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# 3D ADEPT MAG

**3D PRINTING**

POSTPROCESSING - 3D PRINTED ELECTRONICS - POLYMER MATERIALS

N°2 - Vol 2 / April 2019

# 3D Adept Mag

ADDITIVE MANUFACTURING / RAPID PROTOTYPING /  
TECHNOLOGICAL INNOVATIONS

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## Editorial

### Meeting the needs of industry

A mechanical engineer – and regular reader of 3D ADEPT Media – who works in an engineering office reached out to us and asked if we can provide a state of the art of 3D printed electronics. This young field of the industry is increasingly gaining momentum and raises several questions among users.

That is just one example of the many requests we receive per day; requests that enable us to answer as thoroughly as possible questions of industrial users.

So, we answer the questions raised by this engineer in this issue. Furthermore, we also provide a stand-alone analysis of various topics: post-processing, simulation software for additive manufacturing, polymers as well as a state of the art on medical 3D printing.

A closer look reveals a similar strategy applied by additive manufacturing companies: listening to market needs and implementing initiatives that best meet the needs of stakeholders.

This is certainly the most striking aspect of this April issue. Issues tackled in the following pages demonstrate that, although they share the same vision – industrialization of additive manufacturing –, they do not (always) provide the same solutions. So, what will be the right solution for you ?

That's the million-dollar question.

**Kety SINDZE**

*Editor-in-chief*



# 3D PRINT

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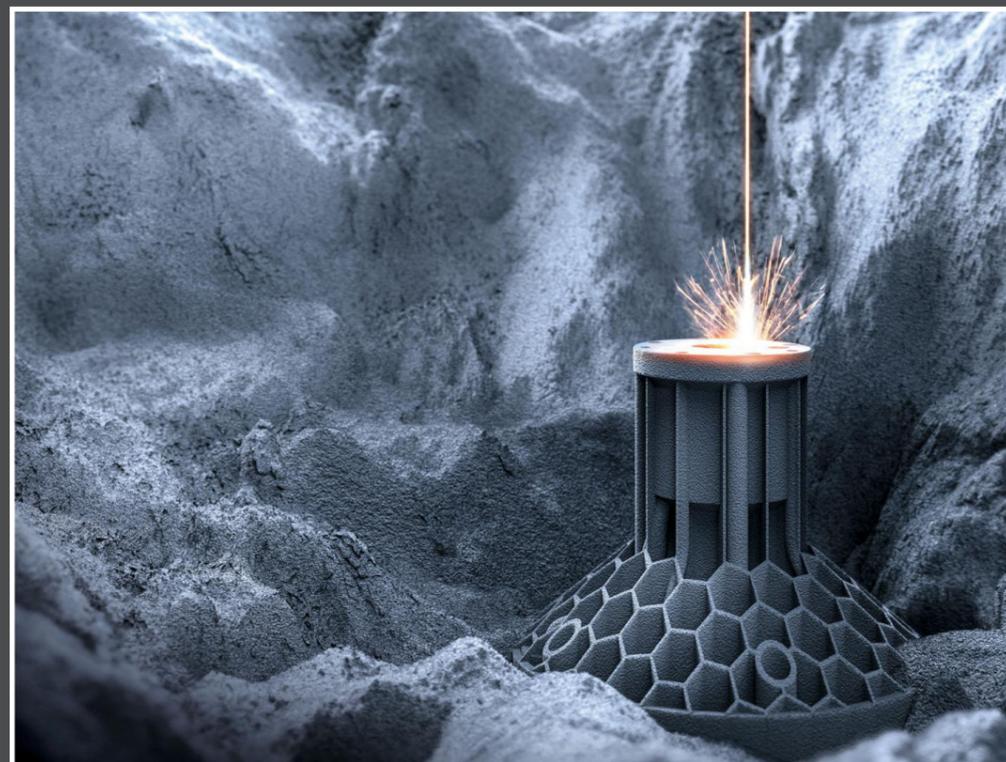
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# Additive Manufacturing

With contributions from  
EOS, SOLUKON & RÖSLER

## Issues raised by metal powder removal

*Post-production, somehow, is the part of the manufacturing process that intimidates professionals most. The industry shows a certain lack of skills and control throughout the entire production chain for a finished 3D printed part – especially when it comes to a metal 3D printed part. It also shows a lack of reliable source when it comes to develop a proof of concept for a safe and reliable process that can remove and reclaim residual powder.*

*That's the reason why we have decided to tackle this issue. In order to fully analyze the outlines of a powder removal process, we invited players that manufacture additive manufacturing systems, manufacturers of post-productions technologies and 3D printing service providers in order to have a user point of view in post-production technologies. Eduardo Alonso, Regional Manager France, EOS, Vincent Raman, specialist of Mass Finishing Technology at Rösler and Andreas Hartmann, Co-founder and technical director of Solukon share their respective expertise in this dossier. Other conversations and analyses from various experts including Lawrence Livermore National Laboratories will be brought throughout the dossier to highlight or give further precisions on some points.*

**Rösler** is a surface finishing supplier that offers two essential finishing technologies, mass finishing and shot blasting, as well as industrial washing systems and in-house production and development. Due to the fact that a 3D printed part manufactured using DMLS, EBW, FDM, PolyJet, SL, SLM and SLS often comes out with corners, edges, burrs and rough spots, grinding, smoothing and polishing technologies of mass finishing are supplied by Rösler to enable manufacturers to get the expected rendering. Last year, the company partnered with PostProcess, another specialist in post-production technologies to complete its portfolio.

**EOS** is a manufacturer of industrial 3D Printing systems. Founded in 1989, the company provides a wide range of holistic solutions in additive manufacturing. Their participation in this dossier is quite atypical to the extent that they often discuss powder removal as part of the general topic powder process or material management.

Lastly, **Solukon** is a German manufacturer of peripheral post-processing equipment for additive manufacturing technologies. The company lays emphasis on automatic depowdering units and unpacking stations for laser-melted metal and plastic parts.

The post production stage consists in a series of additional manufacturing processes such as heat treatment to achieve desirable properties. The removal of excess powder from the internal cavities and complex geometries of the printed parts is a crucial part of this stage. The lack of accurate skills regarding this stage of the AM process often results in outsourcing the postprocessing stage to achieve better results for the finished part. This might therefore explain the fact that single-source production of functional AM parts remains out of reach for several manufacturers.

Speaking of additive manufacturing (AM) technologies themselves, basically, a powder removal process is required for all technologies that melt a powder, for example powder bed fusion,

powder-based direct energy deposition, binder jetting, etc. Vincent Raman from Rösler and Andreas Hartmann from Solukon precise that powder bed fusion processes like Laser-Melting or Laser Sintering mainly require a powder removal process. This process raises several post-production challenges that we aim to demystify.

### Challenges encountered during a metallic powder removal process

As a reminder, metal powder-bed fusion is an AM technology that melts layers of metallic powders together to quickly generate new parts. The only thing is that, at the end of the manufacturing process, one observes that excess powder covers newly printed parts, which poses a risk not only for future manufacturing processes but also for human health.

Furthermore, the removal of this powder is time-consuming since it is removed manually, therefore, creates a bottleneck for large-scale productions hence the need of a system that requires a minimal user input before the next stage.

Although **Vincent Raman** from Rösler explains that AM systems provide solutions for surface treatment & support removal, **Eduardo Alonso** on his side adds that *“the main challenge is getting the powder completely out of the part, especially out of channels and small spaces where it is more difficult. Another important point is worker safety meaning to minimize powder contact during removal.”*

Moreover, according to an expert from **Lawrence Livermore National Laboratories** *“another challenge is being able to tell when all the powder has been removed” on the one hand, on the other hand, as per Andreas Hartmann's words, to “remove residual powder safely, efficiently, economically, with reproducible cleaning results and providing the residual powder contamination free for recycling.”*

The first observation is that these challenges may vary from one user or manufacturer to another because of the type of removal processes they use.

## Types of current removal processes

Current removal processes can usually be divided into three categories: **manual processes**, **liquid immersion**, and **ultrasonic cleaning**.

Nowadays, the most used process remains the manual one, that sometimes, requires the use of compressed air to clear out cavities. It consists in physically shaking parts, using brushes, pipe cleaners, or build plate with a mallet to remove the powder. Furthermore, the process is framed by a strict regulation due to the safety requirements of the machine. Indeed, risks related to this process, mostly concern uncontrolled and airborne metallic powder.

Although it is referred by others as time-consuming, **EOS** believes that the *“manual process is usually fully flexible because it can be done at any time on any 3D printing machine.”* This would certainly be the biggest advantage of this process. However, in the constant quest for rapidity, the company also recognizes the importance of automation in post-processing. Indeed, Eduardo Alonso states that

*“the automation of the powder removal process is in pilot testing at EOS and selected pilot customers: automation in order to remove the majority of the powder for instance by rotating the exchangeable within the 3D printing system frame by 180° or by a robotic arm with a suction nozzle.”*

As far as **liquid immersion** is concerned, a research explains that success of the removal process of powder using this technique often varies from one to another. Devices used in this case are typically made in-house and typically use fluid flow to sweep debris away. A good example of such type of solution is the recently unveiled soluble support material of **XJET**, manufacturer of the metal and ceramic 3D printing technology **CARMEL**. Only intended for metal, the Israel-based manufacturer explained that it requires a few seconds to perfect the whole picture and facilitate the end of the manufacturing process. The solution reduces manual labor requirements while improving the process. Dissolving rapidly in a water-based, hazard-free solution, the advantages of soluble support materials can be striking.



Vincent Raman from Rösler

Speaking of the liquid immersion process, **Vincent Raman** said *“the liquid immersion removes support structures for different print techniques in both large batches but also on a single piece, without manually action needed.”* However, for the *Mass Finishing Technology specialist*, *“a lot of customers use a shot-blasting process which requires a lot of manual labor most of the times, hence the automation feature that Rösler integrated for smaller parts.”*



Eduardo Alonso, Regional Manager, EOS France

As far as the ultrasonic cleaning process is concerned, it consists in immersing the part into a fluid bath (water or solvent), and thereafter, using a transducer to create ultrasound waves. These waves lead to cavitation and once the formed bubbles collapse, they remove debris from the part. One disadvantage of this process is the fact that the immersion of a part into a liquid part makes the removed powder useless while for economic reasons, manufacturers often tend to reuse the removed powder.

The *Co-founder and CEO of Solukon*, **Andreas Hartmann**, provides a general view on the three categories of metallic removal processes:



Andreas Hartmann: Co-founder and CEO of Solukon

*“At first sight manual processes don’t need much know how and can be performed by using blowing or brushing devices. But looking at it closely, manual powder removal is very risky as the operator unavoidably comes into contact with particulate matter.”*

*This metal material is very fine, and is light enough to be airborne in many cases. It is generally harmful to health and there is a risk that it may enter the body via the respiratory tract or through the skin. If the powder is released into the air it can create clouds of dust that may result in a dangerously explosive atmosphere.*

*At the same time, manual powder removal is also time-consuming, and the cleaning results are unpredictable with variable reproducibility*

*compromising the quality.*

*All these factors carry risks for health, safety, quality and high costs.*

*Liquid immersion works very well for cleaning surfaces without leaving a residue but the parts should be pre-cleaned with a dry process as residual powder which often raises issues when internal channels are full of powder.*

*The powder gets stuck and the part is damaged. Ultrasonic can be very helpful but clogged channels are also here possible.*

*In general, when using immersion, the residual powder cannot be reused and has to be disposed.*

*Immersion with chemical solvents or electro chemical pulse methods-are perfect solutions as they can remove support structures and improve the part surfaces.*

*But also, in this case it is helpful to remove most of the powder in a dry process as the powder cannot be reused.”*

Other (patent-pending) powder removal devices and methods are not always intended for AM technologies. Some of them include the use of vibration whereas others use vacuums or magnetic forces to remove powder.

## A close look at each company’s technique to remove metallic powders during a post-production process

### EOS

*As announced earlier, the German manufacturer EOS provides a whole system for powder management. Called, IPCM M pro, it enables to convey out of the AM system, material that is not fused during the building process– without opening the process chamber door and therefore without the operator coming into direct contact with the material.*

*“A vacuum pump conveys the powder out of the system and into the IPCM M pro, where it is sieved under inert gas within the module at a throughput of 120 kilograms of material in 30 minutes – 50 percent faster than previous solutions. Powder treated in this way can be used for a new building process, the powder cycle starts anew.”*



Image EOS: Periphery for powder management

According to the company, it is a comfortable protective equipment due to its advantages in terms of health and safety as well as operability, as the risk of powder contact is minimized.

### Rösler

Rösler does not only provide post-production technologies for metal additive manufacturing.

“We supply post printing & sintering processes. These processes are defined as removal of support structures (both metal and plastic parts) and aim to improve the surface (both metal & plastic parts). Our biggest advantage is the automated feature as well as the long experience the company has as surface specialists”, explains **Vincent Raman**.



Postproduction system of Rösler

### Solukon

As for Solukon, the company has recently unveiled its **SFM-AT800-S** depowdering equipment following the **SFM-AT800**.

Speaking of these equipment, **Andreas Hartmann** said that the “automated depowdering units remove and collect residual powder from complex laser melted parts with targeted vibration and programmable two-axis rotation within a protected atmosphere. The adjustable and high frequency vibration makes the powder flowable so that it can run out easily of very small gaps and intricate channels.

The flowing of the powder is supported by moving the part automated around two axis to all possible 3D positions continuously or to individually programmed positions.

In addition to this, the systems are equipped with manual or automated blowing devices.

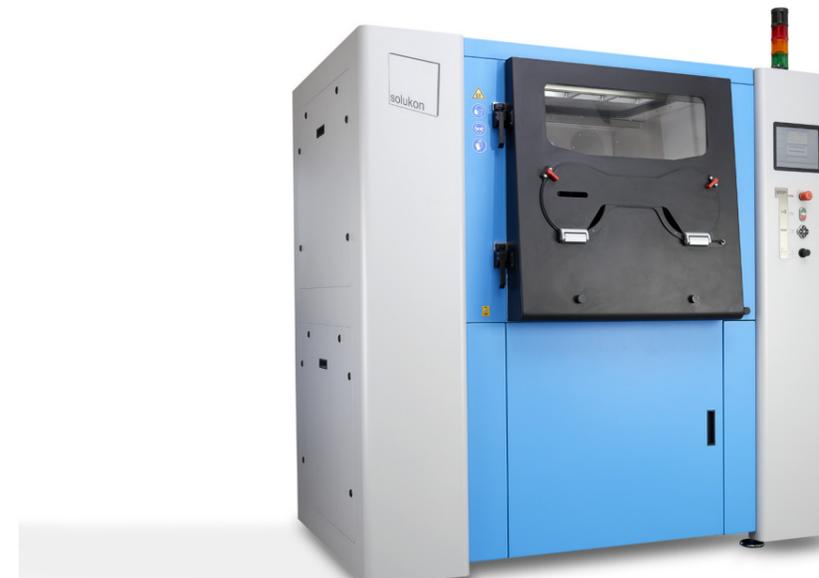
To prevent explosive atmospheres for reactive materials like Titanium and Aluminium the process chamber can be rendered inert due to a safety controlled inert-gas-infusion.

The residual powder can be collected contamination free for recycling in special containers or directly recycled in a connected sieving system.

In addition to mitigating the health and safety risks, users are able to significantly reduce cleaning time and improve the collection and recycling of expensive unused powders.

Some users have reported labor reduction of up to 90% over manual powder removal processes.”

The company adds that, “due to adjustable vibration, the process is very gentle and does not influence the mechanical properties of the part or surface.”



Depowdering system SFM-AT800-S - Solukon

### Getting the desired finished part

At a seminar of GE Additive, one of the company’s engineer states that out of all of the stages that are integrated into the final cost of a part—labor, operating expenses, scrap costs, machining costs, part material costs, solid material waste, powder waste etc.—postprocessing or postproduction often represents nearly 30 percent, which can constitute a big deal for companies. Therefore,

handling the postprocessing operations of a production the good way, might result in significant advantages for companies.

Obviously managing these operations requires to consider all the contours of the idea: the environment, the appropriate equipment and even the final purpose after the removal of powders.



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## INTERVIEW HACKEMAN BERND

*Founder and CEO of TraXer :  
the struggle to provide a healthy  
3D printing environment to  
industrials*

*« Having a perfect 3D printed part is good but enabling workers to produce this part in a healthy environment is much better. »*

Engineer by training, Bernd Hackemann has been working in the additive manufacturing industry for a couple of years. He founded TraXer, a Germany-based start-up that aims at advising professionals from demanding industries such as the automotive, on their use of 3D printing materials. Bernd Hackemann drew our attention last year when he came to us so that we spread the news about his cleaning agent for alkali-soluble support materials (FDM).

With a sense of humour, Bernd shares today what brought him to this industry; most importantly, he reveals a willingness to advance industrial 3D printing processes in a healthy environment.

### **Bernd, what brought you to this industry and what led to the creation of 3DWASH?**

Ebay brought me to this industry. I saw a 3D Printer several years ago on the online store, I bought it and I immediately got infected. :-) However, I share my expertise to the industrial side of the market.

I have been working for a couple of years in the additive manufacturing industry and today, our core business consists in supporting companies in post processing and support material removal processes.

Speaking of what led to the creation of 3DWash, I realized a few years ago that many professionals of the industry use "caustic soda", also known as lye or sodium hydroxide (NaOH) with post-processing. During an experience, I found out that the solution can be quite dangerous if mishandled and can cause health problems to its user. Due to the fact that it can be harmful and to avoid the unhealthy chemical solution, professionals do not like printing with these special soluble materials.

We have therefore developed 3DWASH to remedy this situation and to enable 3D printing professionals to work in a safety environment.

### Tell us more about the specificities of this solution

Simply put, 3DWASH is a cleaning agent that aims to solve 3D printed soluble support materials. The post-processing stage is very important for many customers since a simple 3D printing process is not enough to get an end-product. Furthermore, the main important step in the post-processing stage is to get rid of the support structure which is linked to the complex geometry.

With a low PH value, our soluble support material has some special additive for polymers and protects the model structures of the print.

The three characteristics that enable this solution to stand out from the crowd are:

- Its low PH value: no additional dilution or neutralization is required.
- The fact that it is an eco-friendly solution. Indeed, the user does not require any gloves or goggles to operate 3D WASH.
- The fact that it works with soluble polymers.



### Is the solution only intended for FDM Technologies?

At the very beginning, the solution was only intended for users of Stratasys FDM 3D Printing technologies. However, since Formnext 2018, I realized that the product is also very useful for manufacturers of soluble polymers.

### Is there any specific clarification you can bring on the use of 3DWash for soluble polymers?

For professional use, special soluble polymers are used as support material together with e.g. ABS or PC-ABS model materials. These soluble thermoplastics polymers are unique: although they are insoluble in water, they can be transformed from a solid to a dissolved state in an aqueous alkali solution. Dangerous or toxic

organic solvents are not required. But to avoid high pH levels, 3DWash has been developed.

### How do you manage to develop this market?

Usually, such type of products is developed through manufacturers' network of distributors but they are not always open to add such type of products in their portfolio. However, given the fact that the target consumer base has been recently extended to a wider group, I reach out directly to industrials.

### Is there any recommendation you would like to give to people who do not know such type of product?

My biggest concern while developing this cleaning agent was and will remain work safety. It is a pity that some companies still don't care. Having a perfect 3D printed part is good but enabling workers to produce this part in a healthy environment is much better.

### Your last word?

There is a big difference between professional, industrial 3D printing markets and now common consumer products. I am mostly on the industrial side of the business. I believe, this precision is really important to make.



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**Phone: +49 160 1536392**  
**Website: www.traxer.de**

# Powder Solutions for Metal AM



## Main Powders

- Titanium:** Ti CP, Ti64 Gr5/Gr23, BT9, BT20, Ti6242, Ti4822, Ti2AlNb, NiTi50
  - Nickel:** IN718, IN625, IN713, Hastelloy X, Hastelloy C276, Waspaloy
  - Cobalt:** CoCrMoW, CoCrMo, CoCrW, HA 188
  - Stainless Steel:** 316L, 17-4PH, 15-5PH
  - Die Steel:** 1.2709(MS1), Corrax, H13, S136
  - Aluminium:** AlSi10Mg, AlSi7Mg
  - Refractory Metal:** W,Mo, Ta, Nb, Cr, Zr
- Additional alloys are available upon request*



Advanced Atomization System for Metal Powder Production

**Ti64 Gr5**  
15-45µm

**IN718**  
15-45µm

**Powder Characteristics**

- Controlled chemistry
- Spherical shape
- High flowability
- High apparent density
- High purity and applied to aircraft engine

**Capacity**

- Powder 600t/a
- Powder Atomization System 30units/a

**Particle size range(min/max)**

- 0-20µm
- 15-45µm
- 15-53µm
- 20-63µm
- 45-106µm
- 53-150µm



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# MATERIALS

## The growing use of polymers in Additive Manufacturing : The particular case of PEEK materials



**M**anufacturing technologies can be a true game changer in the production of parts if all components of the manufacturing process are used properly. Materials play a key role in this revolution: producers must not only find the appropriate material for their application; they also need to have a 3D printer that can process it

The challenge is big as all types of materials are involved: metals, polymers, ceramics, concrete and biological cells. This article aims to observe the growing use of polymers in additive manufacturing. A key focus will be made on PEEK materials.

### The use of PAEK materials

PAEK, known as PolyArylEtherKetone is a family of polymers. Under this family, we find several types of materials including PEEK.

Mainly used in the form of poly-ether-ether-ketone (PEEK), PAEK materials have a unique set of mechanical and thermal properties that are compatible with powder bed melting processes such as laser sintering, or with extrusion.

According to Martin Court from Victrex, the key for processing PAEK is to be able to get the polymer over its high melt temperature of

300-400C, and carefully control cooling with heated chambers and process control.

Speaking of PEEK materials in particular, the executive director at Victrex explains: *“PEEK differs from other polymers in that it is one of the highest performing thermoplastics available. Its excellent mechanical and chemical characteristics mean that it uniquely supports a combination of multiple requirements. For example, the versatile light weight, high strength PEEK polymer provides high resistance to wear, temperature, fatigue and aggressive fluids/chemicals.”*

Indeed, given their mechanical properties, PAEK materials are very coveted and are mostly used in demanding applications for the automotive, the aerospace or even the medical industries.

When asked about the importance of polymers for these industries, **Harold van Melick, R&D Director, DSM Additive Manufacturing** said: *“Polymeric materials are widely used in many industries (maybe all industries). Although many applications are cost-driven mass-manufacturing (e.g. injection molding), in many cases the properties of the polymers are decisive in the choice of materials. For instance, it’s impossible to make a connector, a circuit breaker, a tyre, a flexible CVJ boot out of metals. This quest*

*for functionality will drive designers to make applications out of polymers in many industries. The most obvious ones are medical/dental, transportation/automotive, electronics and sports.”*

**Matt Torosian** also lays emphasis on the need to combine the economic point of view with technical requirements. According to the Director of Product Management for Materials



at Jabil, OEMs have applications that they feel are a good commercial fit for polymer AM. The issue is, the material set available does not meet the physical requirements.

*“They have aligned on the DfAM benefits and quantities needed and cost model benefits but if the final part cannot meet the engineering requirements, the application will have to*



*be redesigned into conventional processes where the material set is more aligned with the requirements. If OEMs and all participants up and down the AM Supply Chain want to satisfy those customer requirements, we have to develop Materials, Process and Machines to meet those requirements. Leave one of those three critical pieces out, and you don’t have an ecosystem that can thrive”, adds **Matt Torosian**.*

Even though we understand the importance of using polymeric materials, the reality of the market shows that metal AM remains the technology that pushes the industry forward the

most.

### How can this situation be explained?

Unlike polymer 3D printing, metal Additive Manufacturing is more mature when it comes to deliver desired mechanical properties that one can obtain using conventional manufacturing techniques.

For **DSM**, predictability of part properties and performance are some factors that foster the adoption of metal 3D printing within industries. However, Harold van Melick explains that all applications cannot only be achieved using metallic powders. Various reasons can explain the need for plastic materials: weight, flexibility, accuracy, versatility of properties. All of these reasons drive investments in the development of AM technologies that can deliver functional parts and materials that can provide these property profiles.

**Victrex** on its side, points out the technical aspect, while comparing metallic powders and PAEK materials: “compared to metals, PEEK-based materials are very light in weight, easily shaped, resistant to corrosion and can have considerably higher specific strength (strength per unit weight). In addition to that, potential benefits of using members of the PAEK family of polymers for AM could also include in the future:

- improved economics through elimination of machining waste, improved refresh rates in powder bed fusion (PBF), and improved material utilisation in filament fusion (FF) or
- patient customized implants and improved outcomes through new features and better fit.”

**Jabil** on its side also mentions an interesting point: there is a limited number of players that can address the latent demand of the polymer 3D printing market on the one hand, on the other hand, an already existing market for metal 3D printing that contributes to the growth of the industry: *“Polymer materials in the Additive Manufacturing market, especially powders for SLS and HSS are restrained by a lack of participants. As new applications have emerged, the number of Engineered Materials available has not significantly changed. Beyond the resin producers that offer 3-10 grades of SLS powders each, only a handful of producers globally produce reinforced, custom engineered powder products for SLS. If you compare that to the conventional polymer process market,*

injection molding and extrusion, there are literally hundreds of compounders that fill that need in the AM market. Therefore, companies are investing to fill that gap in the fundamental building block of functional parts i.e. polymer materials. In relation to metals, the number of materials involved in polymer AM is much fewer. Also, in metals, there is an established market for powdered metals.”

There is a clear need for plastic materials that integrate an array of mechanical, thermal and chemical properties that can meet the needs of the industry. The portfolio of polymer materials in AM is still quite limited; about 1% of what is available for injection molding is currently exploited. We therefore understand the increasing investments that can be made to deliver appropriate polymeric materials and technologies.

### Let's speak about the thermoplastic PEEK



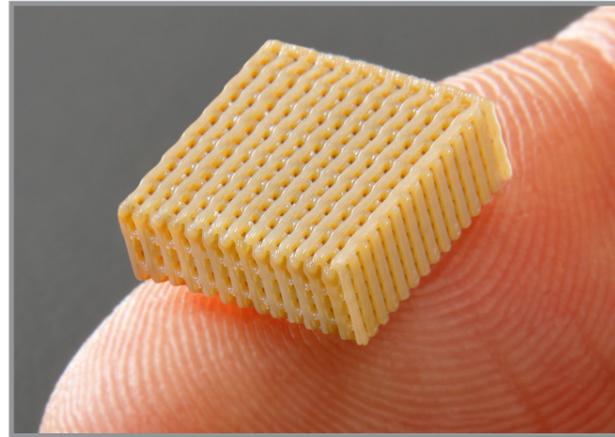
Martin Court : Executive Director at Victrex

In the plastics industry, PEEK is regarded as one of the top materials of the pyramid and this rank is mainly due to both its properties and cost. The engineering material is recognized for its chemical resistance, high temperature as well as flammability properties. Using this material in AM enables to deliver these properties in addition to usual advantages of polymers.

However, it should be noted that there is an array of polymers that are made available on the market: polyamide, polyester, PPA, PPS and more. Each of them has its own strengths and

weaknesses. The set of requirements that an application must meet will determine the choice of material that must be used.

### A huge potential for the medical sector



Fined detailed porous structure printed in Victrex PEEK using BOND3D technology - Copyright: Bond High Performance 3D Technology

3D printing allows the production of custom-made implants and facilitates communication between participants in the supply chain. This new way of working drastically transforms preoperative planning and surgery. PEEK-based implants are the ones that are mostly used because of the benefits they can bring to patients. Current researches on this material and its applications include dental, knee, spinal and trauma implants.

Among the solutions that are currently delivered in the medical field, there is for example, PEEK-OPTIMA polymer from Invibio Biomaterial Solutions, “Victrex’s medical business, enables artefact-free monitoring and assessment of patient healing sites. Additionally, PEEK has a modulus closer to bone which, compared with metal, which helps minimize stress shielding and stimulate bone on growth.”

Although additive manufacturing is still at its early stage in the medical sector, there is every reason to believe that this technology can be a game changer in terms of speed and accuracy in the manufacturing of implants.

### A few issues that need to be tackled

Despite the strong interest from industrials in PAEK materials, a number of issues still need to be tackled to achieve a wide range of applications. Existing and new entrants should work on how new materials can fit with new

processes and new machines.

For Matt Torosian from JABIL, this means working with independent suppliers: “the Polymer materials market needs more entrants that are open and independent of machine manufacturers and the entire machine manufacturers’ supply chain. When you link the material supplier to the machine supplier, you limit the ability for OEMs and Processors to optimize and innovate both the material and the process. This in turn limits innovation at the machine level because they are not pushed to develop new machine technology to fit an ever-changing materials and process landscape. If you look at this like conventional processes, the independence of compounders, resin producers, mold makers and machine producers has propelled the technology to its current state.

The four critical aspects of the process continuously expand the envelope of what can be done, pushing each other to innovate and to be able to use a unique material, complex tools or machine technology that exploit some attributes previously not possible by the current state of the technology.

Our feeling is, the market always wins when it is not restricted. Open platforms and markets should be the focus of the AM ecosystem in order to reach the maximum level of innovation and adoption.”

Unlike Jabil, DSM presents a more holistic approach to develop the market. For the

producer of materials, the key to develop this part of the market lies in “the way one translates the application requirements into material properties (that determines material selection) and a 3D printing technology that will be able to convert those materials.”

### Standardization of materials

To be part of the industrial world, additive manufacturing technologies and materials will have to meet application requirements. From design to production, standards are essential because they enable the various stakeholders to speak the same “language”. Furthermore, they ensure a good quality control of the final product.

International standards organizations have been collaborating for the development of additive manufacturing standards. Although several standards have already been published, there is still a long way to go for materials. The variety of technologies and players does not make things easier but there is no doubt that the future of polymer materials for AM partly depends on this standardization process.

Lastly, enabling high-quality standardization also means strengthening the image of these technologies and giving them more credit. Finally, it means accelerating their integration and strengthening the competitiveness of companies.

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## SIMULATION SOFTWARE use, advantages & limitations



Systems used in the manufacturing industry have a lot of dependences, that are not static. So far, simulation appears to be one of the rare tools that can analyze and improve these complex and dynamic systems. In the additive manufacturing industry especially, operators still wonder how they can ease the transition from traditional manufacturing to actual AM.

We will tackle this issue by laying emphasis on their use, advantages and limitations. **Pareekshith Allu**, Senior CFD Engineer at FLOW Science, Inc. and **Rashid Miraj**, Director of Technical Operations at AlphaSTAR shared their expertise in this dossier.

Both companies have extensive experience in software solutions. They supply their services across

a wide range of industries, and obviously, additive manufacturing is part of them.

Flow Science, Inc. is a software company that develops tools for computational fluid dynamics, also known as CFD. Among its CFD solutions, the company has developed FLOW-3D, a CFD software that provides solutions for free-surface flow problems.

AlphaSTAR Corporation on its side is a software company that provides advanced engineering services for physics-based simulation technologies. Dedicated to additive manufacturing, structural modeling and analysis of advanced composite structures its simulation technologies are exploited in the aerospace, automotive, defense and energy industries around the world. The company

has developed GENOA3DP, an Additive Manufacturing Simulation tool that assists the 3D printing process in predicting deformation, residual stress, damage initiation and crack growth formation associated with as-built AM parts.

Both resource persons will take examples from use cases developed by the company they are working in, to illustrate their arguments.

A simulation tool enables to imitate the operation of a real-world process or system. Those types of software enable engineers to predict the behavior of a system based on the evaluation of the design, the diagnosis of problems with an existing design as well as one or several tests of a system under conditions that are hard to reproduce.

Various reasons can explain the use of a simulation software by engineers and scientists: the need to create and simulate models at low cost rather than build and test hardware prototypes; the need to test several designs before choosing one to build on an additive manufacturing system, or even the need to test the integration of the full design by connecting the simulation software to hardware.

There might be a thousand other reasons why engineers and scientists use simulation software. However, the most difficult part is not to know the reasons why simulation

software can be used – since at this time, its potential is no longer to be proven -, but above all, to know what features of simulation software best meet their needs.

### Main features of simulation software for additive manufacturing

According to **Pareekshith Allu**, Senior CFD Engineer at FLOW Science, Inc., “a simulation software needs to have three features: it needs to implement relevant physics accurately across a range of length and time scales, it needs to be computationally efficient, and it needs to be intuitive for the user.”

Even though simulation can be applied with various 3D printing technologies, the Senior CFD Engineer also lays emphasis on the difference shades that may rise in the use of simulation software for various AM technologies.

“In laser powder bed fusion (LPBF), direct energy deposition (DED) and selective electron beam melting (SEBM) for instance, we need to be able to simulate powder spreading and bed compaction, melt pool dynamics and associated defects such as balling, keyhole formation and porosity, and residual stresses and distortions in the finished part. Our modelling

tool FLOW-3D® accurately simulates these AM processes by implementing all the relevant underlying physics at the micro- and meso-scales” adds **Pareekshith Allu**.

“Through such simulations, users can develop process windows for various parameters such as laser power, scan speed, hatch spacing, and powder size distributions, to successfully additively manufacture different alloys. Computational efficiency allows AM engineers to generate these process windows more quickly than running experiments.

Of course, ease of use is key to successfully incorporating simulation software. An intuitive, process-based interface lets users follow a logical sequence of setup that implements the necessary inputs like material properties, CAD geometries, meshing and boundary conditions in a meaningful way. This translates into a short learning curve for first time users, and a simulation tool that is accessible to a wider audience of industry and academic professionals.”

For AlphaSTAR on the other hand, an accurate simulation of an AM build must consist of the following components and techniques:

- “A validated as-built

virtual material model incorporating temperature dependent material properties.

- Quality assessment of the g-code, laser path, printing process, and printed part.
- Fully coupled thermal-structural process simulation analyzing build deformation and defects.
- Ability to submit virtual as-built part to in-service loading.”

In addition to these general features presented by the company, AlphaSTAR’s software, GENOA 3DP, enables its users to achieve environmental effects (like oxidation), to calculate void and damage using global or local material modeling or even to qualify and certify to achieve part performance prediction.

Moreover, additive manufacturing remains a relatively broad topic and one thing, we have already observed is that 3D printing technologies do not often really look alike and might require a wide range of materials. So, do simulation software solutions change according to a specific type of additive manufacturing process or according to the materials used?

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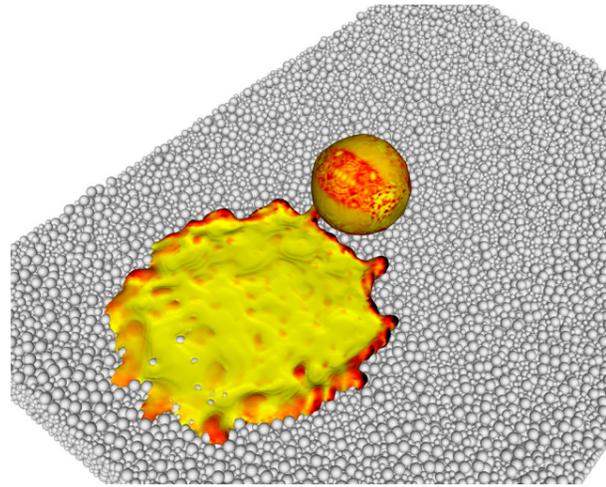
## Simulation software, additive manufacturing processes & materials

When it comes to simulation, both experts believe that simulation software solutions usually do not change according to a specific type of AM process or material.

Speaking of AM processes such as LPBF, DED and SEBM, Flow 3D explains that all these AM processes have an energy source, such as a laser/electron beam that interacts with powders to form a melt pool and eventually a solidified track or a single layer. The process is repeated until the full part is built. The underlying physics – laser/electron beam interaction with particles, melt pool dynamics and solidification - is similar across all three processes.

Taking the example of FLOW-3D, Pareekshith Allu adds that: *“Granted, the setup and analysis of such processes in a simulation tool will be different, but at the end of the day, in FLOW-3D, the users will still be taking a CFD-based approach and solving the relevant governing equations to model all these processes.”*

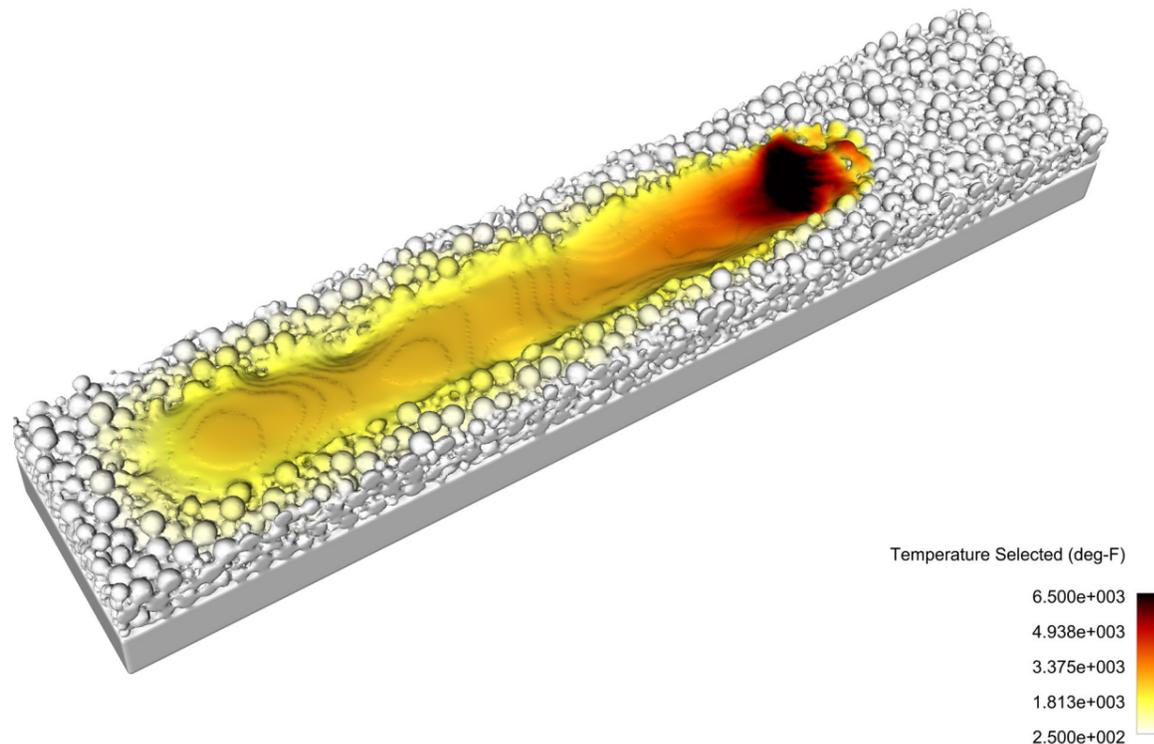
As far as binder jetting simulation is concerned, the senior engineer explains that, since there is no melting of particles, the application of simulation software differs



from the previous AM processes. For such scenario, the company recommends a CFD approach that enables accurate analysis of the interaction between binder resin and particles and leads to better design of process windows for particle size distributions, binder droplet sizes and velocities.

*“As for material properties, they are inputs into FLOW-3D. The software solution will not change in the sense that a physics-based tool still solves the same underlying governing equations, irrespective of the material properties that are input into the model.”*, concludes **Pareekshith Allu**.

This being said, we still have to determine what a simulation software is capable to achieve in practice.



## How does GENOA 3DP distinguish itself among others of the same range?

– **The case of a mount ring bracket for a defense agency**

**GENOA3DP** mainly supports the virtual simulation and analysis of polymers, metals and ceramics. In addition to what has been aforementioned (identification of location and extent of damage and fracture), parameters such as printing speed, intrusion distance, temperature and material type can be modified to improve the manufacturing process. Rashid Miraj, Director of Technical Operations at AlphaSTAR shares below how the software was used in the manufacturing of a mount ring bracket for a defense agency.

*“GENOA 3DP is a micromechanical solution that allows users to virtually qualify each step of the AM process from material characterization, to build simulation/optimization to in-service loading of the printed part.*

*In the case of a mount ring bracket for a defense agency, GENOA 3DP was able to simulate the additive process from start to finish: beginning with a material model that accounted for temperature dependent properties and the effect of defects; secondly, the utilization of multi-scale progressive failure analysis, to simulate the build and identify manufacturing anomalies related to geometry (i.e. the need for supports) and damage initiation/propagation. Furthermore, the software allowed for Design of Experiments to identify an optimal build path and reduced manufacturing defects such as residual stress. Last and most importantly, the virtual as-built part was subjected to service load in order to ensure that finished product met specification and qualification.”*

## How does FLOW-3D distinguish itself among others of the same range?

– **Effects of random powder distribution and material evaporation on melt pool dynamics**

Among its various applications, FLOW-3D stands out by enabling the development of process windows for alloys and delivers analyses of microstructure evolution, which is of paramount importance to both AM machine manufacturers and end users of AM technology.

Indeed, thanks to the company’s proprietary

volume-of-fluid algorithm called TruVOF®, it is possible to track the evolution of the melt pool surface. Coupled to this algorithm are various physics models such as surface tension, viscous flows, laser heating, evaporation pressure, phase change, and solidification. A discrete element method (DEM) has also been integrated to simulate powder spreading and compaction.

To demonstrate the capacities of its software, the company shares today the effects of random powder distribution and material evaporation on melt pool dynamics.

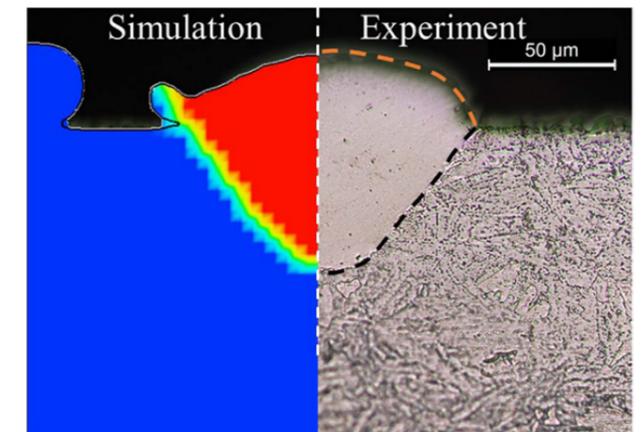


Figure 1: Validation of the melt-pool dimensions (black-dashed line) and the surface morphology (orange-dashed line).

*“A three-dimensional numerical model that incorporates a randomly-distributed powder bed and material evaporation was developed using FLOW-3D to investigate melt pool dynamics with keyhole formation in a laser powder bed fusion process. The discrete element method (DEM) was employed to simulate powder packing, which accounts for the motion of a large number of particles including particle/particle and particle/wall interactions. The model was validated by measuring the particle size distributions in specific areas and ensuring that no powder size segregation occurs. Next the flow behavior of the melt pool is characterized by calibrating parameters in the numerical model to achieve good agreement with the experimental results. The importance of including material evaporation in the numerical model is demonstrated by measuring the melt pool dimensions, which turn out to be narrower and deeper than when evaporation effects are not considered. Moreover, a keyholing effect is observed due to the recoil pressure resulting from evaporation, which affects surface morphology and surface temperatures of the melt pool. As illustrated in Figure 1, the*

contours of the cross-sections of the melt region including the dimensions and surface morphology compare very well between the simulations and experiments, justifying the importance of including evaporation effects.”

**The evolution of the simulation software in the additive manufacturing industry**

This overview in the world of simulation software gives an interesting perspective on the reasons and the features that users consider crucial to take advantage of a simulation software. Although those companies only share their insights based on their customers feedback or their own experience, keep in mind that, in the end, the most important is that the user is able to know how to produce a metal or polymer part with reliable and repeatable

results.

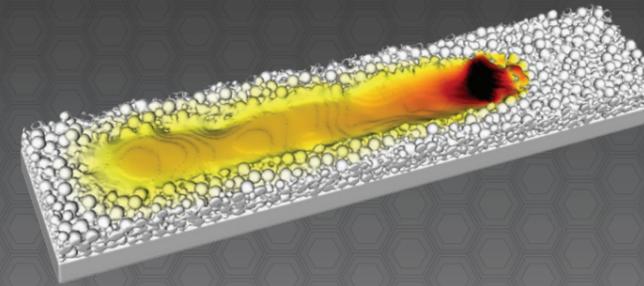
As **AlphaSTAR** said: “the most important role of software in the AM industry is to see who can deliver finished goods that meet customer demands.”

Among the current areas for improvement, experts underline the need for users to have a simulation tool that can run on desktop computers in reasonable time frames and provide actionable information to achieve process parameter optimization on the one hand; on the other hand, the urgency to improve the availability of material properties of various alloys.

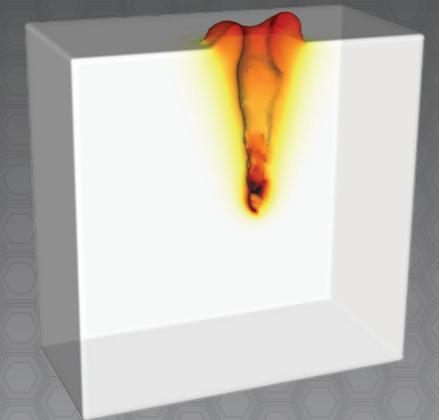
Lastly, it goes without saying that every software company will have its own areas for improvement to watch in order to achieve its business objectives.

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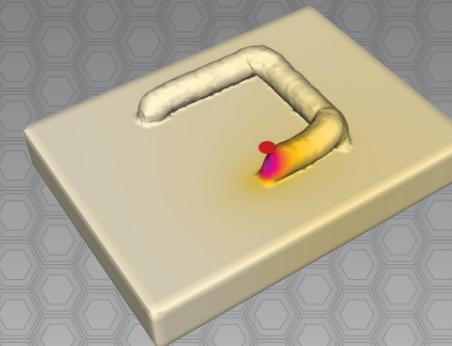
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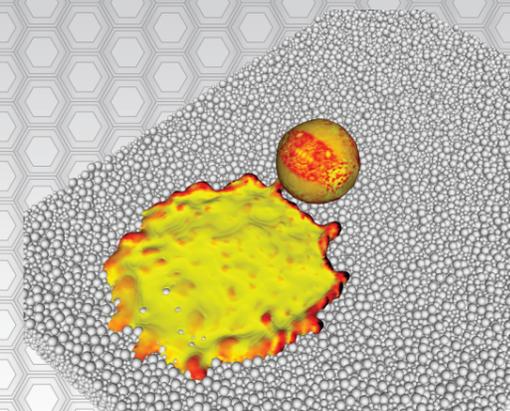


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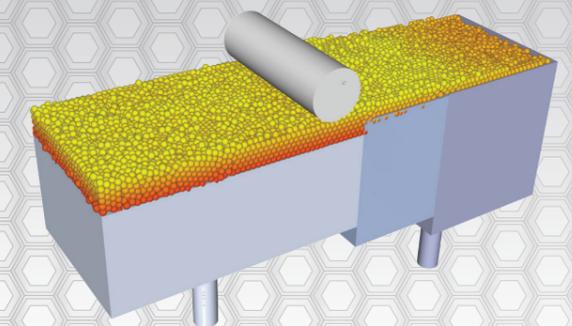


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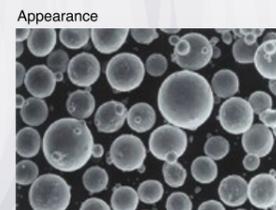


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## Focus on 3D printed electronics

3D Printed electronics is one of the young areas of application of additive manufacturing. In his analysis of the 3D printing market in 2018, President Nano Dimension USA, Inc. **Simon Fried**, told us that the evolution of this market “has been similar to how traditional additive mechanical manufacturing evolved. The companies leading the adoption of additive manufacturing are the same kinds of industries that are now making strides in the direction of additive manufacturing of electronics -- including aerospace, defense and R&D organizations. During 2018, this revolutionary area of 3D printing continued gaining traction, its impact will be felt in products, production systems and design-flows.” This statement left a great number of unanswered questions among additive manufacturing professionals, especially engineers from engineering offices. We have decided to tackle them in this segment.

With the digital revolution, communications technologies are heavily intertwined and products are increasingly being electrified. For this reason, specialists of this field are continuously looking for new ways to improve the production of smaller, complex and functional tools such as inks onto flat surfaces using printing processes usually intended for the graphics industry (screen, ink-jet, flexo, gravure, etc.) or RFID tags, sensors, displays, smartcards, keypads, and packaging. Common characteristics of these applications include low costs and the fact that high-performance is not required.

However, the recent development of tools for AM has raised three main challenges in efficiently applying 3D Printed electronics. For **Christoph Völcker** from the Innovation Lab – AM Würth Elektronik eiSos GmbH & Co. KG, those main challenges are materials, techniques (hardware) and data.

### Materials

Just like classic additive manufacturing technologies such as FDM, we also observe that, combining electronically functional materials to AM enables complex 3D geometries and results in the creation of devices that cannot be created using conventional 2D printing methods.

Depending on the purpose of manufacturing, producers can use two main types of materials: dielectric materials (which means that no current will flow through the material when a voltage is applied) and conductive materials (which means the material can conduct the electric current). A few examples of dielectric materials include Hatchbox PLA, ColorFabb bronze-fill PLA whereas Electrifi (Multi3D LLC), the graphene-based conductive PLA (Black Magic 3D), or even the carbon black-based conductive PLA (Proto-pasta) are conductive materials.

Those various materials raise the challenge of cross-contamination during the fabrication. Indeed, it is difficult to combine two different filaments during the printing process. According to a research from Duke University (in the USA), “cross contamination of conductive materials will result in either shorting between conductive traces, or in the interruption of a conductive trace with non-conductive materials.”

Although several 3D printers with multiple nozzles can be found on the market – understand FDM 3D Printers - most of them are not able to prevent cross-contamination whereas “typical multi-material 3D printers use two separate nozzles at the same Z height, but this method leaves the inactive nozzle in a position where it is likely to scrape across the printed surface and cause cross-contamination”, explains the research from Duke University. According to experts, one approach to solve this issue is to extrude multiple materials through the same nozzle.

This challenge is observed when 3D printed electronics is applied with professional 3D printers. At the industrial level, Nano Dimension, one of the companies that specializes in 3D printed electronics, mentions the need of more material options to produce high-complexity and

high-functionality parts. While comparing all 3D Printing materials used in the AM industry, **Simon Fried** told us: “Polymers are getting stronger and a wider range of metals are now printable. For electronics, additional functional aspects such as dielectric constants and looseness are paramount.”

### Hardware

So far, a few number of companies can efficiently supply 3D printers for electronics. Despite this limitation of hardware, one can mention, in addition to Nano Dimension, Optomec, BotFactory and Voxel 8 as other manufacturers of electronics 3D printers on the market.

Released in 2017, **Nano Dimension's** 3D printer **DragonFly 2020** produces multilayer printing of conductive traces using an inkjet technique at a lateral resolution of nearly 30  $\mu\text{m}$ . Experts from Duke University stated that it is time consuming to develop novel electronic inks for ink-jet processes, not to mention the difficulties encountered. This is mainly due to the need to adapt the surface tension and viscosity (8–12 cp) of the ink to obtain a desired droplet size ( $\sim 30 \mu\text{m}$ ) and reproducible jetting characteristics. Furthermore, “clogging can be an issue if the size of the particles or the amount of solids in the ink is too high”.



Credit – Nano Dimension - DragonFly 2020 3D Printer

**Optomec** on its side, has developed the Aerosol Jet™ process. The 3D printer enables the deposition of polymeric and metal inks for sensors. The process is a non-contact one, compatible with a wide range of conductive, insulating and resistive materials. The 3D printer has already enabled the production of conformal sensors, low loss passives and antennas for on-chip and off-chip electronics.



Credit – Optomec - Aerosol Jet™



Printed with Aerosol Jet 5x System

As for this process, it requires the use of a sheath gas as nozzle, to eliminate the clogging issues that plague ink-jet.

In 2015, the market discovered BotFactory's Squink PCB Printer followed by the SV2, a few months later, a Desktop PCB Printer. It is, as per the company's words, “capable of printing multilayer circuits, dispensing paste onto pads, and pick-and-placing components onto the

board”.

Lastly, the **Voxel8** 3D printer is a mix of conventional plastic filament extrusion nozzle with a syringe-based silver ink extruder. One thing that characterizes this printer is the pause that can be done during the printing process to enable manual placement of circuit components. However, the printer cannot achieve print free-standing structures in the Z-direction, with recommended trace thicknesses < 500 μm.

This overview of 3D printers shows a lack of suppliers of electronics 3D printers, despite the existing quality on the market. Furthermore, based on analyses and researches that have already been carried out on 3D printed electronics, the use of this technology also presents a limitation at the post-processing stage where techniques should be implemented to achieve the full production of a 3D printed part with the desired electronic properties.



Voxel 8

### Data

In much the same way that big data brought a range of benefits to various industries & companies, it has also proven to play a crucial role in the growth of 3D printing. In this particular industry, data enable an accurate analysis at the software level. Furthermore, the more complex the part to 3D print is, the more data might be needed.

Even though, experts weren't able to bring a more in-depth opinion on this part, analysts believe that data have further facilitated applications in 3D Printed electronics. For this reason, this latter field would be a cheaper option for companies.

### Final Thoughts

Although engineering plastics and metals were almost the overriding narrative of 2018, the field of 3D printable electronics aims to enable low-volume, on-site/on-demand production of highly complex and easily customizable electronic structures while reducing material waste, energy consumption, prototyping time, and cost relative to conventional electronics fabrication methods. At this level though, the market is in major need of more material & hardware options and more solutions to overcome the challenges encountered at the post-processing stage.

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# CASE STUDY SINTRATEC

## Application of 3D printing in the medical sector



Crédit : Sintratec 3D printer (S1)



In the medical industry, common applications of the use of 3D printing include prostheses, implants or even 3D Printed models. **EEM AG**, a company that develops custom-made ergonomic chairs to treat back pain and relieve the spinal discs, brings an interesting insight into the way it takes advantage of laser sintering technology to produce prototypes and small series.

**How does SLS technology enable the production of special chairs for extension therapy?**



Cyrill Aemisegger – Head of Technology at EEM AG

The spine is crucial to good health. It provides support for the whole body, protects the nerves and enables to move in many different ways. So, providing a service that aims to relieve people that suffer from back pain is simply giving them the chance to better live. In this vein, EEM AG manufactures various health-promoting products under the 'grow concept' brand. The goal of the company is to enhance well-being and performance at home, in therapy or at work. The company's flagship is its developed and patented special chair, which – using an innovative process – relaxes the back within 10 to 20 minutes.

### It is like selling water in the desert

Back pain is one of the most important causes of inability to work. In Germany, for example, nearly one in three adults suffers from back pain, which results in a high level of absenteeism at work. The number of unreported cases is high, yet, other ailments can also be caused by an unhealthy posture: eye complaints, arthritis, foot pain or sleeping disorders.

Extension therapy turns out to be a

solution that patients use to relieve their pain. The therapy consists in the use of an automatically adjustable relief chair. Cyrill Aemisegger, Head of technology of EEM AG explained the context in which the therapy takes place: "we are in the EEM showroom in a small village in the canton of Thurgau surrounded by green pastures, old apple trees and vineyards – a place where you don't exactly think about back pain. Instead of taking painkillers, the "grow" chairs tackle the health problem at its roots."

According to experts, the daily strain causes our spines to shrink by up to three centimetres in the course of the day, depending on our physical activity. EEM AG explains that the treatment on the grow chair ensures that the spine expands again - with positive side effects that promote the body's regeneration: The nerves are calmed down and stress is reduced. 'It makes a short break feel like a brief holiday,' says Cyrill Aemisegger. So far, the company has already satisfied hundreds of clients with its custom-made chairs.

## So, when does 3D printing come into play?

As you may guess, 3D printing comes into play at the manufacturing level. The medical company wanted to produce various components as fast as possible. Cyrill Aemisegger already has an extensive experience in conventional production methods. The head of technology even manufactures some parts for the electronic cover himself. CNC milling was not the right choice to produce these special components, due to its limited agility.

Two years ago, after an in-depth study of the various 3D printing techniques, he noticed that he had high demands. However, the head of technology did not go for FFF (Fused Filament Fabrication) because of its support structures. He explains that the post-processing stage would have been too costly for him.

Even the SLA process (stereolithography) did not meet his requirements. Indeed, parts printed in SLA would not have been mechanically stable enough and would have required a lot of work and expenses.

He thereafter turned to Sintratec S1, an entry-level technology that was affordable for a SME like EEM. The technology has enabled the production of the first three models of the brand. The 3D printing technology enabled them (and still does) to achieve immediate results and foster their development process.



### More than 20 printed parts per chair

Simply put, a total of more than 20 functional objects per relief chair is now produced using the 3D printing process. The chairs are still at an advanced prototype stage. However, in the models produced to date, the 3D-printed components do not serve as placeholders for injection-moulded parts for the future mass production, but are fully functional.

They have largely the same mechanical and visual properties. Combined with the ability to quickly change printed partial-geometries, the process is proving to be the most efficient production variant for current small batch production. The Switzerland-based company thus strikes a balance between prototyping and small series

production.

In addition to the 16 mobile protective covers, the electronic protective socket, the holder for the remote control and the clever quick-release system for the exchangeable headrest are laser-sintered. The holder for the remote control now distinguishes itself from others of the same range thanks to its new design and eye-catching details that give a modern look to the whole product.

### The uniqueness of the SLS technology

Selective laser sintering offers designers and engineers fascinating 'process-specific' possibilities that allow for completely new designs. An example of this is the quick-release system of the headrest, which impresses with its small but subtle ingenuity: the design of the two moveable parts printed inside each other would not have been possible to achieve with either a conventional manufacturing

system or any other affordable 3D printing system. One advantage of this design is that with the mounted spring, the locking function is also elegantly provided. 'Thanks to SLS technology, we can implement more complex designs and build them precisely for their function,' continues Cyrill Aemisegger.

The use of the Sintratec S1 has had a significant impact on EEM's engineering. '[With] the Sintratec S1, we have been designing in a much more function-oriented way' sums up **Cyrill Aemisegger**. 'The Sintratec S1 is used day and night in our production and it is hard to imagine working without it.'

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## Bonus Topic

### Focus on the use of 3D printing in the medical sector



#### “Just because you can print it doesn’t mean you can use it.”

The use of 3D printing in the medical sector reveals that the technology is already exploited in 7 fields of application: orthopedic surgery, maxillofacial surgery, reconstructive plastic surgery, ENT surgery, neurosurgery, cardiac surgery and urological surgery.

While the technology is increasingly used in medical applications, its main benefits (time saving and pre-operative planning) are almost always highlighted compared to the real challenges encountered by players. Those challenges often include legal restrictions or communication barriers at the level of the process implementation.

A talk with 3D-Side sheds light on these issues in such vital area and reveals that, “just because [one] can print [a model], doesn’t mean [one] can use it”.

#### 3D-Side, a company that delivers a patient specific surgical technology”

3D-Side is a medical technology company founded by Khanh Tran Duy and Laurent Paul. Mechanical engineer by training, Khanh Tran Duy completed a thesis in maxillofacial surgery assistance and Laurent Paul focused his research on surgical assistance for bone tumor. They decided to combine their respective expertise in the surgical field to additive manufacturing and software in order to create 3D-Side. Healthcare professionals can benefit from these services at the international level.

While taking advantage of the results of their thesis, 3D-Side aims to add value to the way surgeons work. Technically speaking, the 3D-Side team uses the patient’s medical images to elaborate a schedule that best describes the procedure that fits his/her need. Once the medical device has been produced, it is sent to the hospital in charge of the patient.

After more than 10 years in R&D, the team has launched “Customize”, a platform that facilitates the creation of tailor-made 3D printed devices/ models on the one hand, on the other hand, ensures communication with surgeons and sets up a complete ISO13485 workflow to plan complex interventions.

#### The use of 3D Printing in the medical field

3D printing or additive manufacturing consists in making three dimensional solid objects from a digital file, using appropriate materials (metal, plastic, ceramic or resin). Until now, the manufacturing process seems pretty much easy to achieve once the user has a 3D printer and the required materials.

However, in the medical field, a number of elements make the use of a 3D printed model complex. That’s why Khanh Tran Duy mentions the difference between “making an STL. file” and “being the legal manufacturer of a medical device (MD)”: “In the healthcare industry, having a 3D printer, software and appropriate materials is not enough. The medical industry establishes a clear difference between the manufacturing process and the legal manufacturer. The legal manufacturer has to comply with the European directives on the use of 3D printing in the medical sector. He takes on responsibility of ensuring his/her technology is compatible as well as responsibility of each 3D printed model, which requires a number of validations to confirm the use of the 3D printed model and its performance.”

#### Legal aspects to consider regarding 3D printed medical devices

At the European Union level, 5 main aspects frame the use of 3D printing for the manufacturing of medical devices. Obviously, the application of these aspects may vary from one country to another according to the current legislation:

- **Requirements for market access.** In general, Khanh Tran Duy explains that a series of actions have been implemented to improve traceability of 3D printed MD. This general requirement includes that distributors and importers must collaborate with manufacturers, so that every stakeholder can identify the previous and next participant in the supply chain. At the level of 3D-Side for instance, the platform “Customize” makes it possible to ensure collaboration between all involved parties in a project. A “co-design” module allows the surgeon to modify and validate the prototype before its production, to handle the production process and to ensure that the right person receives the right information at the right time.

- **Liability.** As the co-founder of 3D-Side states: “the producer is liable for any defect in its



Khanh Tran Duy

product. As far as 3D printing is concerned, there is a deviation from the traditional chain of production, distribution and use. Many parties are involved in the production of 3D devices in this case: the surgeon who makes the initial design, the software engineer who develops the 3D design, the 3D printer’s producer, the materials supplier, the implanting surgeon, the hospital, etc. The complete ISO13485 workflow must carefully be applied. Furthermore, professionals should keep in mind that new regulations will be effective as from May 2020. The EU-MDR (Medical Device Regulation) strongly strengthens all these applications.”



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In addition to these two aspects, one notes 3 other legal aspects drawn from the KCE (Belgian Health Care Knowledge Centre) report on the use of high-risk medical devices: **patient rights, protection of patient data and intellectual property rights.**

### Medical devices and mass personalisation

As in every area of application of 3D printing, mass production and/or mass customization are also part of the concerns raised. In the medical field, there are two types of MD: tailor-made MD and custom-made/personalized MD (CE Marking required).

According to Khanh, in contrast to standard or tailor-made medical devices, manufacturers of custom-made medical devices, regardless of the risk profile, should apply a CE marking to their product. The standard one remains unmarked and requires a mandatory validation process as well as an appropriate PMS (post-marketing surveillance), which takes a lot of time. For these devices, "although it is complex, mass customization can be achieved", concludes Khanh.

### Challenges and development opportunities

Speaking of challenges encountered by the use of 3D printing in the medical sector, the financial aspect remains a substantial hurdle to its full integration.

Indeed, despite the advantages of a 3D printed

guide, the price of a 3D printed MD remains expensive and this is mainly due to the product liability insurance.

According to our resource person, in Europe, MD are not that expensive compared to other markets. However, European countries vary from one to another and apply the requirements for market access according to the existing law.

Surprisingly perhaps, hospitals cannot 3D print their own MD. They must be granted a certain number of qualifications first, not to mention, the mastering of new skills required by 3D printing technologies.

Companies keep developing 3D printing technologies, but they are in fact a "small" step in the production of a MD. The ratio cost/benefit must always be controlled and measured. For the patient and social security.

Despite these financial barriers, the co-founder of 3D-Side sees a future where 3D printing will enable mass customization and where professionals will feel more confident in the use of 3D printing technologies. Lastly, manufacturers, should always keep an eye on regulations, because "just because you can print it, doesn't mean you can use it," concludes **Khanh Tran Duy.**

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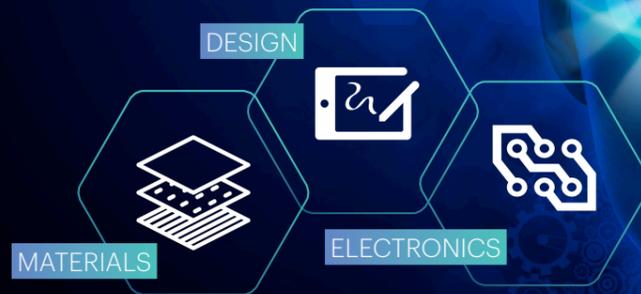
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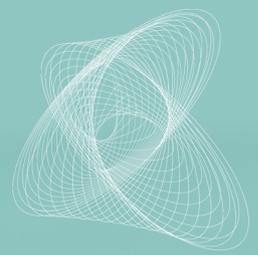
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