Medical Design & OUTSOURCING

WHITE PAPER

Key Considerations for Selecting Orthopedic 3D Printing to Benefit Your Development and Manufacturing Needs

Introduction

This white paper discusses the capabilities and benefits of metal 3D printing and how CDMOs keep project costs on track.

This white paper summarizes key takeaways from the Avalign webinar "Key Considerations for Selecting Orthopedic 3D Printing to Benefit Your Development and Manufacturing Needs."

Want to learn more? Watch the webinar on demand here.

Overview

Additive manufacturing using metal 3D printing provides multiple benefits for orthopedic implants, including complexity, cost, and customization. Metal 3D printing can help manage risk while increasing speed to market for orthopedic products. With different platforms to choose from, understanding the benefits and drawbacks of each is important.

Working with a contract development and manufacturing organization (CDMO) can help guide the right choice and significantly amplify the benefits of additive manufacturing. Avalign, a CDMO with expertise in orthopedic applications, helps customers take projects from powder to package. Avalign experts work collaboratively with customers, fully evaluating all needs and processes for optimal integration and delivery.

Key Takeaways

Additive manufacturing provides complexity, customization, and cost benefits.

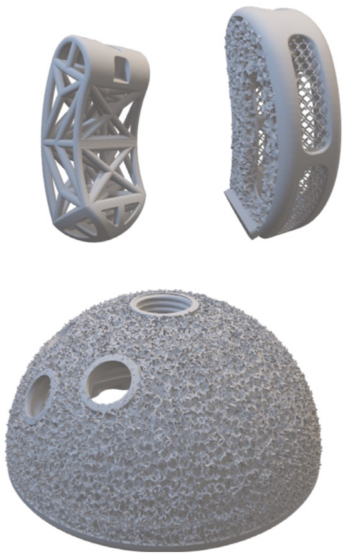
Additive manufacturing is a process by which a part is built layer by layer based on 3D CAD data. Metal 3D printing (using metal as the part-building material) is an additive manufacturing technology that provides three key benefits to orthopedics.

Benefit #1: Increased feature complexity with decreased process and part complexity

Metal 3D printing enables complex product designs, such as organized structures (e.g., lattice) and organic structures (e.g., porous). Design freedom eliminates traditional subtractive manufacturing constraints, such as draft angles, cutting tool access and geometry, and static surface finish. With 3D printing, complexity is free.

In addition, numerous studies have shown that the porous structures made possible through metal 3D printing promote osseointegration (bony in-growth)—not just bony on-growth. Because the features and surrounding architectures of 3D printed parts are produced in a single, highly repeatable process (single-substrate, monolithic construction), additive manufacturing can reduce the number of process steps required. In some cases, additive can combine multiple components of an assembly into a single component, simplifying both part and process.

Figure 1: Additive manufacturing enables lattice and porous structures



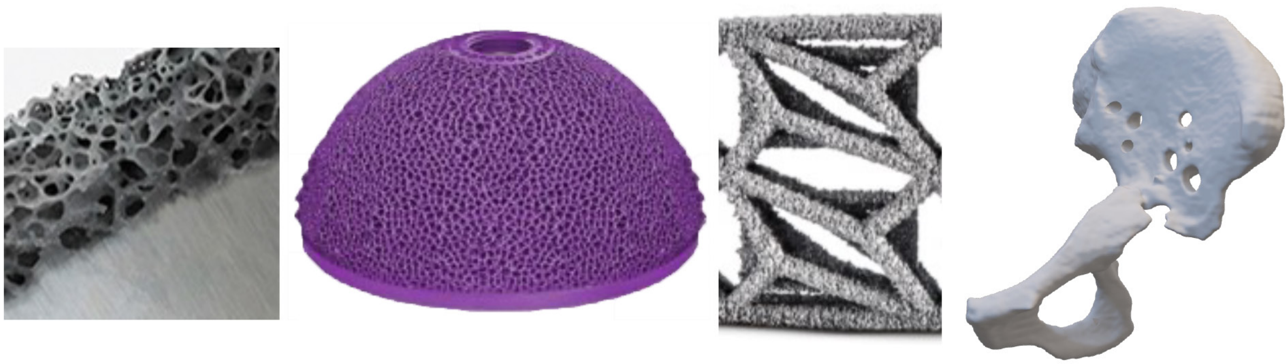
Benefit #2: Near-unlimited customization

When combined with advanced imaging on the front end, additive manufacturing allows for a truly bespoke implant, custom-tailored to a patient's specific anatomy and pathology. However, patient-specific implants (PSIs) are only one aspect of customization enabled by 3D printing. Additive manufacturing allows engineers the freedom to utilize almost unlimited variability and design architecture, including:

- **Load distribution and natural deformation (topology).** Design for mechanical properties, rigidity, and elastic modulus for natural anatomical load transfer, approximating that of natural bone.
- **Variable density, pore size, and depth.** Generate open structures that closely mimic the porous structures of trabecular or cancellous bone for bone graft and weight savings.
- **Surface roughness of the implant bone interface (topography).** Integrate variable surface textures to stimulate bony on-growth and bony in-growth can be added to any structure, no matter its position or shape.

> Pore structures can be designed with varying density, pore size, and depth tailored to match the various services with which they interface . . . while still outputting devices of a single substrate with strength that's near that of wrought material.
>
> –Vice President, Operations, Avalign

Figure 2: Metal 3D printing enables customization of topology and topography



Benefit #3: Decreased total cost by improving speed to market, COGS, and procedure-related properties

The total cost of a part goes beyond the piece price. Although total cost encompasses multiple factors, the largest differentiators are during four key lifecycle phases: development, launch, supply chain, and patient care.

Phase 1: Development: Additive manufacturing provides the ability to quickly iterate design concepts, accelerating time to market.

Phase 2: In the initial launch of the manufacturing process, a single additive operation can combine many traditional steps, shortening the total process flow. Because most product "families" can comprise dozens of SKUs—due to the many parametric permutations available for each part—additive manufacturing allows engineers to import models and prep them for printing in a matter of minutes, rather than days when using traditional manufacturing.

Phase 3: The high-mix, low-volume demand curve of orthopedic implants makes optimization of the supply chain challenging. Additive manufacturing enables a shift away from a make-to-stock strategy and toward a build-to-order strategy, reducing the time and cost of replenishment by tailoring the manufacturing schedule to true demand.

Phase 4: The speed of fixation and early osseointegration of 3D-printed parts reduces post-operative recovery time and patient care. Better patient outcomes support lower total cost.

Figure 3: Additive manufacturing enables high-mix, low-volume demand

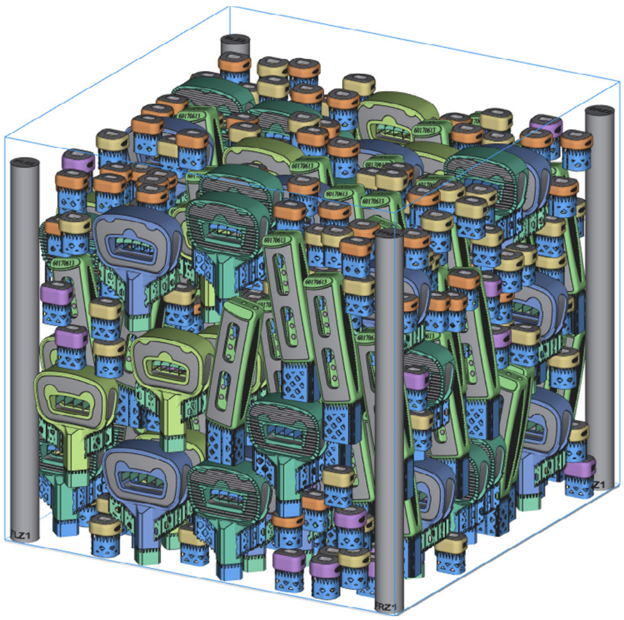
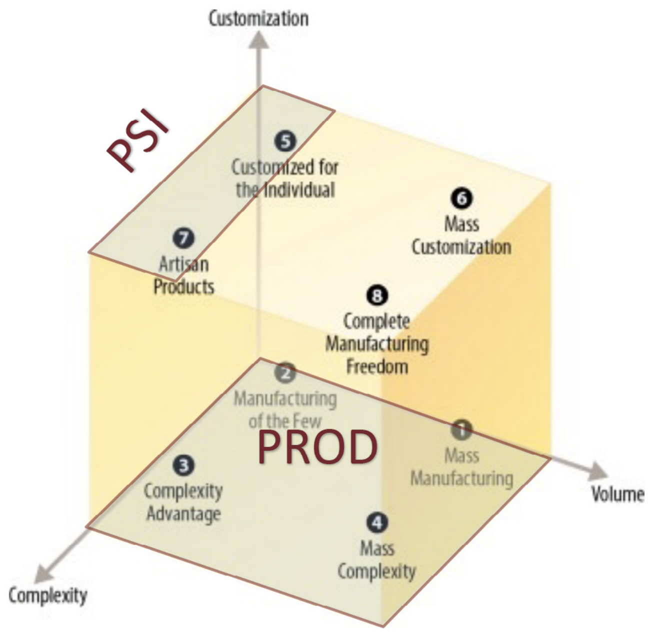


Figure 4: How additive manufacturing impacts complexity, customization, and volume



> At the end of the day, we're looking to improve the lives of our patients and give them a better quality of life, so anything that can help do that—whether in surgery or the final product—is a plus.
>
> –Matt Lawson, Avalign

There are two main additive platforms for metal powder bed fusion.

Powder bed fusion is a method of additive manufacturing that reads a CAD model file (most commonly STL) to fuse powder, layer by layer, to form a part. The two most common types of metal powder bed fusion additive platforms are EBM and DMLM:

EBM (Electron Beam Melting, or "E-Beam")

EBM works by converting electricity into an electron beam guided into the system's build chamber, melting the powder into a part's cross-section before moving the table down, recoating for a fresh layer, and repeating the cycle as many times as required. The EBM platform benefits three key systems:

- **Volume and speed.** Avalign has nine Arcam EBM Q10plus printers in production, all of which utilize the Arcam MultiBeam technology that allows the system to maintain multiple melt pools at once. This better regulates the temperature in the system and reduces thermal gradient in parts.

  The EBM system preheats each layer to a semi-sintered powder state. The powder surrounds and supports the parts, negating the effects of gravity that would typically occur on a part and a laser system. This allows nesting of parts throughout the entirety of the build volume without having to be attached to the build plate. This does not put a restriction on the height-to-width ratio of a part. Build plate removal is simple via media blasting using the same powder with which the parts were built, so there is no cross-contamination.

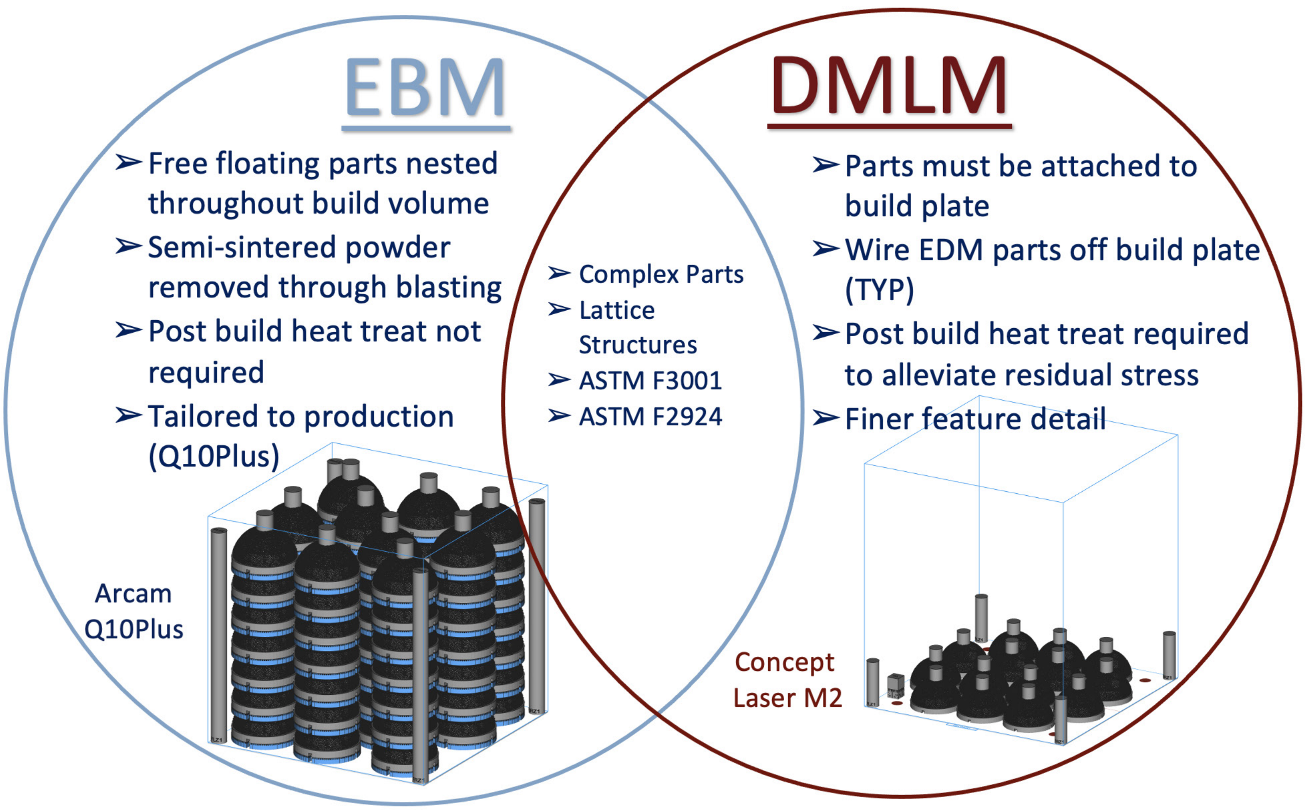
- **Vacuum system.** EBM prints in a near-vacuum during the entirety of the build process, while backfilling with helium to regulate the pressure and keep it at a steady state throughout the build. Because of this, the chemical properties of the build material can be maintained without worrying about introduction of any foreign elements.

- **Hot process.** The combination of vacuum and insulation capabilities allows for high process temperatures during an EBM build. The natural stress relief provided by the Arcam MultiBeam results in low residual stress in parts that come out of the machine, and therefore require no post-process heat treat. EBM yields excellent mechanical properties in parts' green state.

DMLM (Direct Metal Laser Melting, or "Laser")

In a DMLM system, the energy source is typically a laser—whether fiber or CO_2. As with EBM, the energy source (laser, in the case of DMLM) is directed toward the powder bed to melt cross-sections. (Note: In most laser systems, the powder is loose, surrounding the parts.) However, unlike EBM, the parts in a DMLM system must be attached to the build plate and post-build heat treat is required to alleviate residual stress.

Figure 5: Key differences and overlapping benefits between EBM and DMLM 3D printing processes



When determining which technology to use for a part, keep in mind that choosing the right tool for the job depends on the application.

- EBM is often a better choice for large joints and most spine applications due to clinically relevant resolution requirements and the ability to nest significantly more components.
- EBM offers high-volume output with multiple SKUs in a build and reduces the number of process steps required.
- DMLM provides a smoother as-printed surface finish and is a better choice for ultrafine feature details that cannot be machined later. (Although DMLM provides finer feature detail, fine feature details are not a roadblock for EBM—parts can be machined to meet specifications.)

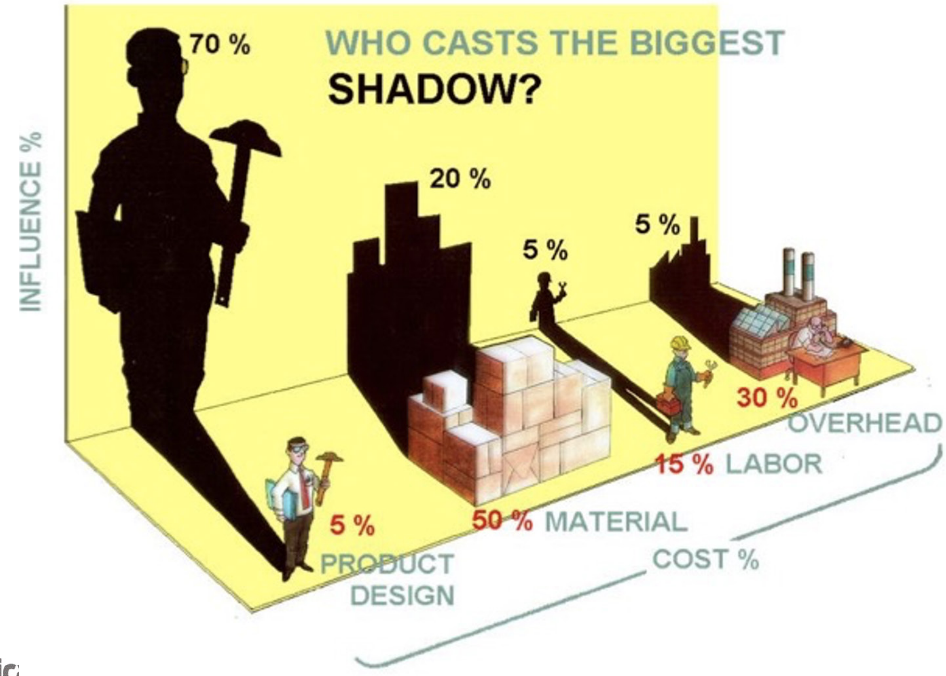
CDMOs such as Avalign provide valuable expertise to manage costs.

The overwhelming majority of the cost of any given product is set by the choices made during the development phase. Although the product design phase represents a small cost in dollars, the decisions made in this stage have an overwhelming impact on the final cost. As the project lifecycle moves forward, the ability to change decreases as the cost of changes grows.

Working with a CDMO such as Avalign can benefit additive projects, as knowledgeable CDMOs can bring speed to market as a contract manufacturer, a collaborative partner, and a competent specification developer. Engaging an experienced CDMO early in the manufacturing process reduces the number of design iterations, decreases project risk, and decreases the likelihood of scope and budget creep.

> "Having a CDMO partner at the table throughout the development process can greatly facilitate product cost estimates at each and every design review and every major design decision point."
>
> – Vice President R&D and Business Development, Avalign

Figure 6: Direct cost of key budget areas versus their impact on final cost



Additional Information

To learn more about Avalign, visit avalign.com

White Paper Contributors

Matt Lawson
Additive Manufacturing Engineer, Avalign

Matthew Lawson joined Avalign Additive|Slice Mfg Studios in February 2020 as an Additive Manufacturing Engineer. Matthew over sees all additive manufacturing related matters. From daily production to new product introduction and everything in between. He is focused on helping customers bring their ideas to reality through the power of 3D printing.

Matthew's passion for additive manufacturing began 10 years ago in his high school CAD class. Since then, he has been captivated by the growth in technology and expanded applications of 3D printing. Prior to joining Avalign, Matthew served as a manufacturing engineer in 2019 for Fitz Frames, a start-up company specializing in 3D printing customer fit eyeglasses for kids and adults alike.

Mr. Lawson earned a bachelor's degree in mechanical engineering from Youngstown State University in 2019. Mr. Lawson has certifications from GE Additive in Arcam and Concept Laser Operations and Maintenance as well as certification in Arcam Applications.

Scott Gareiss
Vice President R&D and Business Development, Avalign

Scott Gareiss was named Vice President, R&D and Business Development for Avalign Technologies in June 2010. Mr. Gareiss has company-wide responsibility for new product development and engineering services which includes the four operating divisions of Avalign: German Specialty Instruments, Cases & Trays, Instruments & Implants and Cutting Instruments.

Mr. Gareiss has over 15 years of experience in the orthopedic industry, having started as a product development engineer with Zimmer in 1999. Prior positions held by Mr. Gareiss include Senior Director, Professional Services with Symmetry Medical, 2004-2010; Senior Product Development Engineer with Medtronic, 2003-2004, and Zimmer, 1999-2003. Prior to his career in orthopedics, Mr. Gareiss served as an officer in the U.S. Army, 1995-1999.

Mr. Gareiss received his M.B.A. from Ball State University in 2004, and a B.S. degree in Mechanical Engineering from Rose-Hulman Institute of Technology in 1995.

Joseph Lah

Vice President, Operations, Avalign

Joseph Lah joined Avalign Technologies as GM and VP of Operations, Avalign Additive | Slice Manufacturing Studios upon acquisition from The Theken Companies in 2020. Holding positions of leadership in Quality, Engineering, and Operations, Mr. Lah has over 30 years of contract manufacturing experience; 25 years in precision machining for the Automotive, Defense, and Medical Device industries; 13 years in medical device manufacturing; and 5 years of metal additive manufacturing.

Mr. Lah holds a B.S., Industrial Management and M.B.A., Finance degrees from the University of Akron.

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Managing Editor, Medical Design & Outsourcing (Moderator)

Jim Hammerand is the managing editor of Medical Design & Outsourcing in WTWH's Life Sciences portfolio. He has more than 15 years of professional journalism experience spanning newspapers, magazines, websites and broadcast news. Jim holds a bachelor's degree in journalism from the University of Minnesota and lives near Seattle.