dap Digital Additive Production | RWTH AACHEN UNIVERSITY

Inventing the Future of Medical Technology

How the DAP Chair and Meotec are inventing the future of medical technology, developing patient-specific resorbable implants with innovative designs and new material compositions.

03/23

The Implant of the Future

Conventional implants are expensive, invonvenient for patients, and often require follow-up surgeries. Patient-specific and bioresorbable metallic implants offer a gentler and more efficient alternative that can meet high demands. However, research in this area is still in its infancy. To accelerate the progress, the Chair Digital Additive Production DAP at RWTH Aachen University has teamed up with materials experts from Meotec GmbH, along with other project partners in the medical technology field. As part of the BMBF-funded BioStruct project, they have developed a procedure that has the potential to revolutionize medical technology.

It could be so simple: when an implant wears out, it is removed from the patient‘s body. However, in practice, removal surgeries carry a significant risk. The alternative could soon be the use of bioresorbable implants, which gradually dissolve in the patient‘s body once the tissue has adequately regenerated. This approach could significantly improve the efficiency and patient experience of treating intricate bone defects, such as those resulting from tumors.

In addition, far more patients could be treated than before, as valuable operating time would be freed up by the elimination of removal surgeries. As a result of rapid technological advancements, the entire implant market is projected to expand to $106.9 billion by 2024, indicating substantial growth opportunities.

The requirements for material, design, and manufacturing technology for the production of bioresorbable implants are complex. A promising economic solution to meet these requirements is Additive Manufacturing, better known as 3D printing. The specialists for Additive Manufacturing from the Chair Digital Additive Production DAP at RWTH Aachen University have therefore joined forces with experts from Meotec GmbH in Aachen and other project partners as part of the BioStruct project. Since its founding in 2013, Meotec has specialized in the production of bioresorbable metallic implants made of magnesium and now covers the entire value chain in this area of production. Together, the interdisciplinary team is now working on the development of a novel zinc-magnesium alloy. The aim is to produce improved patient-specific and bioresorbable implants that

Additively manufactured demonstrator made from a zinc-magnesium alloy with a strut diameter of 200 µm.

will contribute significantly to the natural regeneration and healing of bone defects and ideally make follow-up operations unnecessary. The BioStruct project received an initial funding of approximately 2.8 million euros from the Federal Ministry of Education and Research (BMBF). The Additive Manufacturing process offers decisive advantages, and the first clinical tests are planned for 2024. Once successfully implemented, the digital process allows for the customization of bioresorbable implants to the needs of individual patients while still being manufac-

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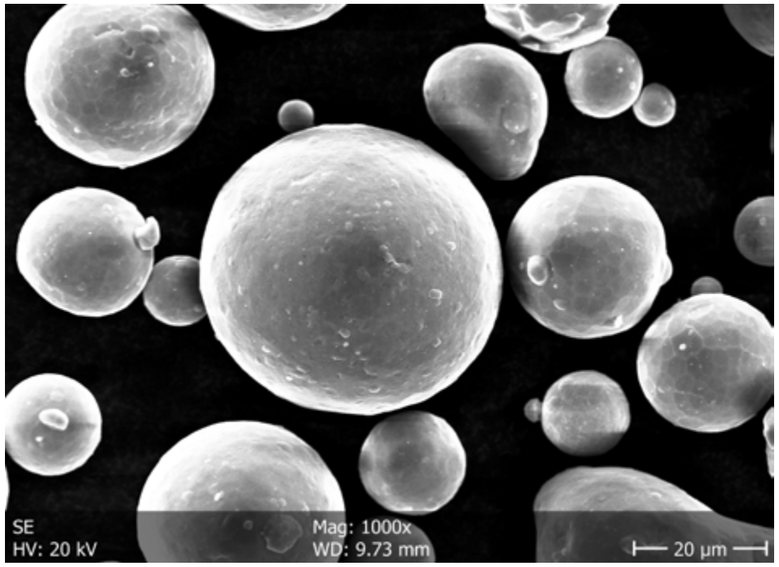
> Alexander Kopp, Managing Director and Founder of Meotec GmbH



Scanning electron microscope image of Zn1Mg powder.

tured in near-series processes. Achieving a precise fit of an implant is critical to the success of the therapy. Therefore, utilizing Additive Manufacturing to produce bioresorbable implants could represent a significant advancement.

Experts believe that in dedicated fields of surgery, up to 40 percent of operations could be avoided in the future. „Additive Manufacturing enables the production of geometries that were previously unimaginable, which are particularly applicable in the field of medical technology," says Maximilian Voshage, head of the Advanced Processes group at the DAP Chair, responsible for the BioStruct project. „With the development of a zinc-magnesium alloy, we are now taking a big step towards optimized patient care."

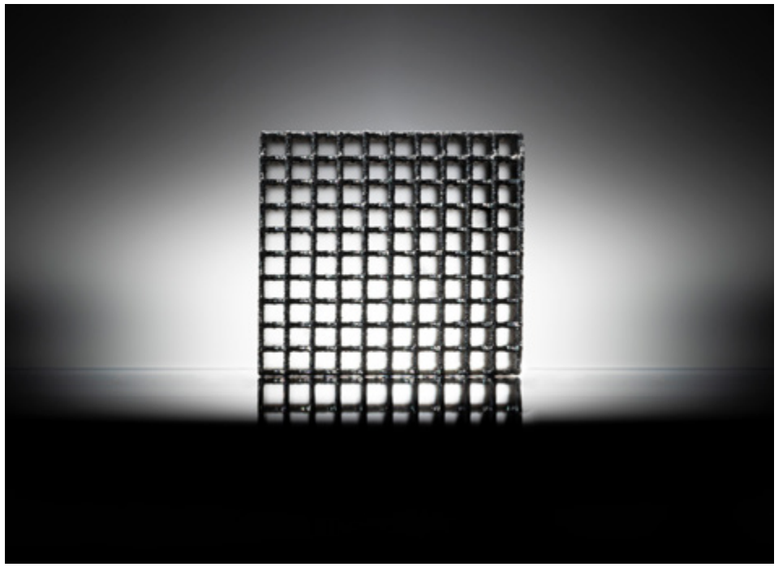
What is it about?

For example: So far, in the case of defects in weight-bearing bones, solid, permanent titanium implants are usually the go-to solution. They are durable, resilient, and well-tolerated by the body. However, their surface structure offers little support for the growing bone cells. The connection remains fragile, and the implant must be replaced in many areas in the long term. In addition, implants made of titanium or surgical steels have different mechanical properties than the human skeleton. They are stiffer, stronger, and thus automatically bear more weight than the bone would naturally. This leads to an imbalance, which in turn can result in further bone degradation and instability. Because to grow, it must be loaded and stimulated. This often makes further surgeries necessary.

> „The interdisciplinary exchange leads to relevant application-oriented research."
> Alexander Kopp, Managing Director and Founder of Meotec GmbH

„Within the coming decade, therefore, one of the most important goals will be to develop treatment methods that minimize the number and duration of necessary interventions and lead to better regeneration and faster healing of patients," says Dr.-Ing. Alexander Kopp.

This is exactly where the BioStruct project comes in. It merges the flexibility, efficiency, and design freedom of Additive Manufacturing with the recent advancements in materials science and medical technology. The project aims to create implants that have excellent biomechanical and biocompatible properties and are also bioresorbable. The idea behind this is that the implant should serve as a scaffold for the regenerating bone tissue, helping it to regenerate naturally by gradually dissolving itself instead of simply replacing the bone.



Lattice demonstrator made of ZnMg.

The Alloy

„There are only three metals in total that are even suitable for the production of resorbable implants," says Alexander Kopp. „Magnesium, zinc, and iron." Implants based on magnesium alloys have proven to be very well tolerated by the body. They are already regularly used in medical practice in the form of bone screws and vascular stents, for example. „Here we are already well positioned with a wide range of products.

> „With Additive Manufacturing, we can pursue completely new paths in implant design."
> Maximilian Voshage, Group Manager at the DAP Chair

However, to give growing bone tissue sufficient support and structure, magnesium breaks down too quickly in the body in certain applications," explains Alexander Kopp. Additionally, there can be gas formation with magnesium in combination with the moist tissue environment. For this reason, the application is still only possible to a limited extent in certain indication areas.

The situation might be different with the related element zinc. As dietary mineral it is is part of our daily metabolic requirements and therefore has a similarly good biocompatibility as magnesium. It can be found, among other things, in meat, shellfish, cereals, and dairy products. Zinc performs numerous functions in the body. It is good for the immune system and wound healing. It also contributes to the regulation of blood sugar, and it has a decisive advantage: it is much slower to degrade in the body than magnesium. „Research is still in its infancy," says Alexander Kopp. „But we had to go a similarly long way in the development of our magnesium materials. In the end, the only thing that matters is finding an optimal solution for the patients." In addition, zinc-based alloys can be processed into patient-specific shapes using 3D printing. This makes the material interesting for industrial production in combination with Additive Manufacturing. So why not combine the advantages of both materials?

The Process

A novel zinc-magnesium alloy (ZnMg) has been developed, which can be excellently processed using Laser Powder Bed Fusion (LPBF). „This process offers us a particularly high degree of design freedom and flexibility," explains Maximilian Voshage. The bone defect is first captured and analyzed through three-dimensional imaging. The data obtained from this is used as a basis to>

design a digital model of a precisely fitting, delicate lattice structure of interconnected porous channels, known as a scaffold. In the 3D printer, the laser melts the powdered alloy layer by layer to create the finished implant.

In the body, the delicate structure of the implant serves as a scaffold and load-bearing bridge for the regenerating bone tissue. The implant absorbs the load, which depends on the weight, size, and age of the patient, and transfers it to the bone tissue, which is stimulated to grow. On the other hand, the implant gradually breaks down once it has been replaced by bone tissue, which gradually grows into the porous interconnected channels of the scaffold. „The struts can currently be made as thin as 200 micrometers," says Maximilian Voshage. „We have succeeded in consistently manufacturing these delicate structures using zinc-magnesium at the DAP Chair. Continuing to develop the process up to the finished implant is the most important part of our further research work." Initial in vitro studies have already yielded promising results on the behavior of the novel zinc-magnesium alloy. Implant and alloy will now be further optimized step by step until the final in vivo test.

Outlook

Resorbable materials have so far been mainly used to manufacture bone screws or vascular supports using conventional manufacturing methods. However, In Europe, a small percentage of individual patients with head-neck bone defects have already received treatment with resorbable implants. Though, the number of cases is still in the low single-digit percentage range. The potential of Additive Manufacturing in the field of medical technology is even greater. Theoretically, the use of additively manufactured bioresorbable implants can also be applied to almost all bony structures, such as the spine or limbs. Even growing resorbable pediatric heart valves is possible. This requires the development of new methods and materials. The BioStruct project offers the opportunity to significantly expand the experience in this field.

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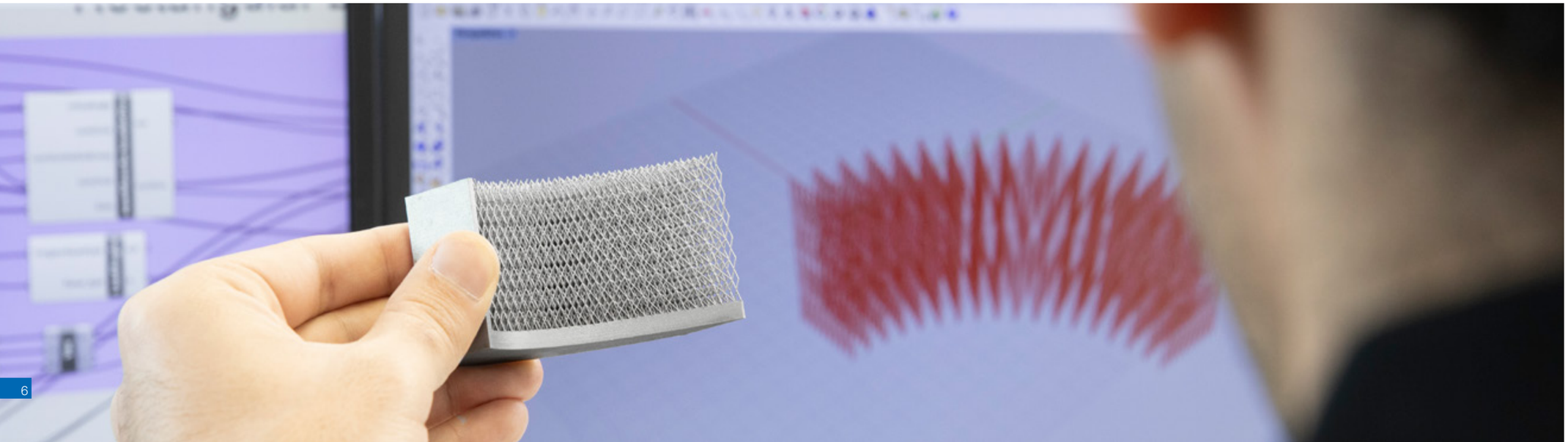
> Maximilian Voshage, Group Manager at the DAP Chair

For this reason, the DAP Chair is collaborating with Meotec and other partners from the Aachen region in the innovation alliance reACT (resorbable, medical solutions from the Aachen technology region), not only as part of the BioStruct project but also beyond it. Their goal: By 2030, the Aachen region should become „the European heart of medical technology for resorbable implants," says Alexander Kopp. The Federal Ministry of Education and Research is funding the project with around 14.3 million euros. A total of 27 medical solutions for a wide range of previously unsolved surgical applications are to be developed.

The reACT innovation alliance comprises not only a medium-sized core of five companies but also four start-ups, two large companies, an industry association, and several institutes and university clinics, which have joined forces to develop innovative medical solutions. They deal with biomaterials, production technology, product development, and surgical applications. As demonstrated by the BioStruct project, the know-how on materials, technologies, and manufacturing processes will be openly shared in the future to develop completely new and promising solutions. „Like a construction kit, where various building blocks and structures are available," explains Alexander Kopp. The BioStruct project should serve as a model. Alexander Kopp is convinced that „through innovative material development and precision manufacturing, as well as carefully designed tests, this research will revolutionize personalized reconstructive implants in surgery for the treatment of bone defects." It is intended to make 40 percent of all avoidable implant removal surgeries unnecessary within 15 years. Further collaborations will follow soon for the BioStruct project. The Aachen economic region is set to become the leading region in Europe for medical-technical solutions. Moving forward, the DAP Chair will continue to serve as the primary point of contact for any inquiries related to Additive Manufacturing and Production Engineering.

The BioStruct project was made possible through funding from the Federal Ministry of Education and Research (funding code 13GW0404D).



Lattice structures for the new design approach of bioresorbable implants are based on an algorithm that considers not only manufacturing restrictions but also patient-specific requirements.

On the Potential of 3D Printing

Meotec founder Alexander Kopp loves to explore uncharted territories and has been successful in doing so. After completing his mechanical engineering studies, he became a tech entrepreneur in his mid-twenties and simultaneously completed his PhD at the age of 30. With his company Meotec, he is now the owner of an innovative start-up in the field of medical technology. Meotec specializes in developing resorbable materials for implants, which will be custom-made using Additive Manufacturing, also known as 3D printing. Maximilian Voshage is currently pursuing his PhD at the DAP Chair in the additive processing of resorbable zinc-magnesium alloys. The first results of his research have already been published as a scientific paper. He has been part of the Aachen 3D printing ecosystem since 2010 and specialized in 3D printing and medical technology during his mechanical engineering studies. Since the establishment of the DAP Chair in 2016, he has been working at DAP and later became the group leader of the Advanced Processes Group. In the following conversation, Alexander Kopp and Maximilian Voshage discuss the potential of digitization in medical technology, collaboration, and the shared goal of making Aachen the heart of medical technology for resorbable implants in Europe.

Mr. Kopp, you took the leap into self-employment with Meotec GmbH in 2012, just one year after completing your diploma. Why so eager? Many companies would have probably hired you with open arms...

Kopp: I think right after completing your studies is the optimal time because you can take more risks at that point. If you don't have a family or kids yet or aren't on a certain career track in the industry, already earning accordingly. These are all points where you have to make compromises as a founder. That's why I think: the earlier, the better.

What exactly excites you about entrepreneurship?

Kopp: I would say the high degree of self-determination as well as the constant ups and downs. It's definetely not an easy path. However it is a very exciting one, despite the challenges. Sure that's not everybodies cup of tea but if you are into that, then it's very fulfilling.

Mandibular model made of PLA with defect-adapted implant made of ZnMg, additively manufactured based on the newly developed design and alloy concept.

Parallel to founding Meotec, you began your PhD studies which you completed in 2018. How important do you consider interdisciplinary exchange between research and industry when it comes to innovation?

Kopp: I generally like interdisciplinary approaches. Medical technology itself is already very diverse. Therefore, I believe that the common prejudice that industry is too unscientific and science is too impractical is too generalizing. My personal experience is that in many cases, it is beneficial for industry>

> „We want Aachen to become the heart of medtech for bioresorbable implants across Europe."
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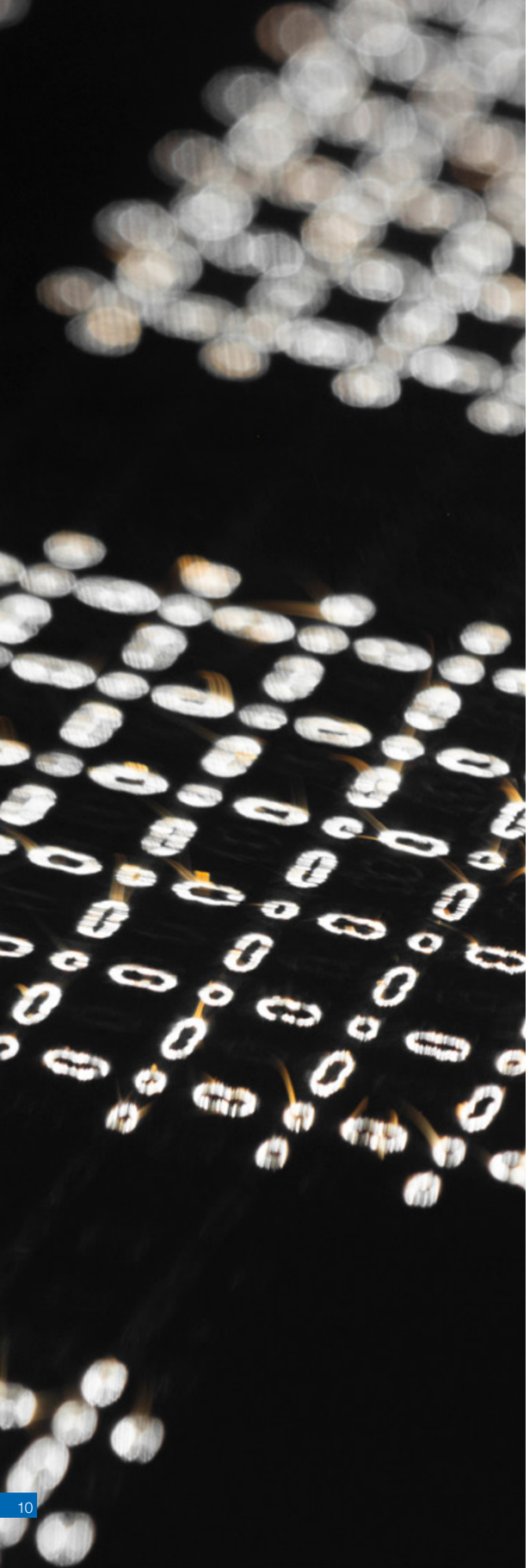
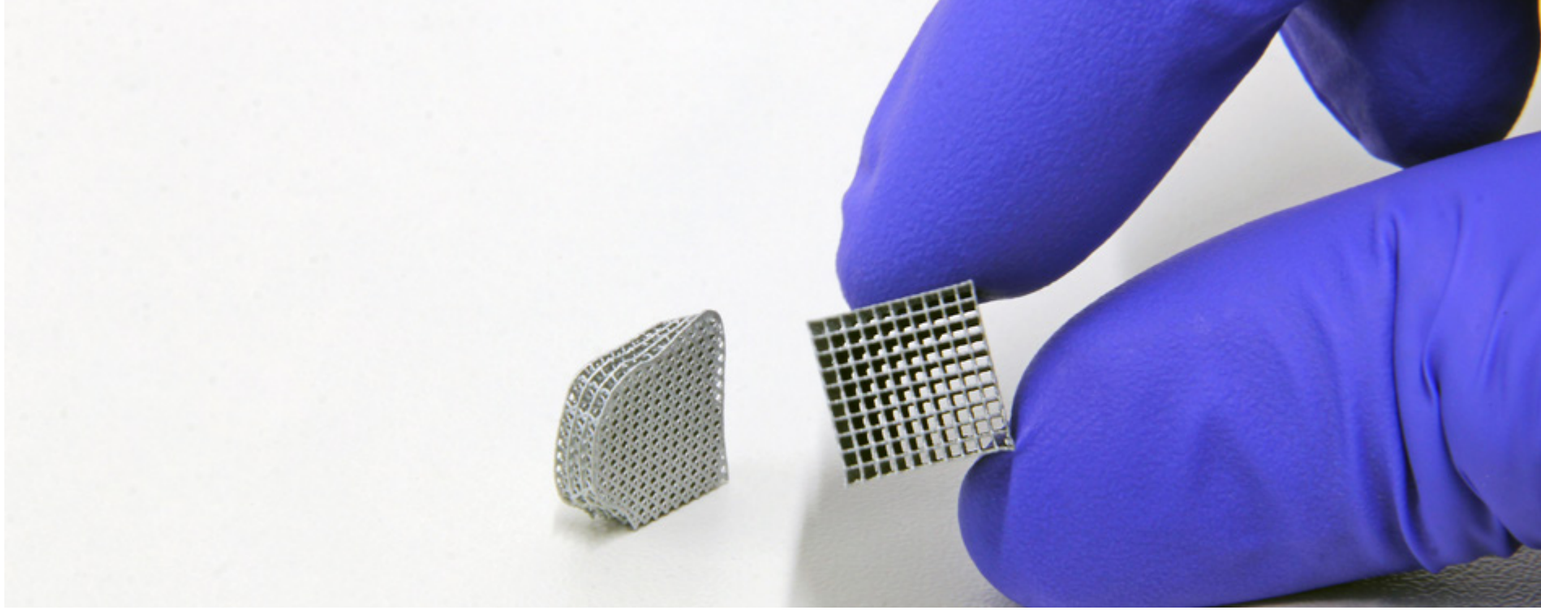
> Alexander Kopp, Managing Director and Founder of Meotec GmbH





Left image: Long-exposure view of the LPBF manufacturing process for lattice structures.

Right image: Lattice test demonstrator for design evaluation and determination of mechanical properties.

to base their work on scientific findings. The interdisciplinary exchange leads to relevant application-oriented research. You can see this especially in the many innovative small and medium-sized companies in Germany that have great success with a good mix of pragmatism and solid scientific approach.

> „It is particularly essential to have a close connection with industry experience in the field of medical technology."
>
> Maximilian Voshage, Group Manager at the DAP Chair

With Meotec you are closely linked to the Aachen research landscape and the RWTH Aachen. You have been working together with the DAP Chair for quite some time. What makes this partnership valuable to you?

Kopp: I believe it is very important that our partners from the DAP Chair are also personally motivated to advance the topic. Many young people with a similar mindset to us at Meotec work at the chair. We are not a sluggish organization, but a group of consistently qualified and highly motivated people who have set themselves the goal of achieving something together. You could say the chemistry is just right. This is of course also good for project progress. And ultimately, the end user, in our case the medical professionals and patients, benefit the most from this.

Mr. Voshage, could you share your perspective on the value of collaboration between research and industry in medical technology, and how it has contributed to the success of the BioStruct project?

Voshage: In general, it's great to see current research moving towards practical applications. Through close cooperation with our industry partners, research at the DAP Chair is not only fundamental but also application-driven. Particularly in the field of medical technology, a close connection with industry experience is essential. For instance, it only makes sense to spend several years researching a bioresorbable alloy if it is accepted by the industry later and finds an application. Here, the BioStruct project is a good example of the collaboration between research and industrial application together with Meotec and other partners.

The digitization of the working world is accompanied by the largest societal upheaval since the Industrial Revolution. What role does 3D printing play in the development of medical technology in this context?

Kopp: I think that digitization in medical technology naturally has great potential because it can further optimize the fundamental principles that we have in medicine. However, digitization also always means collecting more data. And collecting more data means higher complexity. This naturally makes every system more susceptible to errors. Therefore, digitization alone does not necessarily lead to improvement. However, there are areas where it has the potential to greatly improve individualized therapies, patient safety, reproducibility of procedures, or the traceability of material batches or process steps. 3D printing has enormous potential in very select areas of medical technology in this regard and can therefore make a huge contribution to the advancement of medicine as a whole.

Voshage: 3D printing is an outstanding example of the application and implementation of digitization. Medical technology is a good example of the application of small-series or single-item production using 3D printing due to the patient-specific requirements for, for example, absorbable implants. Thanks to the advancement of software, hardware, and community, the barrier of utilizing a CAD program and converting ideas into a digital model and ultimately creating it with 3D printing is decreasing at the DAP Chair, we refer to this interface as the 3D data pipeline and actively research the implementation of generating, adapting, and preparing data for 3D printing.

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Microscopic examination of the manufactured ZnMg samples.

What role will the use of absorbable materials play in the future?
Kopp: Tailoring medical devices to individual patients is always preferred. However, when it comes to implants, there is always a balance between cost and benefit. For some applications, patients benefit relatively little from individualization. In specific applications, on the other hand, digitalization opens up entirely new possibilities for us. In the near future, our jointly developed personalized implants made of magnesium and zinc will hopefully be a valuable addition to a portfolio of different materials, from which the best one can be chosen for the specific application.

For new technologies, materials, and manufacturing processes to become applicable in practical situations, several factors must align. What are these factors?
Kopp: The product must, of course, work. It must have a sustainable benefit. It must be overall better than existing solutions, considering the advantages and disadvantages. However, an often underestimated factor is also acceptance among users in medical practice. A product can be very good, but if it is not accepted, it will not sell. We often experience that physicians, especially under time pressure, prefer to stick to what they know. Therefore, taking the initial step necessary to establish a new product and new routines is not always preferred.

How great is the skepticism, and what do you do to address it?
Kopp: There is a great deal of skepticism because the introduction of new products and routines always carries a risk. Therefore, physicians and users are always concerned about clinical studies. Most of the time, these studies are not even about products that save lives, but rather about new products that offer an improvement but also carry an unknown residual risk. Even if a product is already approved, it often takes years to form an opinion based on clinical data. We address this with transparent communication and education. The basis for this is studies and data, on which we can explain the advantages of the respective product to physicians at conferences or in personal conversations.

To strengthen Aachen as a location for medical technology, you have joined forces with other actors from the region. The DAP Chair is also involved. What is your goal?
Kopp: Our activities take place on many levels. One project where we collaborate closely with many institutes and clinics as part of a consortium, including the DAP Chair, is called reACT in the RUBIN call of the German Federal Ministry of Education and Research (BMBF). Our goal is to establish an entrepreneurial excellence cluster. Aachen is to become the heart of medical technology for absorbable implants throughout Europe. The project started in 2022. The DAP Chair contributes important expertise in the area of 3D printing. Professor Schleifenbaum, the chair‘s director, is a strong link between science and industry, with excellent knowledge of both areas.

Voshage: I agree with Mr. Kopp‘s words. As part of the diverse research network of RWTH Aachen and the Euregio industrial partners, complex issues related to medical technology can be holistically examined and answered. Participation in the reACT project is an important instrument for the chair to combine medical technology and 3D printing profitably and to unite the different activities of the partners from industry and research in Aachen. Furthermore, with our research work, we aim to inspire the experts of tomorrow for 3D printing - for example, in medical technology. Ideally, we can encourage them to take the step towards self-employment in Aachen and follow the example of Meotec.

Kopp: In conclusion, it can be said that the interdisciplinary collaboration of the competence carriers from the innovation ecosystem of the Euregio - both from the industry and research sides - brings a holistic added value for technological progress in medical technology and socio-economic change.

Thinking the Future
Zukunft denken

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