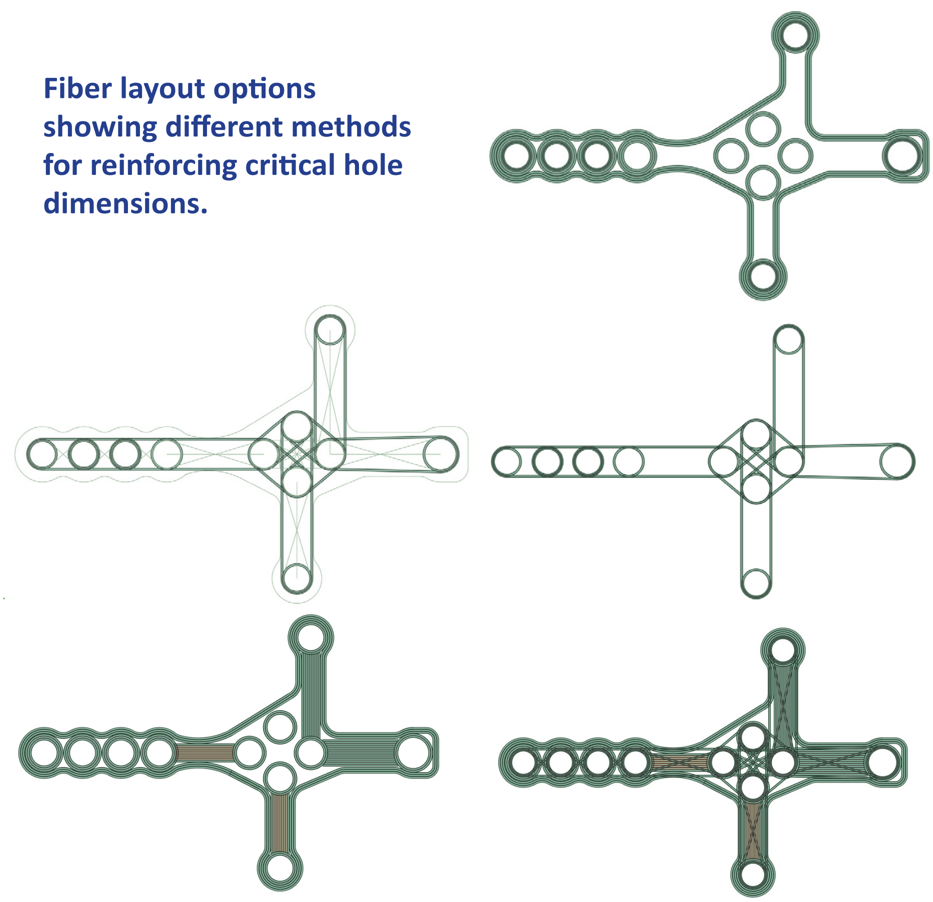
The final design, which was said to provide adequate reinforcement for multiple loading conditions while minimizing fiber use to manage weight and cost, featured 90 printed layers producing a 174 x 107 x 15-millimeter (6.85 x 4.21 x 0.59-inch) part weighing 88 grams (3.1 ounces). No supports were needed, and no waste was produced when printing the net-shape part.

Analyzing Part Costs

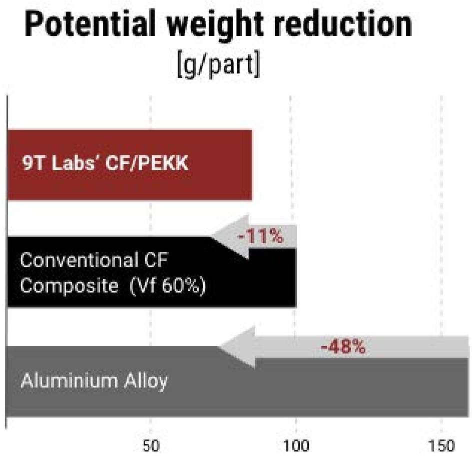
The team next compared mass, materials use and cost of the printed part to benchmark milled aluminum and carbon fiber-reinforced polyetheretherketone (CF/PEEK) composite block. Unsurprisingly, machined composite parts were 22 percent lighter and printed AFT parts were 48 percent lighter

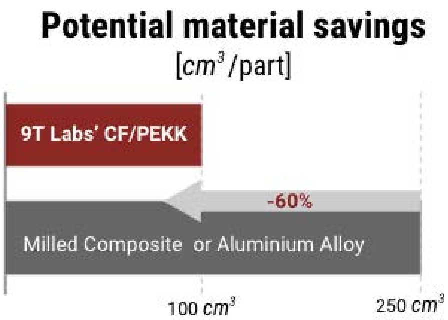
Property	Test Method	Neat PEKK Filament	Test Method	60% Carbon Fiber-Reinforced PEKK tape
Density (g/cm³)	–	1.29	–	1.58
Tensile modulus (GPa)	ISO 527-1BA	3.8	ASTM D 3039	137
Tensile strength (MPa)	ISO 527-1BA	110	ASTM D 3039	2,350
Flexural modulus (GPa)	–	–	ASTM D 790	118
Flexural strength (MPa)	–	–	ASTM D 790	1,655
In-plane shear modulus (GPa)	–	–	ASTM D 3518	5.2
In-plane shear strength (MPa)	–	–	ASTM D 3518	145
Elongation @ yield (%)	ISO 527-1BA	5.2	–	–
Elongation @ break (%)	ISO 527-1BA	20	–	–
Glass-transition temperature (°C)	DSC	162	DSC	159
Melt temperature (°C)	DSC	331	DSC	337

Fiber layout options showing different methods for reinforcing critical hole dimensions.



	Starting Materials	Final Part
Amount of CF/PEKK used (60% FVF)	40%	–
Amount of neat PEKK filament used	60%	–
Final part volume	–	62.5 cm³
Final part mass	–	88 g





than benchmark machined aluminum. Given milling's high waste, the net-shape printed part wasted at least 60 percent less material than either aluminum or CF/PEEK, helping to lower part costs.

One Build Module can layup ≈3,000 preforms/year, while one Fusion Module can mold ≈13,000 parts/year. Assuming production volumes of 3,000 aiming arms/year, 1 Build and 1 Fusion unit (combined utilization rate equivalent to 65 percent) would be needed, and part cost would be ≈ €91 (U.S.$107.45) each. If volume rose to 6,000 units/year, 2 Build modules and 1 Fusion module would be needed (combined utilization rate equivalent to 75 percent), leading to a per-part cost of ≈ €77.57 (U.S.$91.40). Adding a second build module has a modest impact on part cost but allows the second machine to be used for additional development work. AFT cost estimates assume 5 percent labor (including all manual and post-processing work), 35 percent material, and 60 percent equipment use (including software licenses, maintenance fees, overhead and cost to use post-print machine tools).

"Surgical instruments are a great fit for additive fusion technology owing to our materials' radiolucency for accurate X-ray checks, dimensional stability after repeated sterilization, biocompatibility since they have short-term contact with the body, and low mass for lower fatigue and greater positioning accuracy," notes Giovanni Cavolina, 9T Labs chief commercial officer and co-founder. "This study helps us show perspective customers that AFT produces precise, lightweight and lower-cost parts that can meet the harsh requirements seen by surgical equipment."