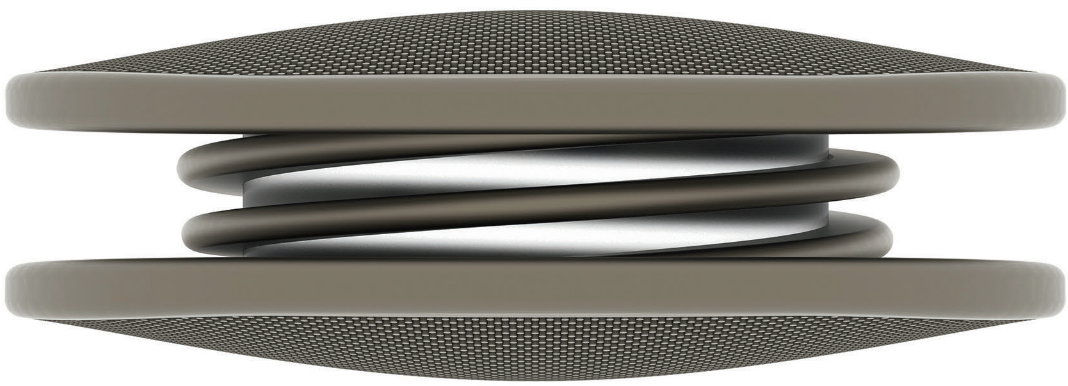
Medical Applications of Additive Manufacturing

Status and Perspectives for Human Medicine

Anyone who introduced additive manufacturing (AM) in a company 15 years ago was a visionary. Anyone who did not do so ten years ago fell behind the early adopters. Anyone who still is not using additive manufacturing today is losing their edge over the competition. What this technology is considered capable of today and how it can be applied in many areas of application is shown (representative) by this expert's view of medical technology.



To enhance the mobility of the spine, the upper and lower shell of this disc prosthesis are connected with an elastic double spring made of titanium. The core also contains a cushioning silicone filling. The prosthesis can be manufactured according to the patient's anatomy using the LaserCusing process © Tsunami

Additive manufacturing (AM) is bringing about increasingly disruptive changes in traditional manufacturing strategies. Often classic procedures such as casting or milling are to be replaced. The benefits of a procedure not bound to a specific form, such as geometric freedom, re-engineering, and resource conservation, are complemented by great economic advantages and excellent availability. But the essential merits are not just the copying of conventional parts but rather the new designs and bionic design approaches. Time-to-market as well as quick availability and idle time reduction also come into play. In light of the debate about long supply chains as a side effect of globalization, AM is also a viable approach for local production. Local production also means that value creation, product development, and product manufacturing will take place closer to the customers. Reducing logistic overhead contributes to achieving climate goals.

Classic material groups include metal, ceramics, and plastics. For the metals and the LaserCusing procedure, a powder bed-based metal laser melting process developed by me (market share approx. 80% of all metal AM systems worldwide), very early adoption for medical applications was possible because we were always able to use certified original materials in powder form. A similar approach also works for ceramics-based solutions. The process is a little more complicated with polymers due to the variety and material behavior of that group. That is why metal applications have a head start of about five to ten years.

When we now shed some light on the medical industry, we will see many isolated application clusters: hip, joint, or spinal implants, cranial or dental prostheses in dental technology. Medical devices, laboratory equipment, or components used in high-tech medicine are added to the mix (**Fig. 1**); currently, the operative word would be valves for reanimation and ventilation devices. Even veterinary medicine knows a range of examples for 3D printed implants applications by now. »

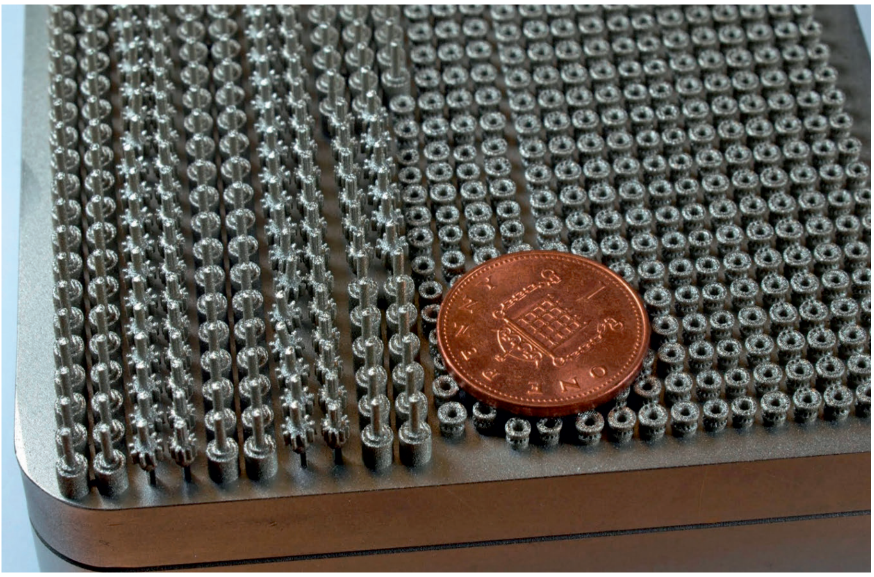


Fig. 1. Several parts for the automated suturing device for heart surgery are made simultaneously on a building board © Sutrue

Market Development of 3D Printing Providers and Users

As reported by the Wohlers Report 2020, the total value of additive manufacturing products and services was estimated at USD 11.9 bn with medical applications representing an estimated about USD 1.7 bn. The total value of AM machines, materials, software, and services for medical applications is projected to reach USD 2.2 bn by 2024. According to Wohlers Report, with such incredible growth, keeping up with developments can be challenging.

The projected global market size estimated by SmarTech Analysis company is approx. USD 55 bn in 2029. More conservative analysts such as 3D Hubs project an expected annual growth rate between 18 and 27 %. But even that outshines many other industries by far. The British market analytics company Context predicts double-digit growth rates for 3D metal printers (**Table 1**) as well for polymer printers (**Table 2**) for the coming years. Industrial mass and mid-scale serial production, however, account for the highest sales increase in the field of additive manufacturing. This includes only part of medical technology.

Provider	Global market share [%]	Revenue change (2018 on 2017) [%]
GE Additive (U.S.)	18	+7
EOS (Germany)	17	+4
MarkForged (U.S.)	9	+4125
SLM Solutions (Germany)	6	-12
3D Systems (U.S.)	5	+20

Table 1. Top 5 providers of metal printing (systems worth 20,000+ USD) Source: Context, AM3DP report 2019

Provider	Global market share [%]	Revenue change (2018 on 2017) [%]
Stratasys (U.S.)	37	-14
Envision TEC (Germany)	16	+2
Carbon (U.S.)	9	+102
3D Systems (U.S.)	9	+11
HP (U.S.)	6	+30

Table 2. Top 5 providers of polymer printing (systems worth 20,000+ USD) Source: Context, AM3DP report 2019

With regard to the global market, EY Research reports that in 2019 722 AM companies hailed from Europe, 421 from the Americas, and 168 from Asia. AM providers in the industry, however, are currently in a consolidation phase. The enormous growth of the past ten years in particular, its numerous innovation pushes, and the consolidation of prices are taking effect. While major players may feel a stronger effect, small start-up companies are still pushing into a dynamic market with creative solutions, a market that is still far from saturation or fights for survival.

For users, on the other hand, things are still going extremely well. That is true for the medical industry as well as others. But it also applies to the numerous 3D printing service providers who guide numerous industries into the world of 3D printing with their AM expertise and manufacturing capacities. The possibilities of improving existing products with AM are just too tempting. Buzzwords include bionic design, lightweight construction, patient-specific components, the one-shot approach drastically reducing the number of components in an assembly group without any assembly required, decentralized manufacturing, and rapid availability.

Example Titanium: Implant for an Acetabulum

In light of the boomer demographics in the West, orthopaedic implants for the human musculoskeletal system play an increasingly important role. Applications for the hip, knee, and spine are considered a relevant emerging market in medical technology. Stryker from Cork, Ireland, therefore developed a new 3D titanium acetabular system (**Fig. 2**) using electron beam melting (EBM) technology. The system received clearance from the US Food and Drug Administration in 2016. Stryker calls this product Trident II Acetabular System and emphasizes that it is a cementless solution, which massively improves its longevity in the body.

The 3D printing process allows for highly complex geometries which cannot be produced using conventional means. The complete implant has the durable mechanical properties of kinematics consisting of a titanium acetabular system, a ball head and a shell-shaped insert made of metal, ceramic, polyethylene, or an aluminum-ceramic composite, depending on compatibility and load, and a locking mechanism. Of course, the providers of such 3D solutions are manifold. For the sake of proportion, here are also B. Braun, Surgival, SurgTech, ImplanTech, Imeco, Medacta, Link, or Rentec.

Example Polyamide: Venturi Valves for Reanimation Devices

Back in March 2020, the EU responded to the SARS-CoV-2 pandemic by reaching out to the European AM industry. The idea was to use 3D-printing strategies, among others, to tackle the lack of protective equipment, such as N95 respirators, masks, face shields, or gowns as well as reanimation and ventilation devices in healthcare and the strong dependence on global supply chains. Major providers such as Draeger in Lübeck, Germany, but also many other plant and machinery installers and processors from a variety of industries heeded the call for help. Many companies had never manufactured products like these before.

Fig. 2. 3D-printed titanium acetabular system © Stryker

Venturi valves for reanimation and ventilation devices are a good example (**Fig. 3**). The challenge here is to 3D-print a conventionally manufactured expendable part within a narrow time frame. That is what happened at the hospital in Brescia, Italy: the Milan-based company Fab Lab set up a polymer 3D printer in the hospital. The hitherto used valves were scanned, and new valves were printed, so the reanimation devices never stopped running. Later, Lonati Spa took over serial production using the polymer laser powder bed melting process in order to print the polyamide parts and supply Italian hospitals.

This is known in our industry as "spare parts on demand": an essential element whenever a solution requiring a specific form is no longer available or takes too long to procure. We must also not forget to mention re-engineering in this context. If you redesign a spare part on top of everything else, an assembly part with many components may be turned onto a 3D-printed component with no assembly required in one shot.

Protective Face Shields for Nose and Mouth for Clinics

Protective equipment for healthcare professionals was a major global challenge when the pandemic broke out. Firstly, there were only emergency stocks lasting, and secondly, a lot of it was not produced in the European area. Supply chains and delivery times were too long. Prices skyrocketed unrealistically, and the quality was often dubious. If more healthcare professionals had been unable to work, the crisis could have turned into a catastrophe the way we have seen it happen in some other countries.

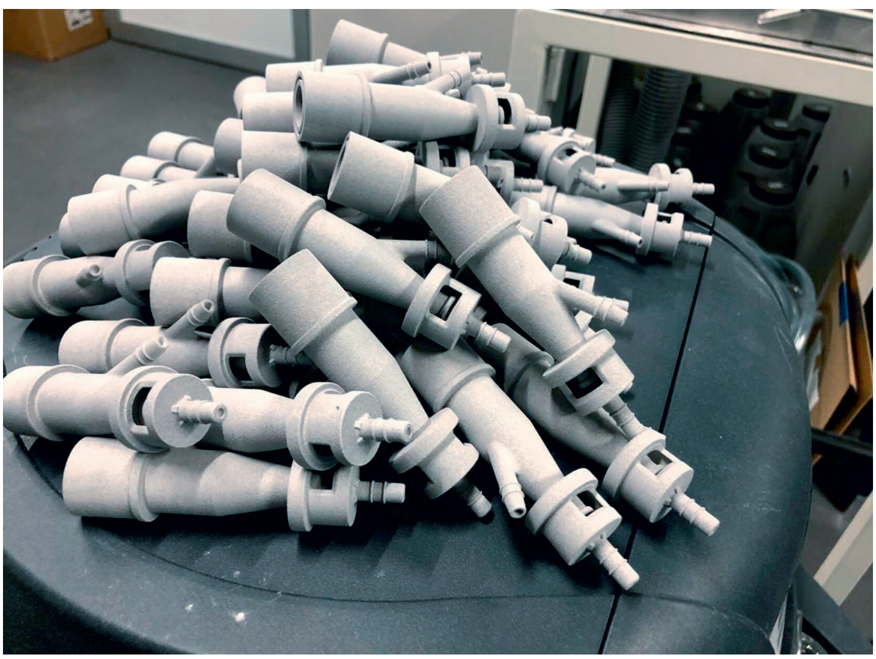


Fig. 3. 3D-printed polyamide Venturi valves for ventilators © Lonati

In this uncertain situation the emergency room of the Bamberg clinic in German asked whether there was a 3D printing solution for face shields. Basically, this is a very simple design consisting of a headband and a sheet of acrylic glass. It was not possible to recreate any certified models, but to produce makeshift equipment consisting of a face shield, protective gown, and respirator mask. And another thing was absolutely clear: this can only work in a proper network, because 3D printing can only ever be part of the solution and not the solution itself.

In this case, the network was the Lichtenfels Center of Next Generation Digital Technologies (Forschungs- und Anwendungszentrum für digitale Zukunftstechnologien, FADZ) currently under development, which brings together numerous companies in the region. Innocept, a Neuses-based company in Germany, developed a new type of respirator mask. The idea was to design a reusable respirator mask that was comfortable to wear, consisting of two soft polymer half-shells between which various filters could be inserted (**Fig. 4**). The benefits: the respirator filter does not sit directly on the face, making it much easier to breathe compared to makeshift fabric masks. Moreover, the large batch production of the respirator mask allows for favorable manufacturer's prices. It is environmentally friendly because not the whole mask must be disposed.

To speed up the development process, five prototypes were produced overnight using the multi-jet fusion HP technology at the company Hofmann – Ihr Möglichmacher in Lichtenfels, Germany. Two and half weeks later, the product reached maturity. The patent was filed by Innocept. But there is another »

Fig. 4. Reusable respirator mask, the filter elements are inserted between two soft plastic half shells © Innocept

essential advantage to digital processes: STL printing files can be used as a common basis on many printers regardless of the manufacturer.

State of the Art Using the Example of Cranial Implants

Artificial intelligence, digitalization, and automation are the pillars of the Industry 4.0 strategy. But they also inspire additive manufacturing. They will also shape the future of 3D printing as well as accelerate, innovate, and help spread it more broadly. This is only of marginal importance in medical technology, where solutions are often patient-specific. But there is still enormous leeway for a digital product. For instance, an operating surgeon can have a perfectly fitting cranial implant custom-made based on the X-ray images and their conversion into STL files (**Fig. 5**).

A defined porous surface makes sure that the implant is optimally accepted into the human tissue structure. But what really stops the show for seasoned medical practitioners is the design at the points where the implant meets the cranium. Thanks to that design, the component can be implanted faster and the surgical risk reduced. Quicker healing is a benefit for the patient, but so is increased quality of life. Both is a major mission of medical AM technology.

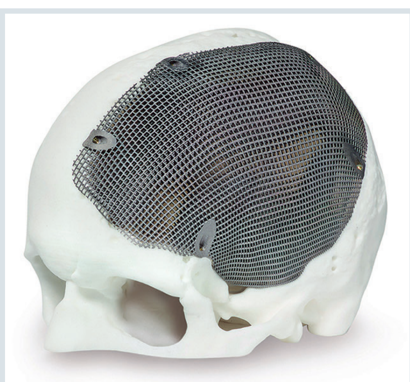


Fig. 5. High precision fit: additive manufactured craniofacial, patient-specific implant © Karl Leibinger Medizintechnik

The Synergy of Hardware and Software

AM plants and machinery make full use of the potential of design, digital process chains, and the synergy of hardware and software. With regard to hardware, installation spaces and construction rates (assembly speed) used to play a bigger role. Currently, the required installation space in powder bed metal printing ranges between up to approx. 800 cm^3. Standard installation spaces are 187 cm^3 or 125 cm^3 in multi-laser environments. These installation space dimensions are absolutely sufficient for any medical application nowadays. Assembly speed, too, has risen impressively due to the use of multi-laser systems. Construction rates today are up to 50 cm^3/h with several 1000 W lasers.

The binder jetting technology has the potential to increase these rates in the future. That technology, developed by the Massachusetts Institute of Technology (MIT), will become increasingly relevant for simple applications with certain tolerances. In binder jet 3D printing, also known as "powder bed and inkjet", the parts are built up layer by layer as "green bodies". 3D data serve to calculate the geometry of every individual cross-section or layer. During 3D printing, a bed of powder or granulate is spread on a height-adjustable tabletop and then a binder is deposited to glue the parts together in the places that form part of the component.

The developments of the past ten years also led to a large increase in batch sizes. Quality assurance and automation are becoming more and more important. Quality assurance is one of the main tasks of the software, though not its only task. The software controls the build-up of a 3D-printed part. It controls the data preparation of the part and design-related tasks and it suggests an exposure strategy and parameter choices, also for the surface or density of the part. The software optimizes the orientation of the part in the installation space as well as the necessary supporting structures.

For quality assurance purposes, it also facilitates thermal behavior simulations (thermal simulation) and warpage simulations (mechanical simulation) based on a part's density or strength. Last but not least, the software provides for a "digital twin". The recorded optimized process parameters of the part can be saved one-to-one. This means maximum reproducibility, which only a digital part can provide.

Additive Manufacturing as a Holistic Manufacturing Strategy

Automation and the digital supply chain round off the development. Automation means the elimination of as many disturbance values as possible, to make the process safe in a protective gas atmosphere, and to design it fast and automated. It ranges from the preparation in containers and the actual setting up of the 3D printing machine to the automated post-processing such as removal of supporting structures, thermal after-treatment, or surface processing. Maximum automation means that the whole process, from powder to the finished part, is handled without any manual activity.

The digital process chain, since its inception a challenge but also a necessity for plant and machinery installers to fully tap into the potential of AM, has been extended by now. One of its core points is the direct yield of digital STL files. Nowadays scanners can be used to capture the files directly. This can be done at the patient bedside, but also for conventional parts which are now to be produced using AM. But the digital process chain also happens in another dimension. The operative word here is modern AM plants with continuous digital process chains for production and process control (**Fig. 6**). This modern type requires data flow in material staging and preparation, parts production, post-processing, and intra-plant logistics, including even autonomous transport systems (automated guided vehicle systems).

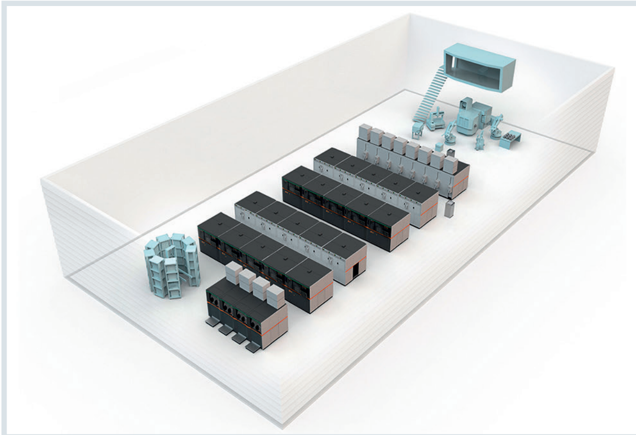


Fig. 6. Tomorrow's factory requires a data flow from material supply (left) through component production to post-processing (right), which also includes the operation of driverless transport systems © GE Additive / Concept Laser

Digital, Not Viral Hot Spots are Needed

Step by step, this technology will become more effective and efficient, even though the development stages are now somewhat more moderate than ten or twenty years ago. We are certainly going to see new bionic products, new designs, new materials, more sustainable products, and a broadening of applications.

Humans are now starting to join technology in the spotlight as a designing factor. While many companies are pioneers, the mainstream remains guarded: in 2019, 71% of companies stated that a lack of expert knowledge was the greatest factor against 3D printing when it came to choosing alternative methods of manufacturing. But in contradiction, 79% of companies stated that the number of parts manufactured by 3D printing in the next three to five years would at least double (source: Jabil survey 2019). In effect, this contradiction means that we may not know how it works, but we do know that it is becoming more important.

Companies are realizing that something is happening, but they are still reluctant to act. There must be a plus in "digital knowledge" in the future in order to shape this transformation in more concrete terms. Training and development of the "Generation 3D Printing" will be the key to the future. A training and development will give everyone anywhere in the world the advantage of site, because AM is a key way to develop and build products locally. I am also saying this in light of the debate about long supply chains all the way to China. AM permits us to manufacture locally, close to demand. There is no need for long transport routes or dependencies. Digital AM plants around the world have similar cost structures.

So we need local AM centers, "digital hot spots". For this to happen, we must provide the technology with developers, draughtspeople, designers, and operators who understand 3D printing and are able to use it. That is the only way for us to translate traditional manufacturing strategies into the new possibilities offered by 3D printing, and to fully utilize future innovation opportunities. 3D will become a competitive factor for many companies and industries.

Final Musings

I do not want to end my outlook on the future of AM without mentioning the 3D consumer market. Just like for any other hardware, there will always be a market for industrial 3D printers and consumer 3D printers. The British market analytics company Context states a market volume ratio of 70:30. There are real quantum leaps in the market here: a state-of-the-art consumer 3D printer costs around 1000 EUR these days. I dare say that around 15 years ago an industrial 3D printer of similar parts quality would have cost between 100,000 and 200,000 EUR. This means that 3D printing is now spreading horizontally instead of vertically.

A home 3D printer – the HP multi jet fusion technology currently being the most popular – will be as much of a staple in the future as an office laser printer. It is therefore conceivable, based on geometry licenses, for numerous practical products to be manufactured at home by "people like us". That outlook is none too bad, I believe, considering that during a pandemic such as SARS-CoV-2 you are longing to print your own protective visors or masks, without leaving the house. Using data found online. ■

The Author

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Service

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