GUIDE TO ADDITIVE MANUFACTURING FOR MEDICAL

INTRODUCTION

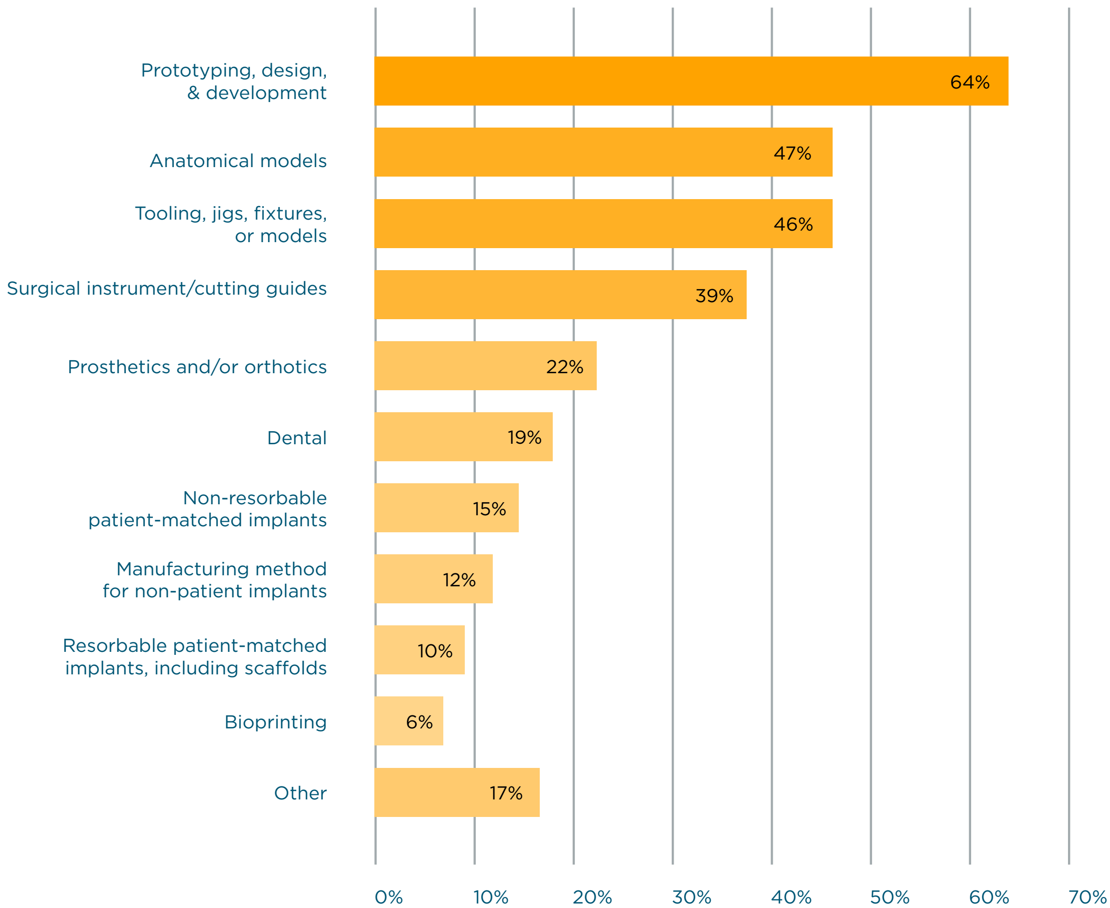
Just a few years ago, additive manufacturing (AM) was purely associated with anatomical models, rapid prototyping, and advanced engineering teams. Now many medical and healthcare organizations are finding 3D printing more accessible and looking to AM as a production solution for a variety of applications.

Additive manufacturing offers the medical community exciting opportunities to reduce cost and logistical hurdles while improving patient outcomes. Huge leaps in additive manufacturing innovation have been enabled by simulation-driven design. In this guide, we will explore the use of simulation and analysis technology in the medical field to design complex AM solutions, explore material decisions, optimize structures for performance, and ensure that designs can be printed efficiently.

APPLICATIONS, TECHNOLOGY, PROCESS, AND IMPACT

HOW ADDITIVE MANUFACTURING IS BEING USED

While prototyping remains the top use, anatomical models and surgical instruments are significant applications areas. Other applications include microfluidics, education, management support, and packaging.



SME Medical Additive Manufacturing/3D Printing Annual Report 2018

Exploiting the full benefits of Additive Manufacturing

Simulation and optimization are the keys to maximizing the value of additive manufacturing. An intelligent design approach enables manufacturers to deliver patient value while simultaneously reducing overall investment.

3D-printed spinal clip designed and printed by Altair and SLM

The total value of AM machines, materials, software, and services for medical application is projected to reach $2.2 billion by 2024

Healthcare 3D Printing Market Size, Global Market Insights, July 2018.

TOPOLOGY OPTIMIZATION: THE TECHNOLOGY POWERING THE ADDITIVE MANUFACTURING REVOLUTION

Additive manufacturing offers the medical community incredible opportunities for design flexibility and customization, as it eliminates many of the limitations of traditional manufacturing processes. AM provides new pathways to lightweighting by enabling the use of new materials and unconventional shapes such as lattice structures.

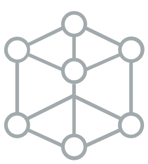
Advanced Materials

But how are these complex forms developed, and most importantly, how do you know that an additively manufactured piece will be safe and perform as expected?

The answer is topology optimization.

Topology optimization is the technology that creates the unique, optimized structures often suitable for additive manufacturing. Instead of validating an existing design like a conventional simulation tool, topology optimization uses physics to enhance human creativity by proposing forms that can be easily evolved into a finished product.

Enhanced Structures

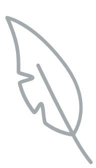


A designer defines where structure must and can't be. Then, they apply the loads the part or system will see in use, and optionally the material and manufacturing constraints. Topology optimization generates the ideal structure for the chosen objective, which is usually minimizing mass or maximizing stiffness.

Run without manufacturing constraints topology optimization shows how loads can be distributed throughout a system, where more support may be needed, and where unnecessary material can be removed.

Applying manufacturing constraints including extrusion, symmetry, draw direction, cavity avoidance, and overhand angles, in a topology optimization generates practical results that can be quickly developed into a production design.

Lightweight



Topology optimization allows for fast design exploration, improved development productivity, and identifies opportunities for part consolidation. Using this method upfront in the product development process means performance targets are met cost-effectively by designing lightweight in early, instead of engineering mass out later.

EXTRACORPOREAL APPLICATIONS OF ADDITIVE MANUFACTURING

If you wear a hearing aide, chances are, that device was 3D printed. In 2013, more than 10 million hearing aid devices are in circulation worldwide according to Forbes. Sweeping adoption of additive manufacturing has taken hold for dental and orthodontic applications as well, where night guards, aligners, and even custom crowns, dentures, and implants can be printed on-site.

Anatomical Modeling

Anatomical models printed with additive manufacturing have provided benefits for surgical planning, patient education, and clinical training. According to the 2020 report "Additive Manufacturing for Production" conducted by TCT Magazine, 71% of Healthcare respondents who utilized AM did so for purposes of medical modeling.

Little to no certification is required for medical modeling, so cost justification, material selection, and post-processing remain the biggest challenges for these types of applications.

Using medical imaging data, anatomical models can be used for surgical planning as well as an instructional tool for physicians to discuss surgery with patients. Having a physical model often provides medical professionals with a unique perspective of how best to complete the surgery before going into the operating room. Both models and sterilized implants can be accompanied by surgical cutting guides.

Orthotics and Prosthetics

Altair simulation technology is widely used in the design of optimized structures in prosthetic and orthotic design, where custom fit is essential to a comfortable supportive structure. Clinicians and engineers have the ability to easily model patient-specific geometry with Altair HyperMesh™, optimize the shape of the device to achieve the desired load transfer with OptiStruct®, and understanding the manufacturing process of polymers with Altair Inspire Mold and Altair Inspire Print3D. This all adds up to custom successful fit for the patient, and ensured function of the device, and ideally a shorter time to wellness.

“Using Altair solutions, we’re able to simulate the dance between the orthosis and the human body.

The software revealed the contact and pressure points and could predict where problems such as bruising would occur. This has helped us to go from guesswork to a place of deep understanding, allowing us to develop whole new ways to treat a condition and improve the child’s life.”

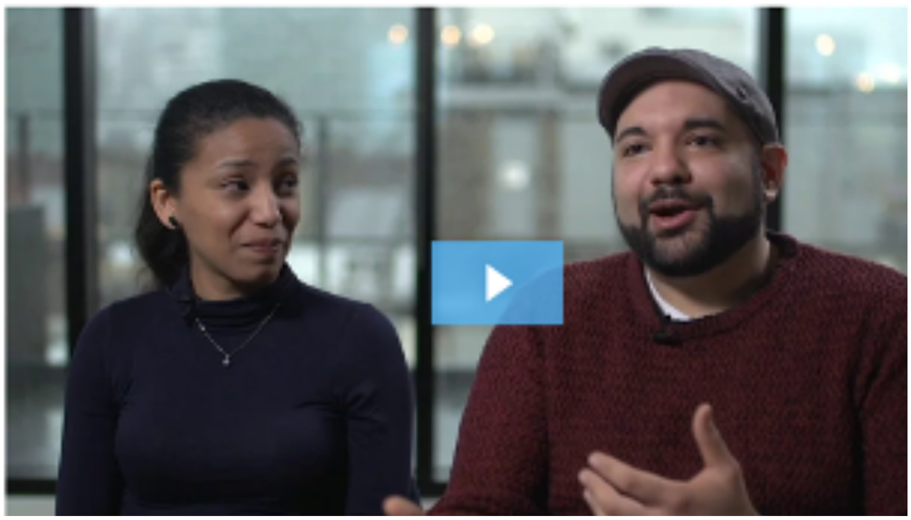
Naveed Parvez, Andiamo

Case Study: Andiamo

The traditional way to make an orthosis (an externally worn support brace to assist body movement) for a child can be a lengthy and difficult process for the entire family. On a first appointment, the limb or torso is wrapped in plaster which can be an unpleasant, messy and traumatizing procedure, especially for children who are not able to communicate. The plaster is then cut off and sent for fabrication where the orthotic device is hand-manufactured based on the plaster mold.

Following the experiences of needing orthoses for their own son, Naveed and Samiya Parvez saw potential in the mass customization benefits of 3D printing as a possible solution to the problem of poorly fitting, slow to deliver devices. Together they founded Andiamo, a London based start-up company aiming to revolutionize the children's orthotics industry.

Andiamo's process does away with the need for plaster casts, instead starting with a digital 3D scan of the body, creating a highly accurate model to start designing around.



Watch the case study video now.

To accurately design devices that were comfortable to wear on a daily basis, the design team wanted to explore the use of simulation technologies to predict and eliminate pressure points before the devices were manufactured, turning to Altair for support.

Altair's own engineering consultancy worked with Andiamo and helped the team to develop a process that incorporated the latest design and manufacturing simulation technologies. The 3D scan data is now used as an input for Altair solvers, OptiStruct and Radioss, to analyze and optimize the orthoses. The challenge came from accurately representing the highly complex interaction of the human body and the device, along with the child's movements, and the multiple contacts between the orthosis and the body in conjunction with the nonlinear material behavior of the polymer device.

Using Altair's simulation solutions for dynamic and static analysis, the design team are able to simulate and predict the behavior of the orthosis and optimize the geometry by morphing the model until the problem is solved. Altair's simulation solutions allow Andiamo engineers to quickly identify pressure points that would lead pain and discomfort, providing design guidance to help solve the problem at the development stage and produce lightweight devices that are like a second skin to wear.

Once the design is complete, the product is 3D printed to the exact specification of each child and at a fraction of the time and cost compared to the traditional handmade alternative. The result is a lighter, better fitting, more comfortable support that makes a huge difference to their users' lives and that of their families.

CORPORAL APPLICATIONS OF ADDITIVE MANUFACTURING

Orthopedic Implants and Replacement Structures

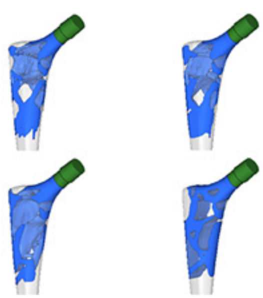
Patients with specific maladies can now be treated with custom-design implantable structures. Such replacement devices can be optimized with simulation technology and manufactured using 3D-printed resorbable biomaterials, serving as a temporary solution until the body grows its own tissue in replacement.

For more than 25 years, Altair OptiStruct™ has been the industry leader in developing and applying optimization technology for strong, lightweight designs. Developed to mimic how mechanical stresses influence optimal bone growth, it is now used to model complex biological structures and design optimized orthopedic structures. This includes lattice-designed, 3D printed components, ideal for osseointegration and promoting vascularization.

Generic Implant

Case Study: Solid-Lattice Hip Replacement

According to the National Hospital Discharge Survey (NCHS), the number of total hip replacement surgeries of patients 45 years or older in the United States has more than doubled from 2000 to 2010, but the total number of hip replacement surgeries for people between the ages of 45-64 has almost tripled during that same time! This is a dramatic change since many implants used for hip replacements haven't been designed for active lifestyles. Additionally, much of the data indicating some prostheses should last more than 20 years is based on patients leading a more sedentary lifestyle.



Topology Results with Different Setups

While total hip replacement surgeries are seeing an increase in demand, 10-20% of the patients may require a revision surgery because of a failure or wearing out of the prosthesis, most commonly due to loosening of the implant stem. This loosening can be caused by bone resorption or loss of bone mass. Revision surgeries can be more complex, especially for elderly patients, and bone resorption can increase the risk of bone fracture. All of this is bad news for younger active patients who will need these prostheses to last several decades.

Applying optimization and simulation technologies to a hip implant can greatly improve the longevity and how it performs. Two ways of accomplishing this are to include more dynamic load cases when designing the hip implant stem and focusing on reducing stress-shielding in the bone surrounding the implant.

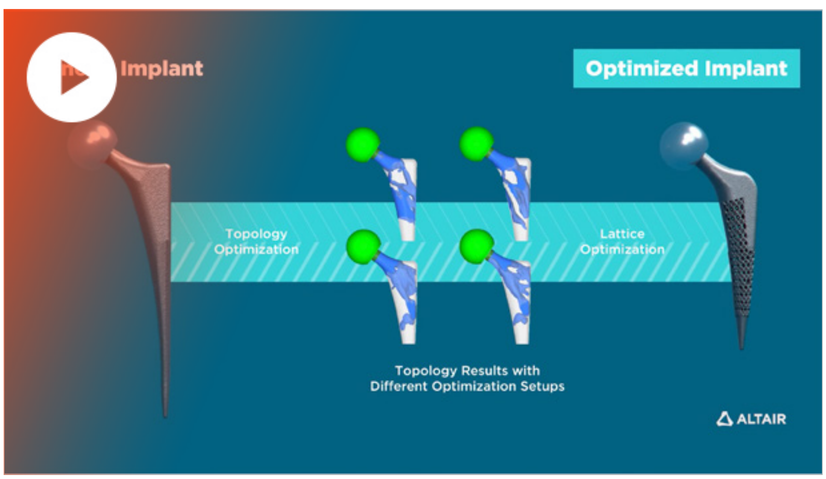
Final Design

When analyzing a design using computer simulation, it is important to include all the various load cases a product might see during its life cycle. The current load cases considered when designing hip implant stems might only involve daily activities such as standing, sitting, walking and climbing stairs. However, with an increasing number of younger patients having total hip replacement surgeries and older patients staying active later in life, additional load cases should be considered. In our study, we included jogging in addition to other standard daily activities, but biking, swimming, and other activities could be included during the design process. Adding these load cases could increase the longevity and performance of hip implant stems.

In considering additional load cases, improving the performance and compatibility with the natural body should also be considered. Most hip implant stems are made of titanium due to its biocompatibility, but titanium is roughly 6.5 times stiffer than the cortical bone of the human femur. When a solid titanium stem is implanted in the femur the load distribution will change in the remaining bone. Often the load into the bone will be reduced because the titanium stem is so much stiffer than the natural bone. This is referred to as stress-shielding. Per Wolff's law, bone remodels itself to adapt to external loading. With a reduction in loading and stress in the surrounding bone, bone resorption and/or loss of bone mass can occur. Therefore, reducing stress-shielding should help reduce the number of revision surgeries.

Topology optimization optimizes the material distribution within a defined material volume based on the provided load cases, design constraints and objective. This optimization process illustrates where material can be removed and the optimal load paths for the various loads. With the recent advances in additive manufacturing capacities, Altair has introduced lattice optimization which generates structural lattice can be incorporated in areas where the solid structure is not necessary. Each beam diameter of the lattice can be fine-tuned to achieve the design constraints and objective.

These technologies have been applied by Altair to the geometry of a general hip implant stem. The goal of this study was to create a methodology and process to better tune the stiffness and strength of the hip implant stem while including load cases like jogging among the other standard daily activities.



Watch the video.

The study started by simulating a healthy femur, then a femur with a generic implant and finally a femur with an implant designed using topology and lattice optimization. The optimized prosthesis was designed for metal additive manufacturing which requires careful selection of the print direction, calculating overhang angles, maintaining minimum size parameters and reducing the need for printed support structures.

In the end, the stress-shielding caused by the implant was reduced by 57% when comparing the generic design and the optimized design. Furthermore, in the optimized design the stresses in the stem were kept below 575 MPa for all load cases including the jogging and two ISO standard fatigue load cases. For the grade of titanium, the implant was designed for, this would equate to an endurance limit of about 10,000,000 cycles or roughly jogging from Los Angeles to New York and back twice.

Coupling this optimization process with additive manufacturing can also provide design freedom and customizability opportunities for these prostheses. For example, if you are working with a 200-pound male who enjoys water skiing and cycling, specific load cases based on individual activities and physiology could be configured to the optimization process. A customized design could be printed and, in the surgeon's, hands the following week.

FROM THE DESK OF DAVE COATES, ALTAIR CHIEF ENGINEER

Dave Coates has more than 24 years of engineering experience in simulation-driven design. His early career focused on managing large, multidiscipline projects which entailed design, CAE (including component- and system-level CAE), multibody dynamics, and system testing. More recently Coates' focus has been on R&D projects combining advanced manufacturing technologies, such as additive manufacturing, coupled with advanced modeling and simulation techniques in developing optimized, lightweight components.

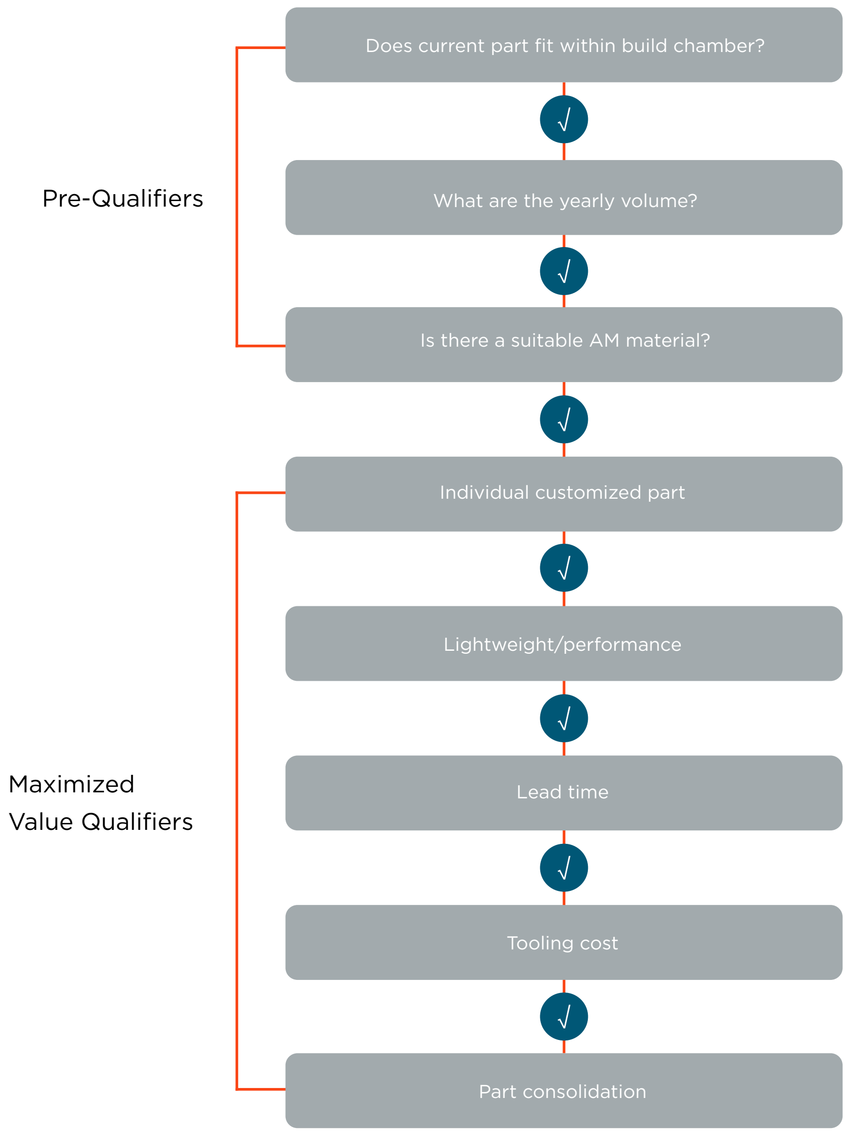
STRATEGIC PART SELECTION

Part selection is a critical milestone when aligning any manufacturing process. It's even more important for additive manufacturing, especially if a company is just starting to investigate the technology. The outcome of the first project will set the expectations for management and determine further funding to support deeper investigations. Because of this, strategic part selection is critical.

Altair has developed a methodology to help guide our clients to:

1. Review many parts down selecting to prime candidates;
2. Weigh those candidates against metrics that consider the complete footprint and;
3. Select a prime that would best demonstrate the value.

By simply answering a few questions the optimal parts will bubble to the top of the list



ENSURING ECONOMIC VIABILITY FOR MEDICAL ADDITIVE MANUFACTURING: AN INTERVIEW WITH DAVE COATES, ALTAIR CHIEF ENGINEER

What competitive advantages does additive manufacturing offer more conventional processes?

1

Customization. Developing customized products is a market opportunity made easy by additive manufacturing. The medical industry is one of the first industries to embrace additive manufacturing as it realized the power of developing individualized parts in a short timeframe. Orthotics, orthopedic implants, dental restoration such as crowns, and external prosthetics are all examples of parts that benefit from the customization offered by additive manufacturing.

In many cases, quick production turnarounds are not feasible with traditional manufacturing methods given the lead-times and change-over costs associated with tooling and fixtures. For instance, the traditional way to make an orthosis, using a plaster mold, can be a lengthy process, taking several months in some cases. If a child is the recipient of this orthosis, they often grow out of the original design by the time it's produced. Additive manufacturing enables the development of specifications tailored to each patient at a fraction of the time and cost compared to the existing alternatives.

2

Cost. Although it has a reputation as expensive, additive manufacturing actually offers a competitive alternative to other manufacturing processes for companies with low volume, high cost parts. Medical parts are a great example where additive manufacturing is perceived as a true production solution. Additive manufacturing offers a huge opportunity for parts that were developed a long time ago with older technologies, where there are often great prospects for improvements.

Hearing aids are an example of the medical industry successfully leveraging AM for high volume production. Other high-volume products like custom orthoses, PPE masks, eyeglasses, and other anatomical, comfort-driven products might gain similar advantage in a few years when the additive manufacturing technologies mature to meet their production requirements.

3

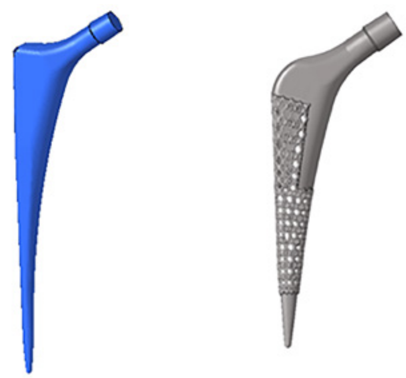
Performance. Performance is another major driver for additive manufacturing, especially in cases where it offers a competitive advantage. Additive manufacturing enables the development of lighter parts without compromising part strength, stiffness, or durability. A lighter product, be it implanted inside the body, attached to it, or worn/used outside the body, can have a dramatic impact on the patient's fatigue, comfort, and overall capability and quality of life.

For applications such as orthopedic implantable structures, companies are willing to incur the incremental costs associated with additive manufacturing to achieve performance advantages and patients are willing to pay a premium for an advanced product. It's a perfect storm for additive.

What are the general characteristics of a good additive manufacturing candidate part?
Two key considerations that can help narrow down the direction between additive manufacturing for tooling or end part are the age of the part and the current manufacturing process used.

The first thing I would recommend is to look for old designs where lightweighting could impact product performance and patient outcomes. Additive manufacturing offers a huge opportunity for parts that were developed 10 years ago with 10-year-old technology. Part consolidation, weight reduction, and improved performance are some of the advantages that can be exploited to improve old parts.

Another place to start is with cast parts. A laser powder bed aligns itself very well with casting either as an alternative or complementary process. Companies can print the tool and get another level of geometry refinement to improve part weight and performance. Typical tooling lead times are months. Utilizing additive manufacturing can turn six months into six weeks. This is a great advantage to reach an optimal design for the end part through tooling.



Geometric Implant Final Design

In the injection molding industry, the conformal cooling loops are somewhat restricted in terms of the manufacturing process. Because of the limitations of the manufacturing process, the blind holes are drilled without the ability to optimize the flow through them. With additive manufacturing, you could almost print any geometry and be able to optimize the cooling loops to minimize part distortion.

How do I identify a specific candidate part?
Although there are relatively few additively manufactured parts in production, and often on specialty, high-end and low volume end products, as the technology matures, more parts will exploit the benefit of additive manufacturing. Until then, it is important for companies interested in additive manufacturing to put time into strategically selecting the right part. Additive manufacturing offers a competitive alternative to other manufacturing processes for companies with low volume, high cost parts.

Due to the additional cost of additive, high production capabilities reaching into the tens of thousands of dollars and above are often cost prohibitive. These increased costs can be worth it if there is a significant value-add such as the part being significantly lighter, stiffer, or offer some other compelling enhanced performance. As soon as production gets into the hundreds of thousands of dollars, it becomes very expensive. Additional costs are a driver that mass production companies won't be able to justify.

As stated earlier, companies would be willing to incur additional costs associated with additively manufactured high-volume parts if customization offers a competitive advantage and their end customers are willing to pay a premium.

We've seen some of the best results when customers employ an auditing process using simulation software, in particular topology optimization, to evaluate part candidates. This helps identify weight reduction opportunity, from there the redesigning process starts. After conducting this a few times, the team involved gains experience to strategically select the part easily using a combination of simulation and growing knowledge.

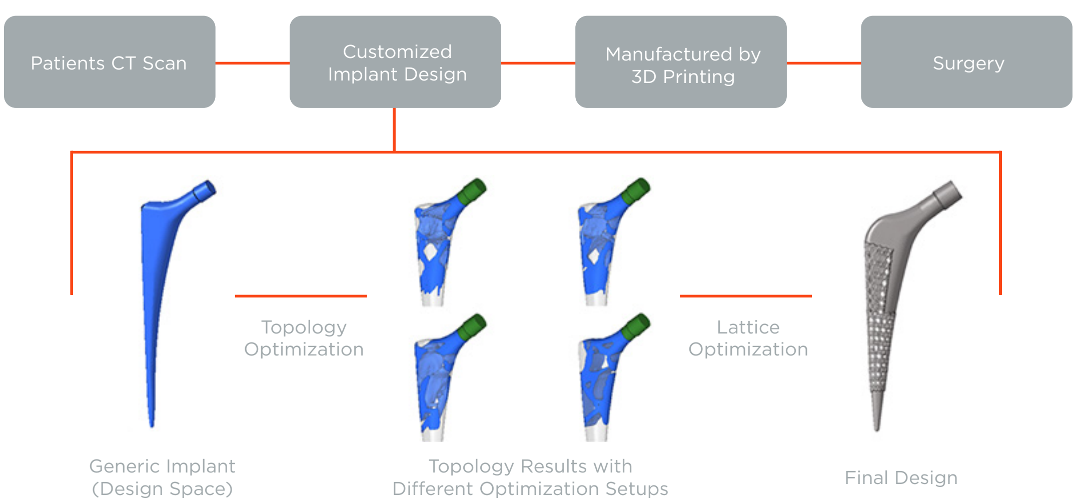
Is simulation important after the candidate selection?

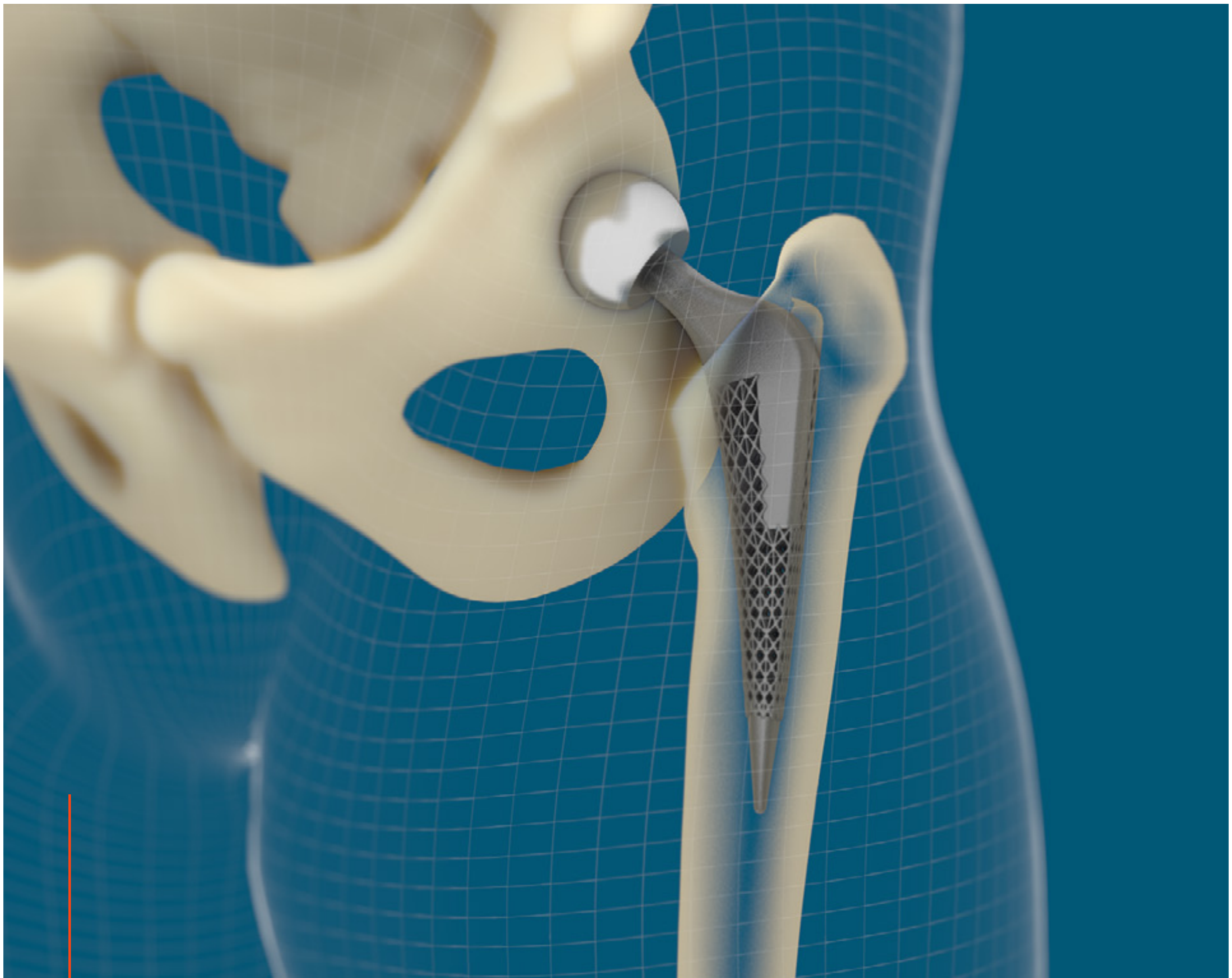
Leveraging simulation to evaluate manufacturability and predict part behavior can save a lot of money spent on trial and error. On average, the use of simulation can cut the costs of low production volume parts by 50% to 75%. I recall working with a client on redesigning a part for additive manufacturing where the client estimated the cost to be around $2,000 which seemed to be very high. When we asked why it cost $2,000, the answer was, "well, it only costs $500 to print one part, but I probably have to do it three, four or five times to get the right build parameters so that I can deliver a quality part to you." Simulation give companies the ability to print right the first time.

The availability of the advanced tools allows designers to design for efficiency regardless of the manufacturing constraints. Designers can explore the most optimal designs enabled by topology optimization technology, then decide on the manufacturing process that offers the best cost-weight metric.

Analysis software is often thought of as virtual testing, but your examples are much more about answering design and business questions. Can you explain a little more about how simulation reduces cost and drives better decisions?

A good question to answer early on is, "what is the minimum amount of material needed to meet performance requirements?" Topology optimization is a type of generative design that enables the creation of an optimal design that can then be targeted towards a specific manufacturing process. When an optimal design is generated, it can be constrained and refined for any manufacturing process. Developing parts based on optimization results ensures efficient, cost effective, and smart manufacturing process.



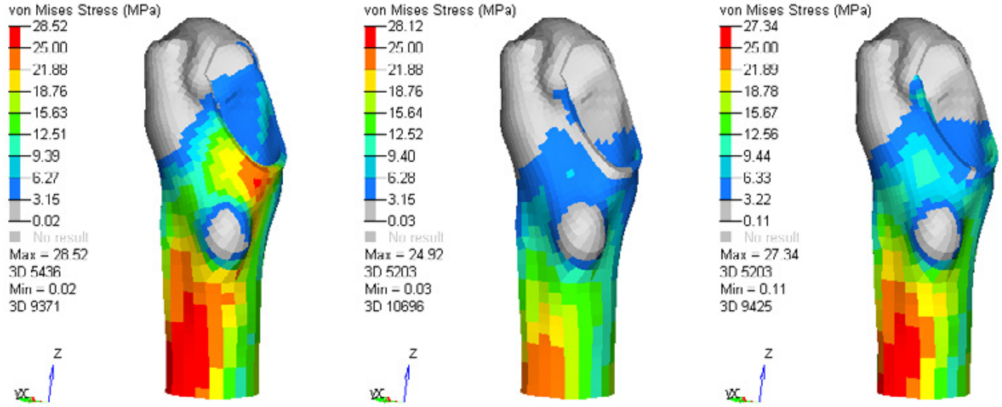


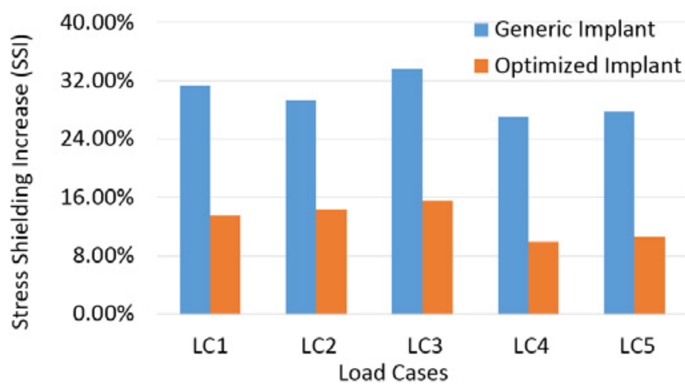
This creates an opportunity for a better performing part manufactured in a process that offers the best cost-weight metric.

Simulation is the key to leveraging additive manufacturing's myriad benefits. It allows you to explore different configurations and placement of lattice structures, the use of different materials, and even the orientation of the part in the print bed to reduce the number of supports needed during the printing process. Analysis and optimization ensure that you're getting the most out of your part in terms of cost, weight, and performance.

Through rigorous simulation, the solid-lattice hip implant below was optimized to reduce stress shielding by 57 percent comparing to a generic implant. The optimized design has a fatigue life of more than 10 million cycles. In addition to its performance gains, printing considerations were factored into the design process, ensuring an overhang angle is smaller than 45 degrees for manufacturability.

EOS PRINTED TI 6AL-4V SOLID-LATTICE HIP PROSTHESIS





Are there certain process or manufacturing considerations for medical additive manufacturing that differ from those of other industries?

Certainly, each industry and even each product you're designing has its own unique considerations and challenges, but FDA regulation comes to mind as one that uniquely shapes medical product design. Other industries have regulatory oversight, from the FAA in aerospace to crash and emissions testing in automotive, but often additive is used in these industries to redesign existing parts which already meet those standards. The medical community in many cases is developing brand new solutions where no previous guidance exists, so it is extremely importance to using FDA controls as initial design variables so you can thoroughly document and validate performance through analysis. Simulation ensures potential issues are recognized and addressed early in the development cycle so you have confidence that the part will meet performance claims and pass the quality assurance and physical testing stage.

Another consideration is ensuring safety from the powder used in additive manufacturing. There are stringent OSHA safety requirements in AM facilities because the powder granularity is so fine that it can enter the pores of your skin and cause considerable damage. There are additional protocols necessary to remove all traces of loose powder from a finished part. On top of the typical costs associated with adherence to sterility and medical cleanliness in the manufacturing process, these post-manufacturing powder removal costs should be weighed when choosing an AM candidate part.

You worked with customers in many different industries. Have you developed a standard workflow that translates across different organizations?

The first step to consider when designing for additive manufacturing is the part's function. Medical products often have specialized functions that can greatly influence the design and validation process, such as whether the product will be implanted within the body, used as a surgical instrument, or used apart from the body as a wellness or monitoring device. FDA requirements and testing factor differently depending on the application, so identification of part function has a trickle-down effect on the rest of your design and production process.

The next step to consider is the manufacturing requirements. It may be a bit of a paradigm shift to be concerned with production so early in a design process, but it ensures that the part that you will be so meticulously designing can actually be produced.

Traditionally, designers picked up the pencil and started designing based on historical part design or past experiences. Over time, designs get morphed to meet those requirements, and then released for production. The full understanding of the manufacturing requirements early in the process enables driving designs and influencing design directions, which eliminates inefficiencies in trial and error.

Then you move to the prequalifying questions such as how big the part is, determining if it will fit in the build chamber, and understanding if there is enough material to meet stress and stiffness requirements.

A lot of engineers and companies really struggle with this direction, thinking, "Why am I spending all this time up front like this when I should be sketching and making progress?" This is another aspect of the paradigm shift, understanding the system design. Even if redesigning the system is not considered, looking at the overall system helps identify opportunities to combine parts or eliminate joints. For many medical applications, adherence to FDA guidelines is critical, so in many ways, the design ultimately falls out of the input and output controls placed upon it by these guidelines. Using FDA controls as initial design variables allows you to thoroughly document and validate performance through simulation to prove the part's claims and streamline downstream physical testing.

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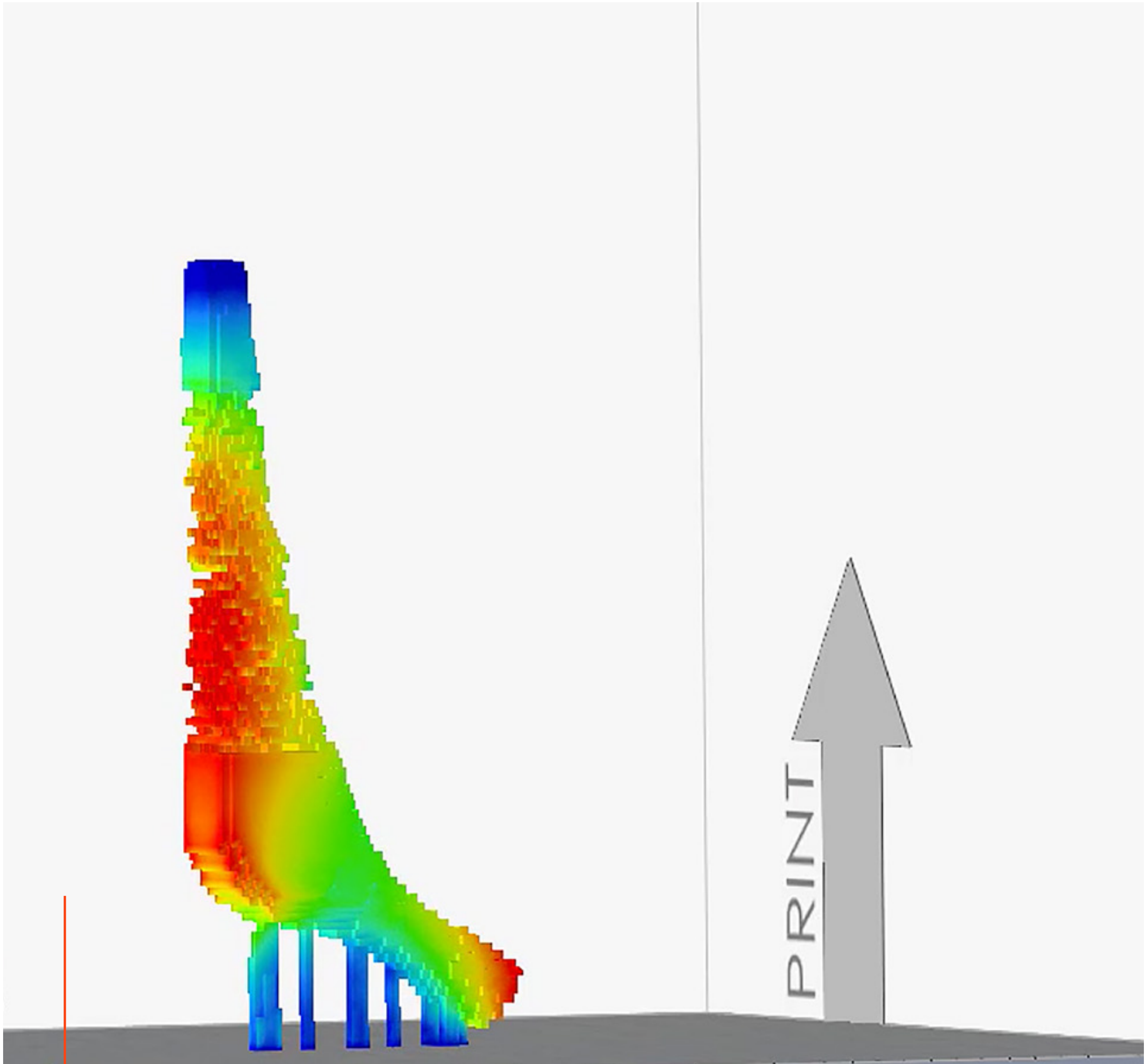
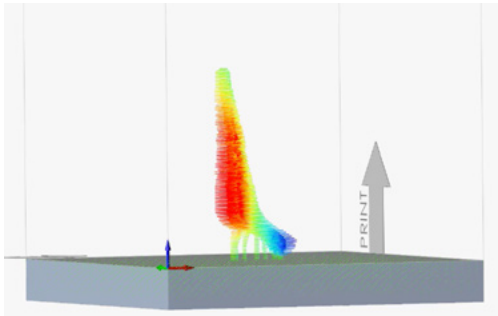
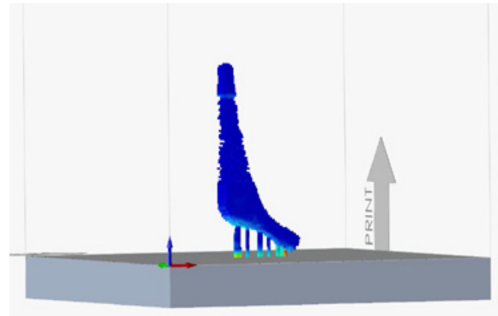


Print simulation is then utilized to ensure part distortion and certain quality metrics are met, which eliminates the need for physical testing.

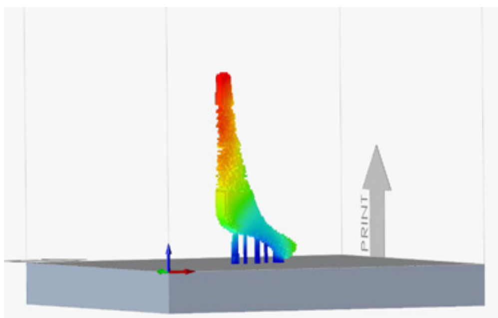
Once you have a solid design, you are now at the point where you know the material, requirements, and geometry. Then the design preparation is complete. Next would be preparing for the printing process that includes the orientation and support structure. The more thorough the virtual workflow, the more efficient the printing process becomes. Steps 6-9 in the workflow below doesn't change much regardless of the manufacturing process selected.



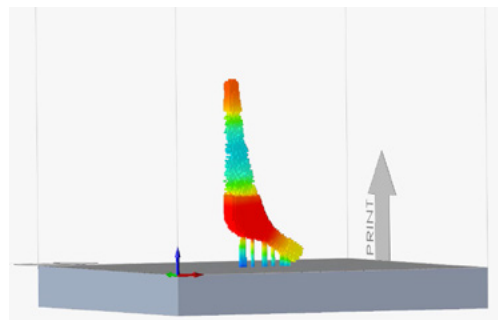
Displacement



Plastic Strain

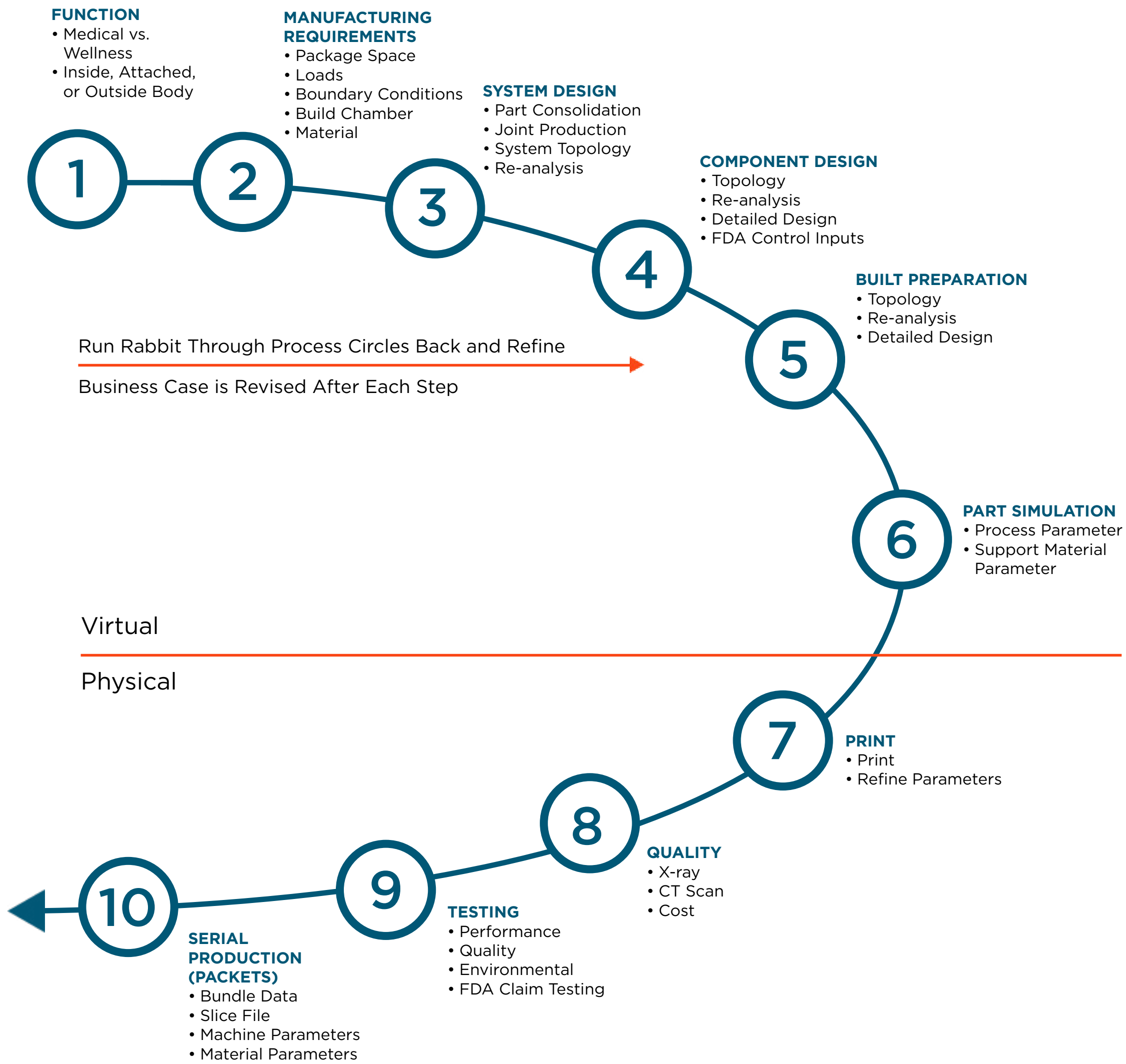


Springback



Temperature

The workflow below fully exploits the manufacturing process, demonstrating how to realize the potential of additive manufacturing early in the design process. For instance, the ability to of absorb functionality of different systems is explored in the third step of the workflow.



What is the one take-home message you'd want every person to consider when embarking on a medical additive manufacturing project?

Additive manufacturing by itself not a magic bullet. The manufacturing method is only as good as the design you feed into it. In order to maximize the value delivered to the patient and reduce your overall investment, product design and manufacturing need to work in harmony. I see the use of simulation and optimization as imperative to arriving at an optimal part design for your selected manufacturing method.

An intelligent approach to design that includes the proper choice of material layout is critical but is perhaps the most overlooked aspect of AM part design. Topology optimization details the ideal load paths for minimizing stress distribution, giving you confidence that your part will not only be lightweight, but also meet your cost, fatigue, and performance criteria. Enabling the engineer to individually tune a part or system for a particular use case maximizes the value to the patient and gives manufacturers a clear competitive edge in terms of part quality and time-to-market.

Simulation in the design and development process is also very much grounded in practicality. You need to be able to build what you design with quality and consistency. By simulating part build, cooling, cutting and springback, you can anticipate and address manufacturing issues before they happen and deliver designs using the fewest supports, optimally oriented on the print bed. Trial and error iterations in the prototyping phase are an absolute killer to your bottom line, which is why I firmly believe in a “first-time-right” approach to design, driven by simulation and optimization.

If you want to fully exploit the benefits of additive manufacturing, you need to incorporate simulation and optimization or risk leaving opportunity on the table.

WORKING WITH ALTAIR

Simulation can be the key to understanding complex issues, unlocking medical breakthroughs, and getting the latest advancements to the public faster, safer, and making them more broadly accessible. Altair helps medical companies across the world design better products, improve patient care, and reduce costs with simulation-driven design. Our simulation and optimization tools enable device designers and manufacturers to deliver quality and reliability while meeting regulatory standards, and our data analytics technologies empower healthcare providers to make faster, more informed decisions.

For more than 25 years, Altair OptiStruct™ has been the industry leader in developing and applying optimization technology for strong, lightweight designs. Developed to mimic how mechanical stresses influence optimal bone growth, it is now used to model complex biological structures and design optimized orthopedic structures. This includes lattice-designed, 3D printed components, ideal for osseointegration and promoting vascularization.
