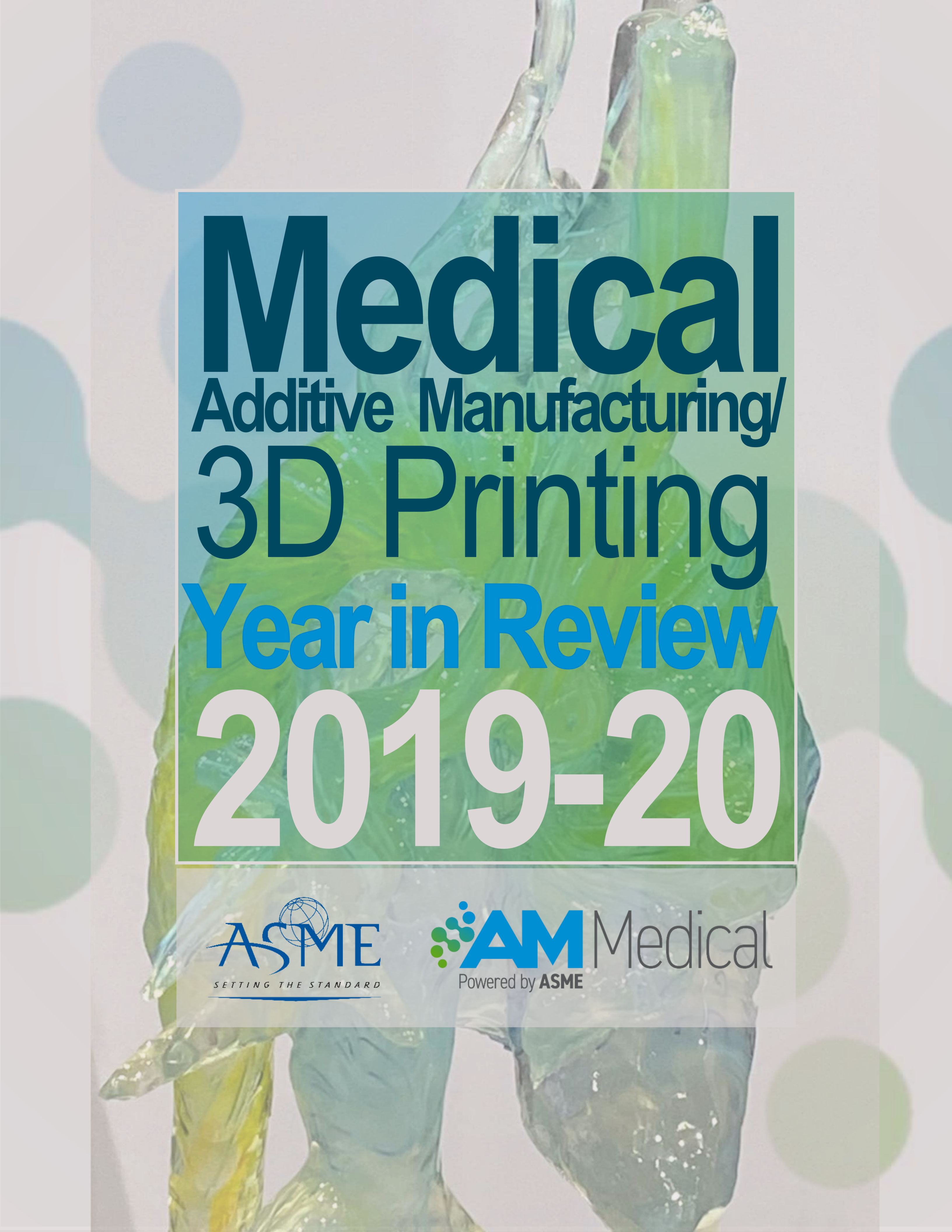

Medical
Additive Manufacturing/ 3D Printing
Year in Review
2019-20

ASME
SETTING THE STANDARD

AM Medical
Powered by ASME

ASME and America Makes collaborate to support the Medical Additive Manufacturing/3D Printing Community.

Cover photo: 4D flow model showing blood flow through the cardiovascular system in a pediatric congenital heart disease patient produced on a Stratasys J750 by Alex J Barker, MD; Lorna P. Browne,MD; and Max Mitchell, MD at Children's Hospital Colorado and Stratasys.

In 2019, the total value of additive manufacturing products and services was estimated at $11.875 billion[i] with medical applications representing an estimated $1.65 billion[i]. The total value of AM machines, materials, software, and services for medical applications is projected to reach $2.2 billion by 2024[ii]. With such incredible growth, keeping up with developments can be challenging.

With improving patient care as the primary goal, 3D printing has directly impacted more than 3 million patients. The estimate increases to more than 5 million if indirect uses such as patterns for clear dental aligners are added. Supported by continually improving machines, materials, and software, new users and applications are being found regularly.

> "…3D printing has directly impacted more than 3 million patients."

The ASME Medical AM/3DP Advisors took on this challenge and gathered and reviewed what are believed to be the best developments from **April 1, 2019 through March 31, 2020**. From new machines and materials to collaborations and new resources that facilitate quality processes, the group considered whether a development increased the medical AM/3DP community's impact on patients and whether it qualified as new.

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[i] Wohlers Report 2020

[ii] Healthcare 3D Printing Market Size, Global Market Insights, July 2018

ASME Medical AM/ 3DP Advisors

Thank you to the ASME Medical AM/3DP Advisors for their contribution to this Year in Review and for their commitment to improving patient care through the benefits of additive manufacturing/3D Printing.

- **Amy Alexander**, *Mayo Clinic*
- **Anthony Atala**, *Wake Forest Institute for Regenerative Medicine*
- **Shawn Burke**, *KLS Martin*
- **David Burns**, *AMT*
- **Annie Cashman**, *Protolabs*
- **Roland Chen**, *Washington State University*
- **Andy Christensen**, *Somaden*
- **Rex Christensen**, *Weber State University*
- **Meghan Coakley**, *NIH*
- **James Coburn**, *FDA*
- **Michael Coleman**, *HCL America*
- **Chris Collins**, *Tangible Solutions*
- **Philip Corvo**, *Trinity Health*
- **Daniel Crawford**, *Axial3D*
- **Benjamin Danker**, *Trinity Health*
- **David Dean**, *The Ohio State University*
- **Carl Dekker**, *Met-L-Flo*
- **Michael DeRossett**, *Trinity Health*
- **Hunter Dickens**, *Mayo Clinic*
- **Matthew DiPrima**, *Food and Drug Administration*
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- **Phil Dommel**, *Renishaw*
- **Kristen Eisiminger**, *EOS of North America*
- **Dima Elissa**, *VisMed3D*
- **Luca Emili**, *InSilico Trials*
- **Dave Emmett**, *GE Additive*
- **Alejandro Espinoza**, *Rush University Medical Center*
- **Kanwal Farooqi**, *Columbia University Medical Center*
- **Sarah Flora**, *Geisinger Health*
- **Jenna Franklin**, *EnvisionTec*
- **Dan Fritzinger**, *Depuy Synthes*
- **Lexi Garcia**, *ARMI|BioFabUSA*
- **Giles Gaskell**, *Hexagon*
- **Mariah Geritano**, *Boston Children's Hospital*
- **Anish Ghodadra**, *UPMC*
- **Laura Gilmour**, *EOS of North America*
- **Lucy Grainger**, *Renishaw*
- **Irene Healey**, *New Attitude Prosthetics Designs*
- **Evan Hochstein**, *Stratasys*
- **Yu-hui Huang**, *UIC College of Medicine*
- **Rachel Hunt**, *Protolabs*
- **Adam Jakus**, *DimensionInx*
- **Joseph Johnnie**, *Johnson & Johnson*
- **Benjamin Johnson**, *3D Systems*
- **Craig Johnson**, *Formlabs*
- **Michael Joyce**, *Royal College of Surgeons Ireland*
- **David Keedy**, *SLM*
- **Ryan Kircher**, *Additive Industries*
- **April Krivoniak**, *UPMC*
- **Gene Kulesha**, *Onkos Surgical*
- **Shuai Leng**, *Mayo Clinic*
- **Elizabeth Lezama**, *Mayo Clinic*
- **Peter Liacouras**, *Walter Reed National Military Medical Center*
- **Orlando Lopez**, *NIH*
- **Gaurav Manchanda**, *Formlabs*
- **Jane Matsumoto**, *Mayo Clinic*
- **Sean McEligot**, *Mayo Clinic*
- **Eyal Miller**, *Stratasys*
- **Jonathan Morris**, *Mayo Clinic*
- **Robert Morrison**, *University of Michigan*
- **Reese Myers**, *WishBone Medical*
- **Renee Nester**, *Johnson & Johnson*
- **Caralynn Nowinski Collens**, *Dimension Inx*
- **Philip Oris**, *SLM Solutions*
- **Ibrahim Ozbolat**, *Penn State University*
- **Todd Pietila**, *Materialise*
- **Michael Pisani**, *Advanced Regenerative Manufacturing Institute (ARMI)/MassMEP*
- **Michael Raphael**, *Direct Dimensions*
- **Ryan Ratkowski**, *Avalign Technologies*
- **Brandon Ribic**, *America Makes*
- **Beth Ripley**, *University of Washington*
- **Becky Robinson-Ziegler**, *ARMI|BioFabUSA*
- **Justin Ryan**, *Rady Children's Hospital*
- **Ben Salatin**, *US Department of Veterans Affairs / Albuquerque Veterans Hospital*
- **Janelle Schrot**, *Materialise USA*
- **Ramille Shah**, *DimensionInx*
- **Rami Shorti**, *Intermountain Healthcare*
- **Brian Strezelecki**, *VA Puget Sound health Care System*
- **Jude Sudhakar**, *NMC Healthcare*
- **Dale Swarts**, *Stryker*
- **Kim Torluemke**, *3D Systems*
- **Maria VanHaverbeck**, *SLM*
- **Mihaela Vlasea**, *Univeristy pf Watrerloo*
- **Nicole Wake**, *Montefiore Medical Center*
- **Robert Wesley**, *Jabil Healthcare*
- **Jan Witowski**, *Massachusetts General*
- **Atif Yardimci**, *Exponent*
- **Ken Yuen**, *Acuitive Technologies*
- **Stephan Zeidler**, *GE Additive*

In reviewing the year, several trends were seen...

COVID-19: No review of developments could begin without recognizing the early response of the medical AM/3DP community to the COVID-19 pandemic. Early response included free files for 3D printing door handle attachments that enabled opening doors with your arm. The unprecedented MOU between the US FDA, VHA, and NIH/NIAID with collaboration of America Makes, facilitated connections to address supply chain interruptions and the dramatic increase for personal protection equipment. With support of ASME, the community came together and became a critical part of the response team. A special section begins the Community Developments section; providing a summary of the earliest activities by the medical AM/3DP community.

New Devices: Traditional device manufacturers are expanding their use of additive manufacturing. More than 50 devices using additive manufacturing as a production method received 510(K) clearance during the year, representing approximately 25% of all devices 510(K) clearance in the last 10 years. Point-of-care manufacturers are using access to 3D printing in the hospital to also develop new applications. These include new tools for different types of brachytherapy.

3D Printing-Enabled Tissue Generation: With new materials, new bioprinters, printing processes patented, advancements demonstrated in tissue printing, an online tissue design platform, and initiation of bioprinting standards, the community took significant steps toward clinically viable 3D biofabrication.

Patient-specific devices while still uncommon outside of dental applications, may become more common soon. More than 10 software packages designed to facilitate the segmentation and design process for an individual patient received 501(K) clearance. Together with development of quantum blockchain to protect the privacy of patient files and the demonstration of a distributed manufacturing model feasibility seen in response to the COVID-19 pandemic, these developments hold promise for more patient-specific devices.

Quality and standardized processes continue to be a challenge for additive manufacturing. Several standards important to medical applications of AM were published. Development of new standards and a new group focused on medical applications also began. From validation and verification of AM processes to bioprinting hardware, the growth of standards points to increased use of additive manufacturing.

Reimbursement for new products enabled by 3D printing advanced with several developments including:

- Category III CPT codes became active.
- RSNA 3D Printing SIG and the American College of Radiology (ACR) announced the launch of a 3D printing clinical data registry.
- Completion and initiation of a significant number of clinical studies.

Community Developments

COVID-19 Responses

The Medical AM/3DP Community continues to respond to the increased need for PPEs and disruptions in supply chains. Below is a summary of the efforts that took place before March 31, 2020.

FDA, NIH, VA, and America Makes Partner for COVID-19 Response

The FDA entered into a Memorandum of Understanding (MOU) with the Department of Veterans Affairs and the National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIH/NIAID), and worked with America Makes to facilitate connections between patients and healthcare providers, local manufacturers with capabilities, and designs for needed medical products. The MOU provided a framework for collaboration intended to facilitate regulatory and basic science innovation with 3D printing technologies to respond to COVID-19. Through this collaboration, the U.S. government and partners helped to ensure that veterans and civilians had access to the most innovative medical solutions and technologies, including medical products that are manufactured close to the patient or at point of care. The FDA also issued FAQs on 3D Printing of Medical Devices during COVID-19 for entities who 3D print devices, accessories, components, and/or parts during the COVID-19 pandemic. MORE

Quick Links

- FDA COVID-19 Emergency Use Authorizations for Medical Devices
- America Makes
- NIH 3D Print Exchange

ASME

ASME responded quickly, bringing together experts, providing insights, and facilitating connections between members of the medical AM/3DP community. These efforts included:

- Convened ASME Technology Advisory Panels in bioengineering, manufacturing, and robotics along with public policy task forces including FDA & NIH to identify challenges.
- Shared insights with America Makes which became a key element of the FDA, NIH, VA, and America Makes efforts
- Convened weekly meeting with the medical AM/3DP community to discuss activities, answers questions, and facilitate connections
- Made relevant elements of ASME's journal collection free to download: Digital Collection

Materialise Releases Hands-Free 3D printed Door Openers to Help Against the Spread of Coronavirus

Materialise shared a free design file for a 3D printed door opener that can be operated with elbows instead of hands to avoid spreading the coronavirus COVID-19. MORE

3D printed frame enable by Beluss3D's face scanning app.

Bellus3D Created Personalized 3D Printable Mask Fitters

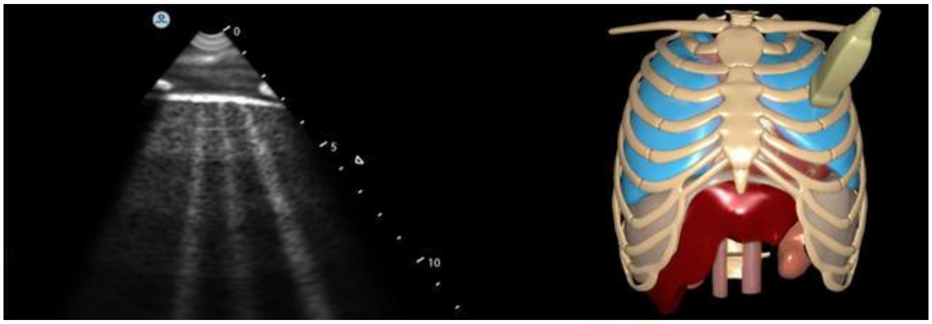
Bellus3D, Inc. offered personalized 3D printable Mask Fitter frames to improve seals on face masks. The application allows anyone to scan their face and generate a 3D printable file of the Mask Fitter that can be used with most 3D printers. This personalized, precise-fitting frame can be placed over an existing surgical mask to ensure a tighter seal. MORE

3D Printed Nasopharyngeal Swabs

Formlabs, the University of South Florida (USF) Health, and Northwell Health teamed up to produce 3D printed nasal swab to address emergency shortages that hospitals and health care teams faced in the US as testing for COVID-19 ramped up early on in the pandemic. MORE

Additional Responses from Leading Organizations

- 3D Systems
- Formlabs
- HP
- Stratasys
- University of Waterloo



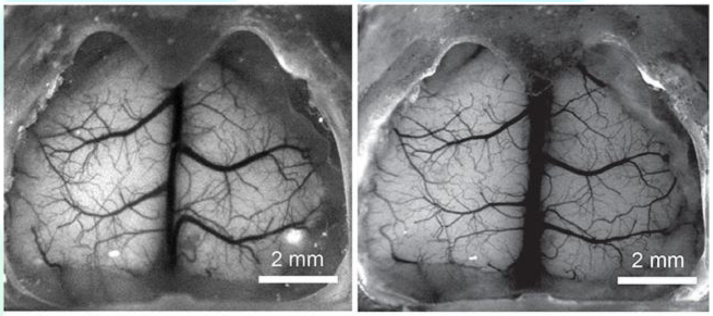
3D Systems' new COVID-19 module to help provide hands-on experience in the education of point-of-care ultrasound skills that are essential in triage and monitoring of the coronavirus.

NOTE: This summary indicates only efforts before March 31, 2020. The community has and continues to do so much more.

Applications & Devices

3D Printed Transparent Skull Implant for Mice

Scientists at the University of Minnesota produced a 3D printed transparent skull implant to observe the inner workings of mouse-brains in real time to provide new insights for human brain conditions such as Alzheimer's and Parkinson's disease. MORE



6 weeks after implantation 36 weeks after implantation

3D printed transparent mouse skull allows for researchers to study brain activity. PHOTO: University of Minnesota

3D Printed Gynecological Brachytherapy Applicators with Curved Needle Channels

Patient-specific vaginal topography-based 3D printed brachytherapy applicators developed from MRI data have been demonstrated. The applicators include curved needle channels that can be used for guided interstitial needle placement. Spatial optimization of brachytherapy source channels to the patient anatomy is expected to increase brachytherapy conformity and outcome. MORE

3D Printed Non-melanoma Skin Cancer and Keloid Brachytherapy Device

A working prototype of a novel CSBT device was 3D printed that provides a safe and economically attractive means of improving radiation delivery to complex treatment sites. The device has a hexagonal lattice array of retractable rods with radioactive seeds placed at the tip of each rod which can be displace to conform to the patient's skin. The device design permits the delivery of radiation to complex targets using readily available beta-emitting radionuclides, such as Yttrium-90 (Y-90) or Strontium-90 (Sr-90). MORE

3D Printed Template for Percutaneous Localization of Multiple Lung Nodules

A 3D printed template was designed that could guide hook wire localization of multiple lung nodules. A pilot study preliminarily validated the feasibility of template-guided localization for multiple lesions. CT images were used to create a thorax model from which a navigational template was designed and 3D printed. Demonstrating with 16 patients and 34 lung nodules, all nodules were successfully localized with a median procedural time of 10 minutes and a median radiation exposure of 235 mGy • cm (IQR, 195-254 mGy • cm). MORE

Examples of Depuy Synthes' interbody platform with EIT Cellular Titanium Technology. PHOTO: Johnson & Johnson

3D Printing Portfolio Launch of Conduit Interbody Platform

The Johnson & Johnson announced that DePuy Synthes launched the CONDUIT Interbody Platform with EIT Cellular Titanium Technology, expanding its comprehensive offering to treat degenerative spine disease. The portfolio, which includes 3D printed titanium interbody implants for spinal fusion surgery is designed to mimic natural bone and help facilitate spinal fusion. MORE

Materials

Stratasys Launched Three New Materials for Medical Applications

Along with its introduction of the J750 Digital Anatomy 3D Printer, Stratasys introduced three new materials called TissueMatrix™, GelMatrix™, and BoneMatrix™. These materials were created specifically for cardiac, vascular, and orthopedic 3D printing applications. MORE

BEGO Released VarseoSmile Crown Plus

Bego introduced a tooth-colored, ceramic-filled hybrid material developed for the 3D printing of permanent single crowns, inlays, onlays, and veneers; available in seven VITA™ shades (A1, A2, A3, B1 , B3, C2, D3). The material fulfills all requirements for a class IIa medical device in accordance with the EC directive "Medical Devices" 93/42 / EEC. MORE

BEGO's VarseoSmileCrown Plus material.

TheWell Bioscience Launched VitroINK™

TheWell Bioscience released VitroINK, a family of ready-to-use, xeno-free tunable bioink systems that require no UV, no temperature/pH curing, or chemical cross-linking. The system is ready-to-use at room temperature, neutral in pH, and has excellent visibility after printing and cell culture. Different versions of VitroINK may incorporate multiple biological functional ligands to promote cell attachment, cell-matrix interactions, cell proliferation, motility/migration and differentiation for many different applications. MORE

UPM release new bionks.

UPM Released GrowInk™ Bioinks

UPM released a non-animal derived, ready-to-use hydrogels mimicking the *in vivo* environment to support cell growth and differentiation. The new GrowInk™ Bioinks product range is designed for a range of bioprinting applications, including cell encapsulation and scaffold preparation for tissue engineering, drug discovery and regenerative medicine. MORE

Hardware

BIO X6

CELLINK released the BIO X6, a six-printhead bioprinting platform with clean chamber and exchangeable printhead technology. The capability to combine more materials, cells and tools has the potential to enhance research applications across the bioprinting field. MORE

Varseo XS

BEGO released the Varseo XS 3D printing system for dental applications, enabling the 3D printing of permanent restorations. MORE

B9Creations Released 3D Printer for Medical

B9Creations released a medical upgrade to its B9 Core Series 3D printer line with the launch of the B9 Core Med 500. MORE

B9Creations B9 Core Series for medical and dental applications.

Software

Online Design Tool: TissueWorkshop

Prellis Biologics launched a web-based platform for the download and generative design of 3D printable tissue scaffolds. TissueWorkshop was created to reduce the amount of time required to create scaffolds, and labor-intensive design cycles. MORE

Quantum-Secure Blockchain Network

GE Research developed a quantum-secure blockchain network for 3D printing/additive manufacturing, which can manage digital transactions for making parts from powder to finished part. The blockchain-enabled transactional platform combines the need for pervasive data integration with a high degree of cryptographic communications and data storage enabled by quantum communication channels and ultra-fast quantum key distribution technologies MORE

Quality, Certification, & Standards

ASME

V&V 40 Standard Team receives FDA Award

The ASME Validation & Verification 40 standards team received an FDA Tier 1 Group Award “for exemplary performance in developing and establishing the first international standard for verification and validation of biomedical computational models for medical products.” V&V 40 outlines a risk-informed credibility assessment framework that helps an organization or team determine the level of rigor required to support using computational modeling and simulation for decision-making and has been adopted by stakeholders in the medical devices and pharmaceutical industries internationally. The ASME V&V 40 standard is the first consensus standard for evaluating the predictive

V&V 40 team members received FDA Award; pictures left to right are Jeff Bodner, Medtronic; Tina Morrison, FDA, & Pras Pathmanathan, FDA.

capability of computational models for medical devices and represents a landmark moment for the medical device modeling community. The standard is officially recognized by the FDA. MORE

The ASME V&V team continues their work with several standards development initiated, including:

- V&V 40.1 Using (historical) clinical data as a comparator
- V&V 40.2 Extending an appendix example or create example that's end-to-end
- V&V 40.3 V&V for patient-specific models: surgical planning and clinical-decision making - software as a medical device
- V&V 40.5 Mock Submission – V&V 40 Practice in Regulatory Applications
- MORE

B46 Surface Texture (Surface Roughness, Waviness, and Lay)

Standard B46 was updated to B46.01-2019 to include measurement and analysis methods to address surfaces created by additive manufacturing. B46 explains how to find parameters that can describe the topography so they can correlate and discriminate between processing and performance parameters MORE

B89.4.23- 2019 X-ray Computed Tomography (CT) Performance Evaluation Standard

ASME released B89.4.23 covering dimensional measurement accuracy of X-ray computed tomography (CT) systems for point-to-point length measurements of homogeneous materials. The standard is applicable to dimensional measurements made at the surface of the workpiece, i.e. at the workpiece material – air interface, including those of internal cavities.

Model-Based Enterprise Standards Established Working Groups

The ASME MBE Standards Committee established working groups (WGs) to kickoff technical work toward the development of MBE Standards. The first two WGs are:

- **Terms WG:** The Terms WG's focus is to begin collecting and defining terms, acronyms, and abbreviations for use in the MBE Standards. The WG will support consistent definition and application of terms across all ASME MBE Standards using a model-based lexicon and approaches.
- **Use Cases & Model-Based Standards Development (MBSD) WG:** The Use Cases & MBSD WG's focus is on the system architecture, tools, and development methods for various viewpoints to create models and artifacts that define the MBE standards and can be interpreted by an automated system. The Use Cases & MBSD WG will identify and develop the system that the ASME MBD SC activities will use to develop and release model-based standards. MORE

Bioprinting Hardware

Collaborating with the Standards Coordinating Body (SCB), ASME established a Bioprinters Standards Committee to develop a bioprinter hardware standard on extrusion bioprinters. Initial work is being done to provide guidelines for extrusion bioprinting calibration of devices, operations, compatibility, and interoperability of these components to best print *ex vivo* "outside an organism" tissue results. MORE

Tissue Material Properties and Lexicon

ASME, together with the Society for Thermal Medicine, established the Thermal Medicine Standards Committee. The first efforts will focus on tissue material properties and lexicon. MORE

Advanced Regenerative Medicine Institute

ARMI and the SCB Begin Standards Development Work with ASME, ASTM, and IEEE

The Standards Coordinating Body for Regenerative Medicine (SCB) serves as conduit from the regenerative medicine community to established SDOs by synthesizing the often poorly defined perceived need into a coherent scope of work for an established SDO. In the case of bioprinting, these efforts in collaboration with the Advanced Regenerative Manufacturing Institute (ARMI) resulted in standards projects in three SDOs based on each SDO's area of specialty:

- ASME: Bioprinting Hardware Standard
- ASTM WK72274: Test Method for Printability of Bioinks for Extrusion-based Bioprinting

- IEEE P2864: Guide for a Software Change Control System for Three-Dimensional (3D) Bioprinting of Tissue-Engineered Medical Products (TEMPs)

With SCB support, ARMI has taken the lead on each project at the three SDOs and has been instrumental in recruitment of subject matter experts to these efforts. MORE

ASTM F42

New Medical Applications Subcommittee

ASTM F42 set up a new subcommittee, ASTM F42.07.03 for medical/biological applications of additive manufacturing. The subcommittee is co-chaired by Rod McMillan, Johnson & Johnson, and Matthew DiPrima, FDA. MORE

New Standards Published

- ISO/ASTM52902-19 Additive manufacturing — Test artifacts — Geometric capability assessment of additive manufacturing systems
- ISO/ASTM52904-19 Additive Manufacturing – Process Characteristics and Performance: Practice for Metal Powder Bed Fusion Process to Meet Critical Applications
- ISO/ASTM52903-20 Additive manufacturing — Material extrusion-based additive manufacturing of plastic materials — Part 1: Feedstock materials

New Standard Development Initiated of Greatest Interest for Medical Applications

- ASTM WK69731 New Guide for Additive Manufacturing -- Non-Destructive Testing (NDT) for Use in Directed Energy Deposition (DED) Additive Manufacturing Processes
- ASTM WK69732 New Guide for Additive Manufacturing -- Wire Arc Additive Manufacturing
- ASTM WK70164 New Practice for Additive Manufacturing -- Finished Part Properties -- Standard Practice for Assigning Part Classifications for Metallic Materials
- ASTM WK71268 New Test Method for Additive manufacturing -- Qualification principles -- Laser-based powder bed fusion of polymers -- Part 1: General principles, preparation of test specimens
- ASTM WK71269 New Practice for Additive manufacturing -- Qualification principles -- Quality requirements for industrial additive manufacturing sites
- ASTM WK71375 New Guide for Additive Manufacturing Qualification principles Part 1 :Qualification of Machine operators for metallic parts production
- ASTM WK71376 New Guide for Additive manufacturing -- Qualification principles -- Part 2: Qualification of machine operators for metallic parts production for PBF-LB
- ASTM WK71378 New Guide for Additive manufacturing -- Qualification principles -- Part 4: Qualification of machine operators for metallic parts production for DED-LB
- ASTM WK71379 New Guide for Additive manufacturing -- Qualification principles -- Part 5: Qualification of machine operators for metallic parts production for DED-Arc
- ASTM WK71391 New Guide for Additive Manufacturing -- Static Properties for Polymer AM (Continuation)
- ASTM WK71393 New Practice for Additive manufacturing -- assessment of powder spreadability for powder bed fusion (PBF) processes`
- ASTM WK71395 New Practice for Additive manufacturing -- accelerated quality inspection of build health for laser beam powder bed fusion process
- ASTM WK71507 New Guide for Additive manufacturing -- General principles -- Overview of data processing
- ASTM WK71616 New Specification for Additive manufacturing -- Qualification principles -- Part 2: Requirements for industrial additive manufacturing sites
- ASTM WK71891 New Specification for Additive Manufacturing of Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion for Medical Devices
- ASTM WK72172 New Practice for Additive manufacturing -- General principles -- Overview of data pedigree
- ASTM WK72237 New Test Method for Additive manufacturing -- Qualification principles -- Part 2: Requirements for industrial additive manufacturing sites

- ASTM WK72391 New Guide for Additive manufacturing -- Environment, health and safety -- Standard guideline for use of metallic materials

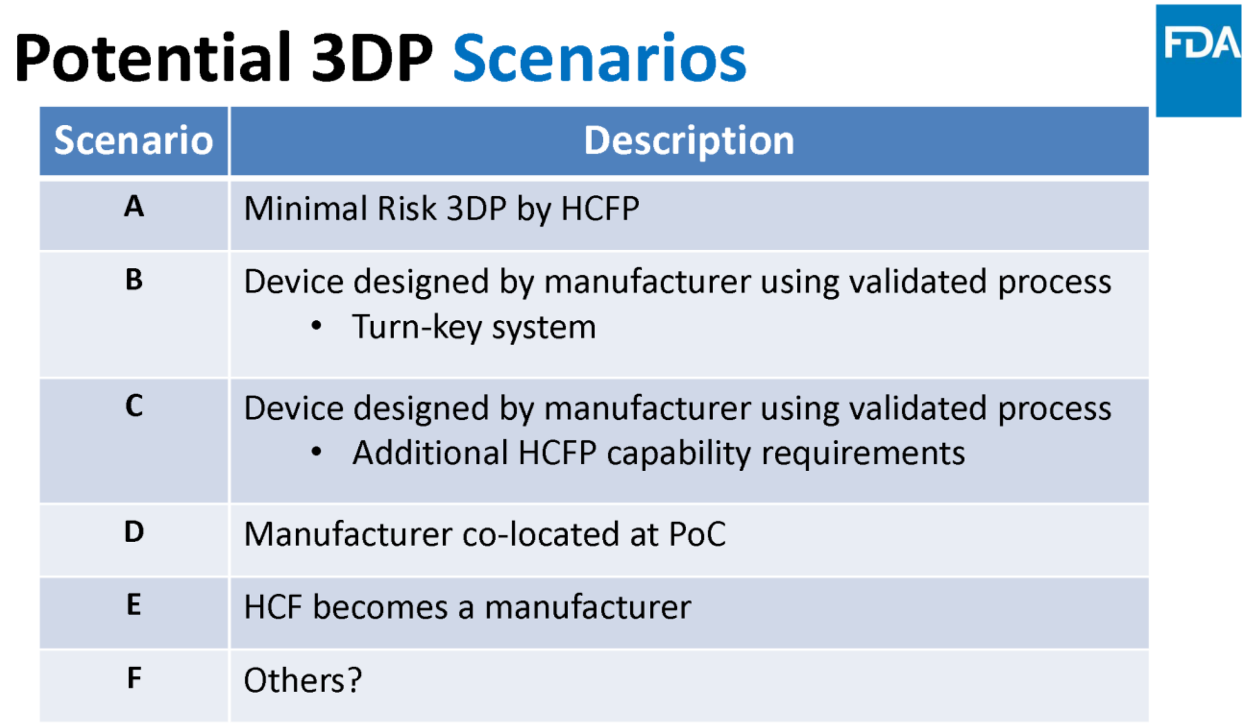
Additive Manufacturing Standardization Collaborative

America Makes and the American National Standards Institute (ANSI) released an online, interactive portal to track activity by the standardization community to address the gaps identified in the Standardization Roadmap for Additive Manufacturing. The portal, accessible to all interested stakeholders, will be regularly updated based on input from AMSC members, particularly standards developing organizations. MORE

Regulatory

3D Printing at the Point of Care

With the growth of hospitals with 3D printing facilities, the US Food & Drug Administration shared a regulatory concept framework for 3D printing at the point of care. Bringing together the diverse community including hospitals, medical device manufacturers, technology developers, professional societies, and government agencies, ASME hosted a series of discussions to clarify, identify critical needs, and provide feedback. Debriefs, notes, and on-demand recordings are available for these discussions. MORE



Potential 3DP Scenarios

Scenario	Description
A	Minimal Risk 3DP by HCFP
B	Device designed by manufacturer using validated process • Turn-key system
C	Device designed by manufacturer using validated process • Additional HCFP capability requirements
D	Manufacturer co-located at PoC
E	HCF becomes a manufacturer
F	Others?

FDA Cleared Products

The FDA's searchable database does not provide a clear method to identify all additive manufacturing products and supporting tools cleared through the 510(k) premarket approval process. With this limitation, more than 50 were identified that received clearance from April 1, 2019 to March 31, 2020.

3D Systems D2P & VSP software platforms received FDA 510 (K) clearance.

Spinal Products

510(K) Number	Device	Company	Details
K180347	3D Cage™	FIMS Co., Ltd.,	MORE
K190092	UNiD Patient specific 3D printed TLIF cage	Medicrea International S.A.	MORE
K190291	Addivation Medical Cervical Interbody System	Addivation Medical, LLC	MORE
K190870	Cervical Spinal Truss System-Stand Alone (CSTS-SA)	4Web, Inc.	MORE
K190959	ARTiC-L™ 3D Ti Spinal System with TiONIC™ Technology, ARTiC-XL™ 3D Ti Spinal System with TiONIC™ Technology	Medtronic Sofamor Danek USA, Inc.	MORE
K191134	IB3D ALIF	Medicrea International S.A.	MORE
K191243	HEDRON™ Cervical Spacers	Globus Medical Inc.	MORE
K191354	Ti3Z Cervical Interbody System	Zavation Medical Products, LLC	MORE
K191391	HEDRON™ Lumbar Spacers	Globus Medical Inc.	MORE
K191489	Genesys Spine 3DP Cervical Interbody System	Genesys Spine	MORE
K191812	ADI Cervical Interbody Fusion Device	restor3d	MORE
K192115	SABLE™ Expandable Spacer	Globus Medical Inc.	MORE
K192687	TrellOss™-L MPF	Nexxt Spine LLC	MORE
K192993	Scarlet AL-T	Spineart	MORE
K193320	KMTI Tesera SA Anterior Lumbar Interbody Fusion (ALIF) System	Kyocera Medical Technologies, Inc	MORE
K193359	SureMAX™ Family of Cervical Spacers	Additive Implants, Inc.	MORE
K193370	Nexxt Matrixx® System	Nexxt Spine, LLC	MORE
K200543	NEXXT MATRIXX® Stand Alone Cervical-Turn Lock (-TL) System	Nexxt Spine, LLC	MORE

Dental Applications

510(K) Number	Device	Company	Details
K191838	Clearform Aligners	Motor City Lab Works	MORE
K191911	3Shape Splint Design	3Shape A/S	MORE
K192806	DENTCA Crown and Bridge	Dentca, Inc.	MORE
K192338	NEOLab Clear Aligners	New England Ortho Lab, Inc.	MORE
K193064	Atlantis® suprastructures	Dentsply Sirona Inc.	MORE

Software

510(K) Number	Device	Company	Details
K182889	KLS Martin Individual Patient Solutions (IPS) Planning System	KLS-Martin L.P.	MORE
K183489	D2P	3D Systems, Inc	MORE PRESS
K183676	DentiqAir	3D Industrial Imaging Co., Ltd	MORE
K190044	VSP® Orthopedics System	3D Systems, Inc.	MORE
K190096	R2GATE	MegaGen Implant Co., Ltd.	MORE
K190595	Signature™ ONE System	Orthosoft, Inc (d/b/a Zimmer CAS)	MORE
K190767	AnatomicAligner	The Methodist Hospital Research Institute	MORE
K190874	Materialise Mimics Enlight	Materialise N.V.	MORE PRESS
K191026	Medip Pro	MEDICALIP Co., Ltd	MORE PRESS
K191247	SmartSPACE Shoulder System	TechMah Medical LLC	MORE
K191550	Broncholab	Fluidda Inc.	MORE
K192074	Signature™ ONE System	Orthosoft, Inc (d/b/a Zimmer CAS)	MORE
K192192	VSP® System	3D Systems	MORE
K192979	KLS Martin Individual Patient Solutions (IPS) Planning System	KLS-Martin L.P.	MORE

Other Products

510(K) Number	Device	Company	Details
K182743	Patient-Specific Airway Stent	New COS Inc.	MORE
K190439	Engage™ Partial Knee System	Engage Surgical	MORE
K190660	G7 Acetabular System	Zimmer, Inc.	MORE
K190915	OsteoFab® Suture Anchors	Oxford Performance Materials, Inc	MORE
K190926	Hammertoe Truss System (HTS)	4WEB, Inc.	MORE
K191047	ADI TiDAL Osteotomy Wedge	Additive Device, Inc. (ADI) d/b/a restor3d	MORE
K192002	Lucy Point-of-Care Magnetic Resonance Imaging Device	Hyperfine Research, Inc.	MORE
K193143	Stryker Facial iD Plating System	Stryker	MORE
K200075	3DMetal Diaphyseal Femoral Cones	Medacta International SA	MORE

Clinical Developments

CPT Codes for 3D Printing Models and Guides Live

Category III CPT codes for 3D printed anatomical models and guides went live on July 1, 2019. RSNA 3D Printing Special Interest Group leaders worked with the American College of Radiology (ACR) to apply for new Category III (CPT) codes. These codes allow the Centers for Medicare & Medicaid Services (CMS) to track the use of 3D printing. MORE

3D Printing Registry Announced

RSNA and the American College of Radiology (ACR) announced the launch a new medical 3D printing clinical data registry to collect 3D printing data at the point of clinical care. Registry data will enable essential analyses to demonstrate the clinical value of 3D printing, which has been challenging to date because of the rich diversity of clinical indications, the different technologies for generating physical models from medical images and the complexity of the models. MORE REGISTRY

Metal 3D Printing Comes to Mayo Clinic

Mayo Clinic installed its first metal machine, an EOS M 290, believed to be the first metal machine installed at a hospital not connected to a university engineering department. Mayo Clinic engineers plan to work with physicians and researchers to produce prototype parts for new medical devices and patient-specific medical solutions. MORE

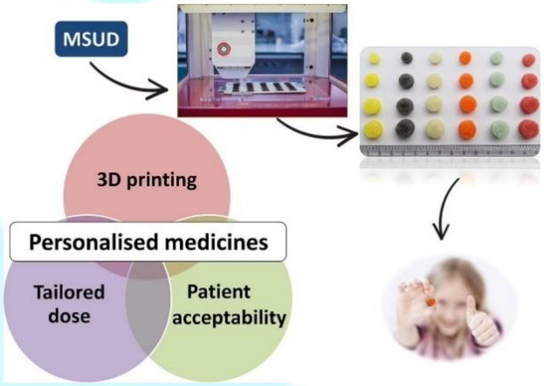
Clinical Trials, Clinical Studies & Case Series

This section reflects studies completed and begun between April 1, 2019 and March 31, 2020. Much of this can be found on the NIH US National Library of Medicine which provides for registration of clinic trials at clinicalTrial.gov.

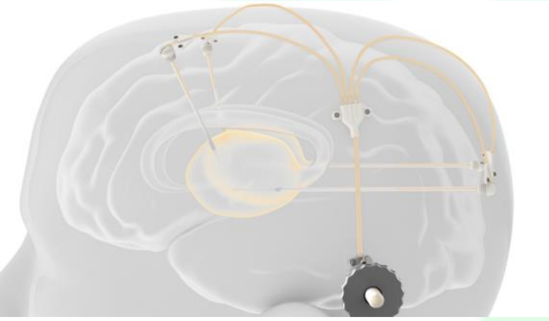
NOTE: Not all clinical studies begun, are completed.

Clinical Trials & Studies Completions—Results Published

- **The Use of 3-Dimensionally Printed Models to Optimize Patient Education and Alleviate Perioperative Anxiety in Mohs Micrographic Surgery: A Randomized Controlled Trial** MORE
- **3D printed Dosage Forms to Treat Children Diagnosed with Maple Syrup Urine Disease** MORE
- **Randomized Controlled Trial of the Effects of 3D printed Models and 3D Ultrasonography on Maternal–Fetal Attachment** – MORE



FabRx completed clinical trials for 3D printed dosage forms to treat maple syrup urine disease.



Renishaw: 3D printed intraparenchymal drug delivery device in clinical trials.

- **3D printed Intraparenchymal Drug Delivery Device Critical in a Phase 1-2 Clinical Study:** The trials looked at the investigation of cerebral dopamine neurotrophic factor (CDNF) as a treatment for Parkinson's disease. The 3D printed parts are titanium transcutaneous ports that are implanted behind the ear to allow medical professionals to access the catheters implanted within the brain. MORE

Clinical Trials & Studies Completions—Results Pending

- **Personalized Titanium Plates vs CAD/CAM Surgical Splints in Maxillary Repositioning of Orthognathic Surgery** – Primary completion January 14, 2019 MORE
- **Left Atrial Appendage Occlusion Guided by 3D Printing (LAA-PrintRegis)** – completed December 1, 2019 MORE
- **Patient Satisfaction & Retention of Milled, 3D Printed and Conventional Complete Dentures** – completed January 1, 2020 MORE
- **Surgical Planning With Patient-specific Pancreaticobiliary Disease With 3D Models** – completed January 10, 2020 MORE
- **Digital Assessment of a Full Digital Implant-Prosthetic Workflow for a Prefabricated Single Implant-Supported Restoration** – completed February 1, 2020 MORE

Case Series Completions

- **3D Printing Method for Next-Day Acetabular Fracture Surgery Using a Surface Filtering Pipeline: Feasibility and 1-Year Clinical Results** MORE
- **Custom-Made 3D Printed Subperiosteal Titanium Implants for the Prosthetic Restoration of the Atrophic Posterior Mandible of Elderly Patients: A Case Series** MORE

Clinical Trials & Studies that Began

- **A Descriptive, Prospective Clinical Study to Evaluate Full Dentures Fabricated by Additive Manufacturing** MORE
- **Clinical Efficacy of Stereotactic Radiotherapy and Microwave Ablation for Liver Metastases from Colorectal Cancer** MORE
- **I125 Seed Implantation vs Stereotactic Radiotherapy for Pancreatic Cancer (Ckvssip)** MORE
- **Experimental Evaluation of Back Braces for the Treatment of Spinal Deformity Produced With 3D Printing Technology** MORE
- **Evaluation Of Innovative 3D Printed Space Maintainer Versus Conventional One** MORE
- **Precision Orthodontics: Virtual Treatment Planning for Orthodontic Braces** MORE
- **Calibration and Validation of High Quality Low-Cost 3D Printed Pulse Oximeter** MORE
- **Digital Design for Maxillofacial Prosthetics** MORE
- **Talus Replacement Registry (3DTalar)** MORE

Case Studies

Case studies published that demonstrate quantifiable benefits are included in an effort to support the community's efforts to build the value case for the use of additive manufacturing/3D printing.

Medical 3D Printing Cost-Savings in Orthopedic and Maxillofacial Surgery: Cost Analysis of Operating Room Time Saved with 3D Printed Anatomic Models and Surgical Guides

Seven studies using 3D printed anatomic models in surgical care demonstrated a mean 62 minutes ($3720/case saved from reduced time) of time saved, and 25 studies of 3D printed surgical guides demonstrated a mean 23 minutes time saved ($1488/case saved from reduced time). An estimated 63 models or guides per year (or 1.2/week) were predicted to be the minimum number to break even and account for annual fixed costs. MORE

Shukla Medical's Cost Savings Using 3D Printing

A surgical tool manufacturer, Shukla Medical, announced that their company saved $120,000 each year by using a metal system to print prototypes for their surgical instruments. MORE

3D Printing Utilized to Save Money and Time at the UK's Leading Spinal Unit

3D printed surgical models saved over 120 minutes of time during a complex surgical procedure, equating to nearly $10,000 of cost avoidance for the hospital. The surgical model helped a medical team more effectively approach a spina bifida surgery by allowing surgeons to assess the possibility of conducting a shortening osteotomy which helps reduce the spinal cord tension without causing direct neural damage. MORE

3D Printed Patient-Specific Guide Improves Accuracy

For the study, a total of 20 patients (10 females and 10 males) were selected for the optimal outcome after orthognathic surgery. Postoperative CT scan were used to create 3D digital models of each skull. The digital models were registered and an average virtual skull model was computed. The overall mean deviation from the average 3D model was 1.3 ± 0.6 and 1.6 ± 0.5 mm in male and female subgroups, respectively. The female average three-dimensional skull model was effectively used for guiding surgical planning. MORE

Assessment of Body-Powered 3D printed Partial Finger Prostheses

Remote fitting of a 3D printed partial finger from 2D photographs of the patient's affected and non-affected limbs resulted in improved performance in the Box and Block Test (22 blocks per minute) as compared to when not using a prosthesis (18 blocks per minute). MORE

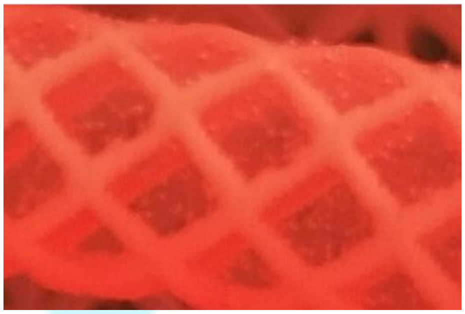
Patents

Issue of Patent to Dimension Inx

Dimension Inx received a patent covering the "3D painting system" used by the company to design and manufacture biomaterials for organ and tissue repair and regeneration. U.S. Patent No. 10,584,254, "A Universal Method for Production and 3D printing of High-ParticleContent 3D-Inks," is directed to compositions, materials, and methods for production and 3D printing of high-particle-content 3D-inks. MORE

Louisiana State University Received Patent for New 3D Printing Technology

Louisiana State University researchers developed a new technology to 3D print polyvinyl alcohol (PVA) medical devices, allowing for the production of a wide variety of biosynthetic tissues, drug delivery devices, and stents with a goal to address the need to have on-demand tissue replacements for patients with diseased/damaged tissues. United States Patent Application 20190099516 MORE



PVA collagen tissue from LSU patent. PHOTO: Christen Boyer & Steven Alexander

Poietis Received Third European Patent

Poietis announced the issuance by the European Patent Office of a third patent covering its laser-assisted bioprinting technology: Patent No. EP3233499 entitled "Laser printing method and device for implementing said method". MORE

Collaborations

HP Jet Fusion 580/380 3D printers, in combination with Mimics software technology, can be used to print full-color anatomical models.

Materialise and HP Expand Partnership

Materialise and HP announced an expansion of their partnership towards industrial-scale 3D printing, including integration of a new version of the Materialise Build Processor to support HP printers, free access to the Materialise Magics Essentials software for a period of six months for any customer purchasing an HP Jet Fusion 500/300 Series 3D printer, and certification of HP Jet Fusion 580/380 3D printing solutions as part of Materialise's program to test and validate 3D printing technology as fully compatible with the latest version of Materialise Mimics and Mimics inPrint software. MORE

Formlabs and BEGO Collaborate for Dental Applications

Formlabs and BEGO announced a partnership that will allow Formlabs' dental customers to 3D print temporary and permanent crowns and bridges directly for patients with BEGO's dental materials. MORE

Merck and AMCM/EOS Partner in the 3D Printing of Tablets

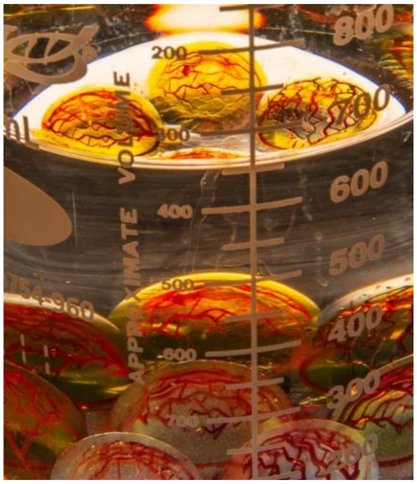
Merck and AMCM announced a cooperation agreement on the 3D printing of tablets. The cooperation targets GMP-conform tablet formulation development and production for clinical trials in a first step and later also commercial manufacturing services. MORE

3D Systems and CollPlant Biotechnologies Sign a Joint Development Agreement

3D Systems and CollPlant plan to jointly develop tissue and scaffold bioprinting processes for third party collaborators. MORE

3D Systems and Antleron Collaborate to Accelerate 3D Printing Biomedical Breakthroughs

3D Systems and Antleron announced a collaboration to support Antleron's development of bioprinting solutions utilizing 3D Systems' printing technologies. MORE



3D bioprinted soft tissue implant with vascularization channels printed with 3D Systems' SL bioprinter and BioInk that is based on CollPlant's rhCollagen.

PrinterPrezz and Osseus Partner for Development of 3D Printed Spine Implants
PrinterPrezz announced an agreement to work together on new spinal interbody fusion devices with Osseus Fusion Systems. MORE

Formlabs and GE Healthcare Partner
GE Healthcare and Formlabs announced collaboration to enable clinicians to easily make 3D printed, patient-specific models from imaging data at a lower cost. MORE

Development Watch

As the medical AM/3DP community continues to evolve, the following proof-of-concepts and demonstrations provide possible solutions.

Applications

3D Printed Skin with Blood Vessels

Researchers funded by the National Heart, Lung, and Blood Institute (NHLBI) demonstrated 3D printed living skin, complete with working blood vessels. This research and findings are promising to overcome the obstacle of printing functional vascular systems. MORE

3D Printing Artificial Bones

Researchers at Rice University and the University of Maryland outlined a new proof-of-concept for 3D printing artificial bone tissue. Experimental structures were made from a custom mix of polymer and ceramic materials, and the 3D printing design was made to mimic the structure of osteochondral tissue with embedded pores with the goal of improving the treatment of injuries where small cracks and pieces of bones break off. MORE

Bioprinted Microscopic Model of the Human Body

Researchers at the Wake Forest Institute for Regenerative Medicine bioprinted a microscopic model of the human body that contained most of the vital organs. The miniature system could potentially be used to detect harmful effects of drugs before they are trialed with humans. MORE

Technique developed at Human Genome and Stem Cell Research Center, produced hepatic tissue. PHOTO: Daniel Antonio/Agência FAPESP

Bioprinting of Hepatic Organoids with Clearing Functions

Scientists from the Human Genome and Stem Cell Research Center/University of Sao Paulo utilized bioprinting to develop functional hepatic organoids. These organoids are made from human blood cells and can replicate functions such as producing vital proteins, storing vitamins, and secreting bile. Even though the researchers are far away from a full-sized organ, this is a step towards that goal. MORE

Steps Towards Bioprinting Hearts

BIOLIFE4D demonstrated its ability to 3D bioprint a mini human heart shape. The mini heart replicates partial functional metrics. Although the printing of a full-sized functional human heart is still far-off in the future, this represents a step toward the goal of producing a full-sized human heart viable for transplant. MORE

Materials

3D Printed Drug-Eluting Mesh

Canadian researchers demonstrated a drug-eluting 3D printed mesh for better treatment of glioblastoma, one of the most aggressive forms of brain cancer. The 3D printed alginate hydrogels are filled with temozolomide-loaded PLGA microspheres. This development holds promise by reducing the side effects of chemotherapy and circumventing the blood-brain-barrier. MORE

Hybrid Living Material (HLM) Fabrication Platform

Researchers from MIT Media Lab, Harvard University's Wyss Institute, and the Dana-Farber Cancer Institute demonstrated a platform that can 3D print objects to control organisms. Using a multi-material inkjet-based 3D printer, they integrated chemical signals into resins that will allow the 3D printed part to communicate to the cells that live on the surface of the 3D print. MORE

Printing Technologies

Handheld 3D Skin Printer

Researchers at the University of Toronto and Sunnybrook Health Sciences Centre developed a handheld 3D skin printer that can deposit sheets of skin to cover burns, stripe by stripe. The bioink dispensed from the roller has mesenchymal stem cells to promote regeneration of skin and reduce scarring. Successful *in-vivo* trials on full thickness wounds have been reported in *Biofabrication* journal. MORE

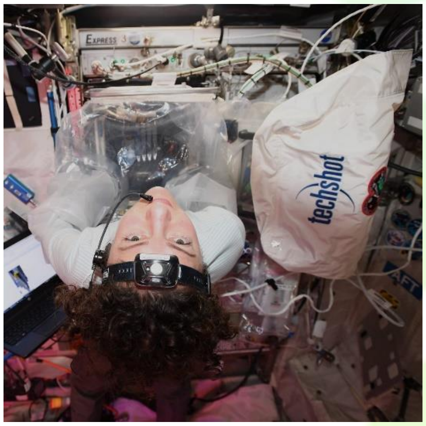
Handheld 3D skin printer developed at the University of Toronto; PHOTO: Daria Perevezentse)

High-Area Rapid Printing (HARP)

Northwestern University demonstrated a 3D printing technology called HARP that can print an object the size of an adult human in a few hours. It uses a patent-pending version of stereolithography and bypasses the typical problem of generating excess heat by flowing a nonstick liquid over the window to remove heat. MORE

Update to Volumetric 3D Printing

Researchers from the Swiss Federal Institute of Technology Lausanne have demonstrated a new volumetric 3D printing method that enables the production of small, soft objects in seconds. The high-precision 3D printing approach could have important applications in the medical and bioprinting fields, by enabling the rapid production of hearing aids, cellular scaffolds and more. This technology has been reported to be similar to the volumetric 3D printing method developed by Lawrence Livermore National Laboratory (LLNL) that was highlighted last year. MORE



Tissues manufactured on the ISS on the TechShot BioFabrication Facility returned to Earth in January 2020 in SpaceX capsule.

Other

Bioprinting in Space

A 3D bioprinter privately owned by Techshot has successfully printed a large volume of human heart cells aboard the International Space Station U.S. National Laboratory. The 3D BioFabrication Facility (BFF) was developed in partnership with nScrypt, a manufacturer of industrial 3D bioprinters and electronics printers. MORE

Community Survey

During the first quarter of 2020, the medical additive manufacturing/3D printing community was surveyed to better understand how the technology is being used, what challenges exist, and expectations for growth. A total of 308 responded from diverse application areas. The information provided is a snapshot of those responses.

Key observations include:

- Development and prototypes remains the top application area being used by more than 60%.

- Material Extrusion is named as the most-frequently used process, followed by power bed fusion.
    - Powder bed fusion is the top process for tooling & patterns, serialized devices, and active devices.
    - Vat photopolymerization is the top process for surgical planning and dental applications.

- Polymers remains the top material used overall and for each application area with the exception of serialized and active devices (metals) and 3D biofabrication (biological materials).

- 80% expect the applications of medical and dental additive manufacturing to increase more than 5% and nearly half (48%) expect more than 10% in the next year.

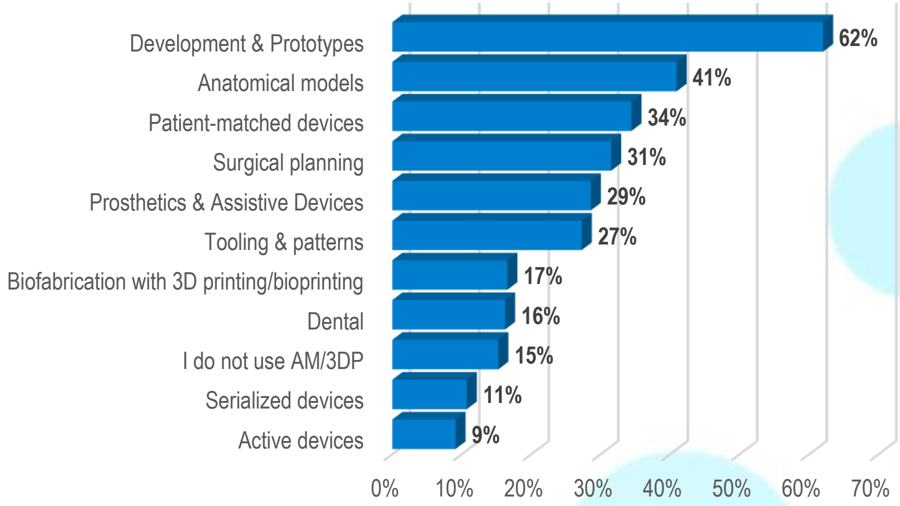
- Growth is expected in all application areas with nearly a quarter (24%) expecting the greatest growth in patient-matched devices.
    - Although available as a survey option, “decrease in use” was not chosen by any responders.
    - A few responders chose “stay the same for every application area with the exception and medical devices and active device. All responders expect growth in these areas.

- Need for standards, understanding of regulatory compliance, and shortage of skilled workforce are named as top challenges to increase the number of patients impacted by AM/3DP.
    - For medical and dental device manufacturers, regulatory compliance and the related process validation and verification are cited as challenges by the largest number. When asked for the greatest challenge, available materials becomes the top challenge.
    - For point-of-care manufacturers/hospitals, the lack of qualified workforce is cited by the largest number. When asked for the greatest challenge, reimbursement becomes the top challenge.

- Terminology and classifications continues to vary including the difference between bioprinting and 3D printing-enabled biofabrication. Even in this review, additive manufacturing, 3D printing, and AM/3DP are used interchangeably. Responses to several questions reflect these variances.

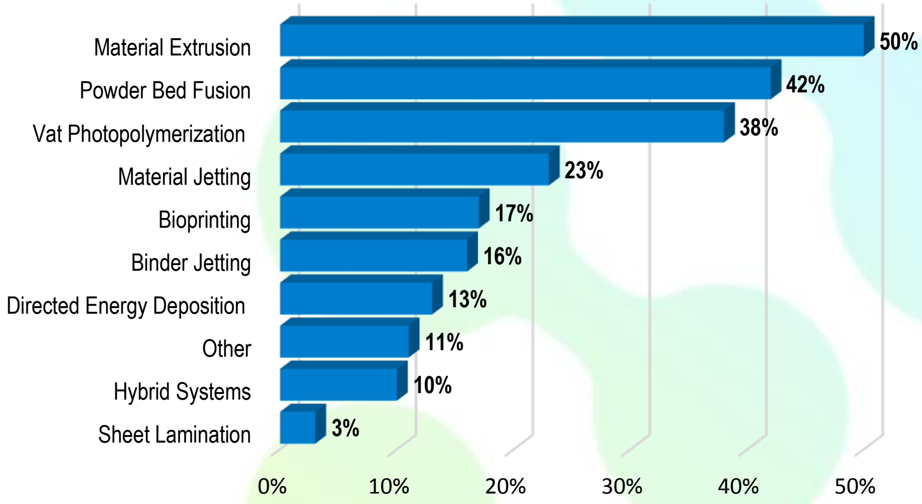
NOTE: Responses in total provide a snapshot of the medical additive manufacturing/3D printing community. Filtered results are shared for discussion only.

All Responses



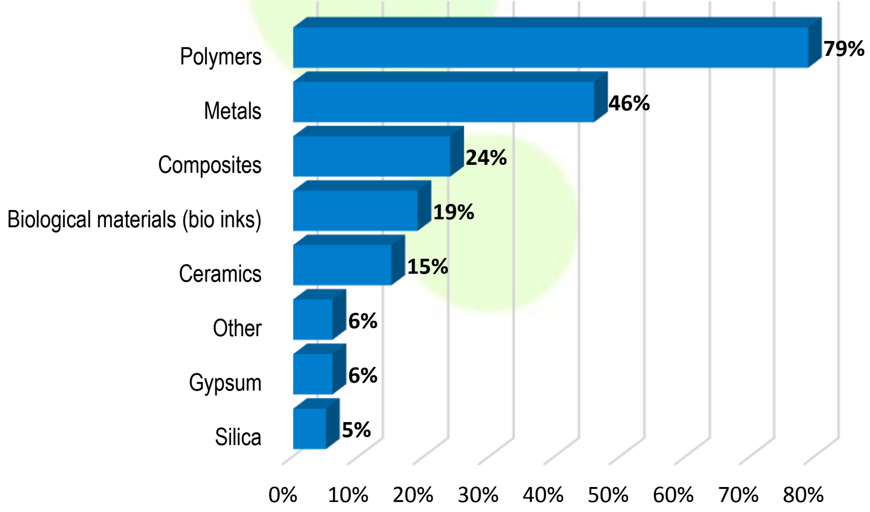
APPLICATION AREAS

Development and prototypes remains the top application area being used by more than 60%.



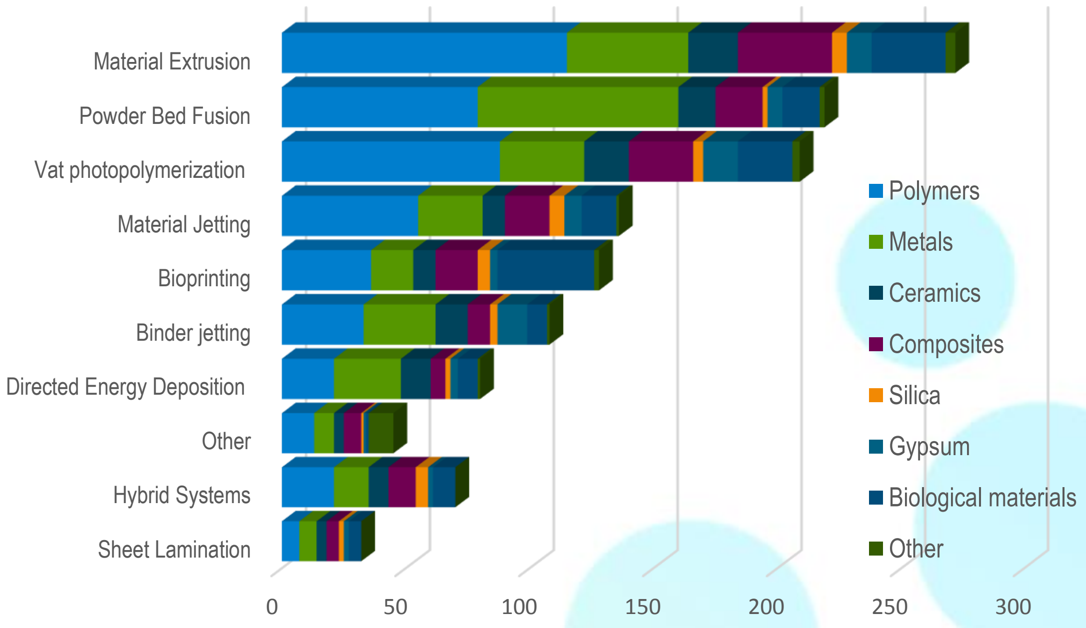
PROCESSES USED

Material Extrusion is named as the most-frequently used process, with higher usage rates for prosthetics & assistive devices and surgical planning.



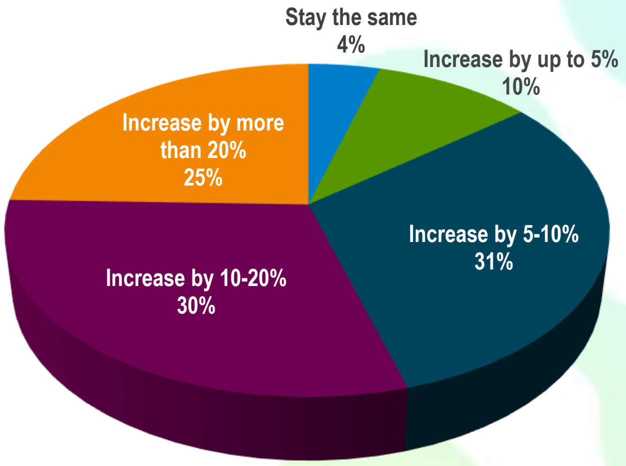
MATERIALS USED

Polymers remains the top material used with growth in metals and composites.



PROCESSES BY MATERIAL USED

Some of the metal use is indicative of use as the process for casting patterns rather than a direct use. This can be seen clearly seen in the responses for vat photopolymerization.

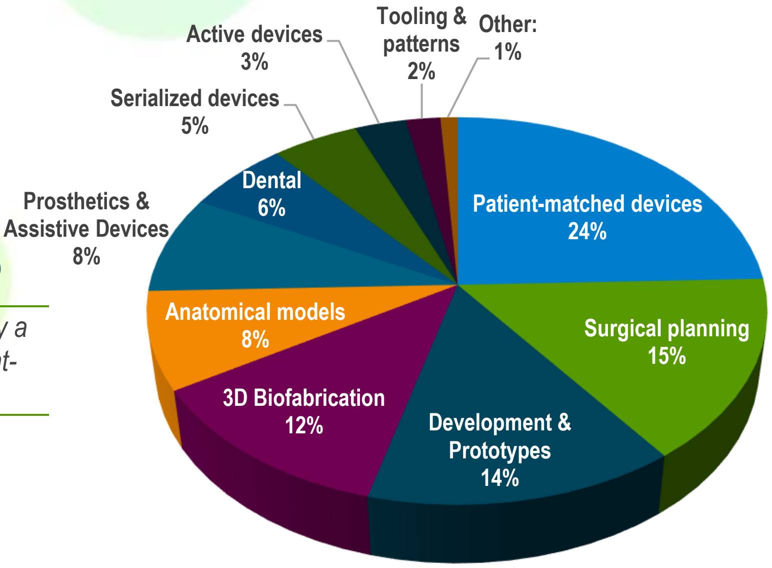


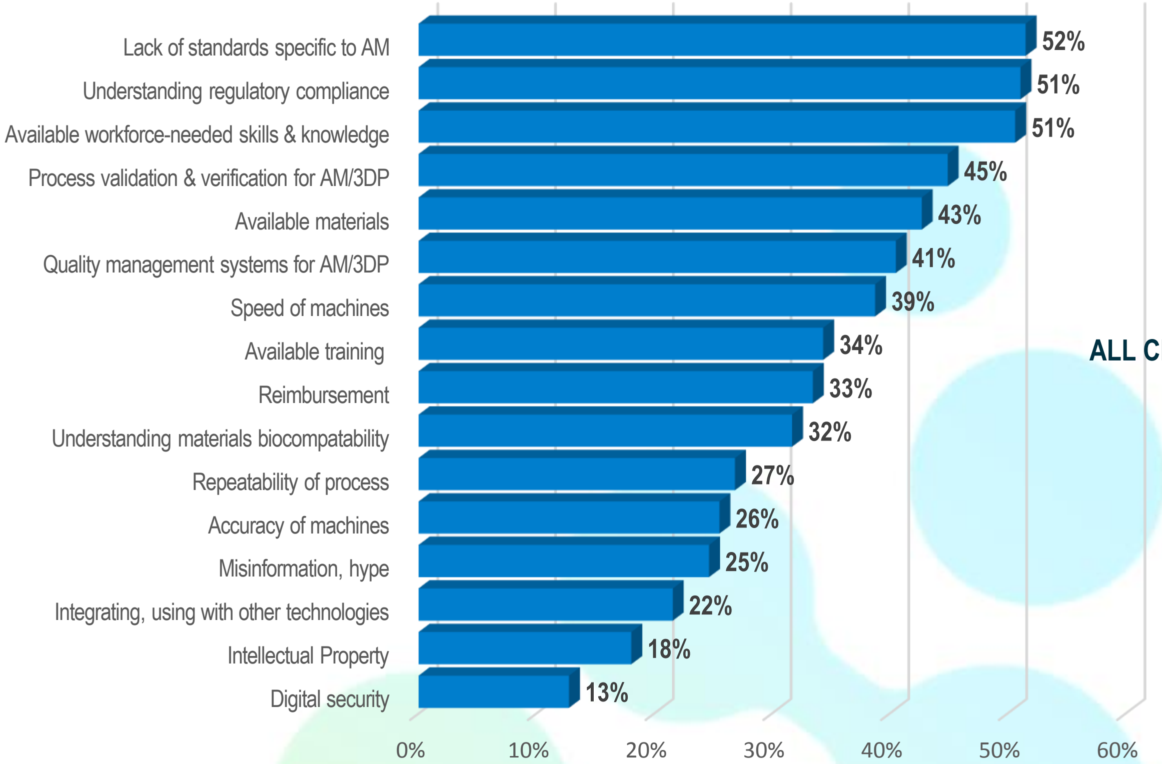
GROWTH IS EXPECTED WIHTIN 1 YEAR

80% expect the applications of medical and dental additive manufacturing to increase more than 5% and nearly half (48%) expect more than 10% in the next year. Although "decrease" was a survey option, no one responded that they expect to see a decrease in use.

WHERE THE GREATEST GROWTH IS EXPECTED

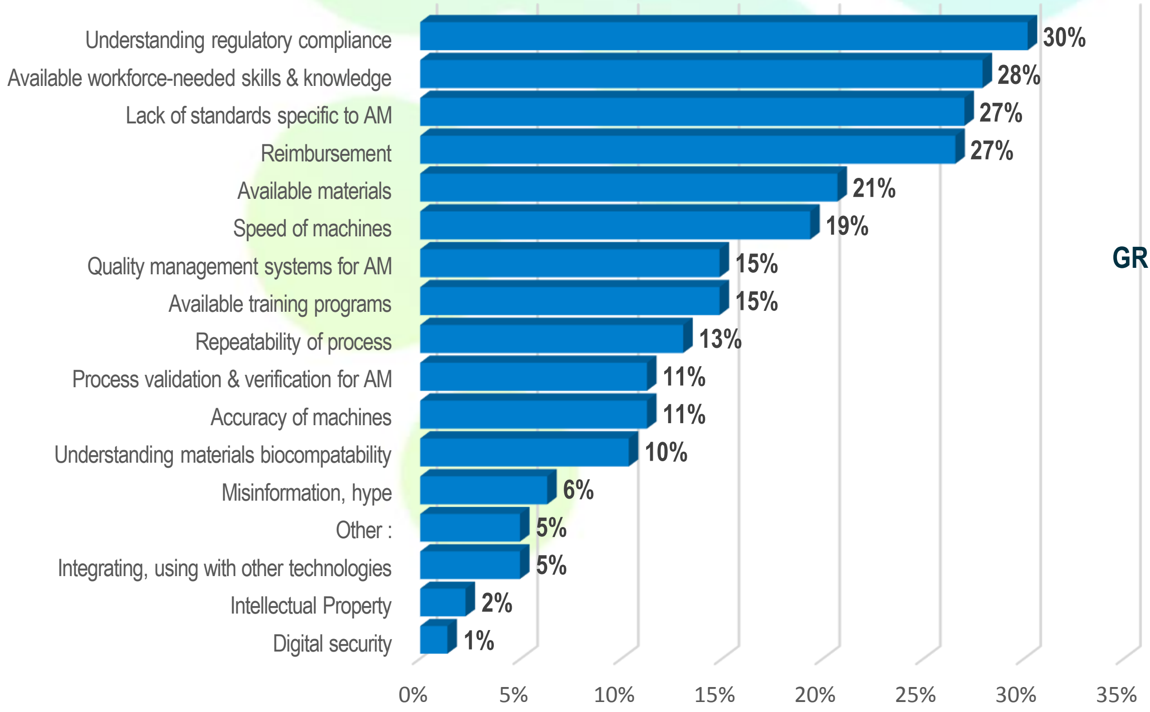
Growth is expected in all application areas with nearly a quarter (24%) expecting the greatest growth in patient-matched devices.





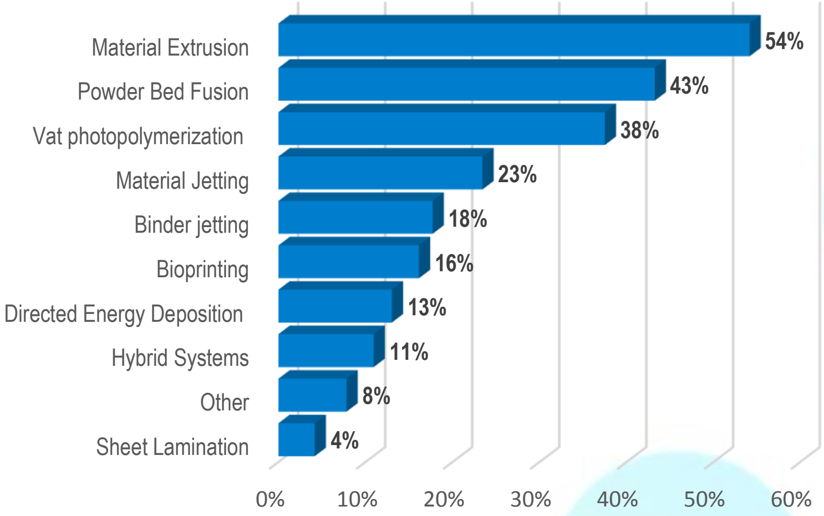
ALL CHALLENGES

Need for standards, understanding of regulatory compliance and shortage of skilled work-force are named as top challenges to increase the number of patients impacted by AM/3DP.



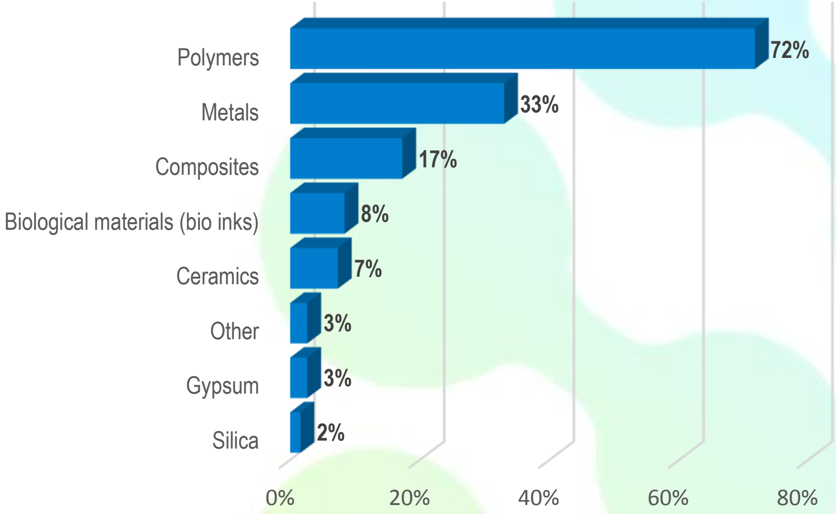
GREATEST CHALLENGES

Development & Prototypes



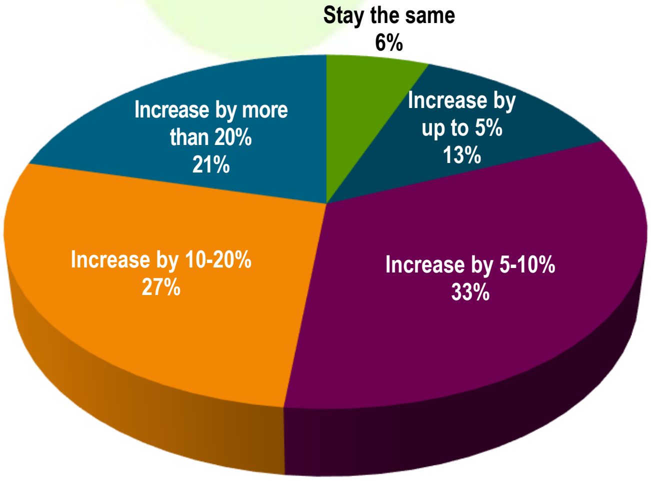
PROCESSES USED

Processes used for prototypes closely resembles overall usage reflecting prototypes as the largest application area and the introductory application area for many organizations.



MATERIALS USED

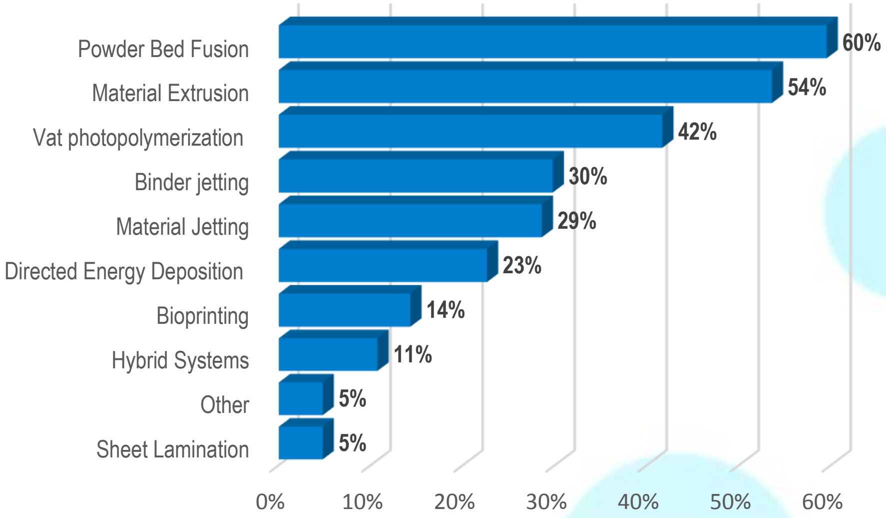
Polymers have the highest usage rate for prototypes, with nearly 75% of prototypes being made with polymers. Composites includes reinforced polymers.



EXPECTED GROWTH

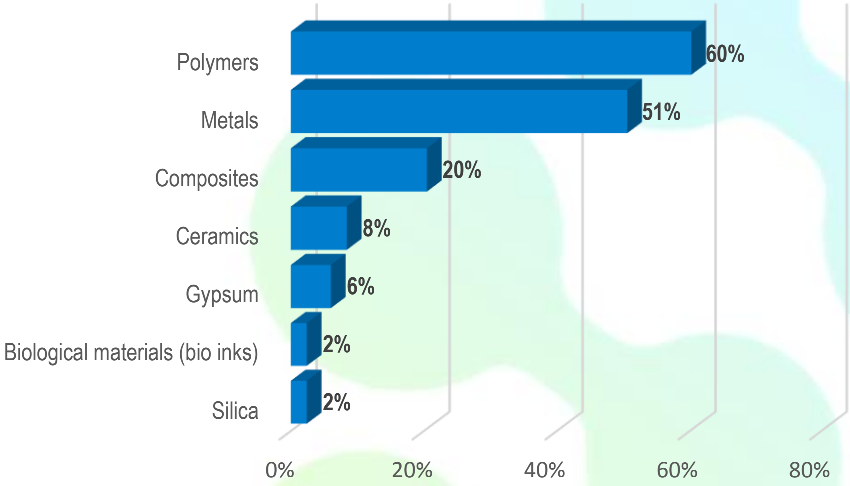
Although additive manufacturing has been used for prototypes for more than 30 years, nearly 95% expect continued growth.

Tooling & Patterns



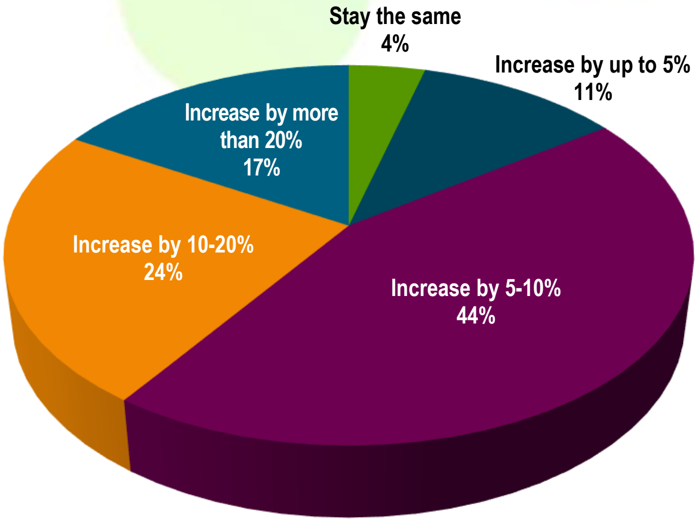
PROCESSES USED

Powder bed fusion is the top process for tooling & patterns.



MATERIALS USED

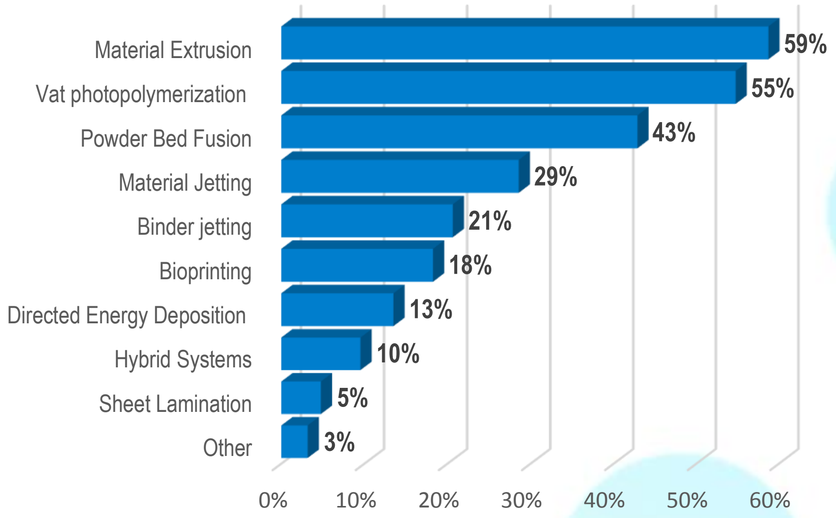
The usage rate of metals for tooling & patterns reflects the availability of tooling steels for additive manufacturing as well as additive manufacturing being used for casting patterns.



EXPECTED GROWTH

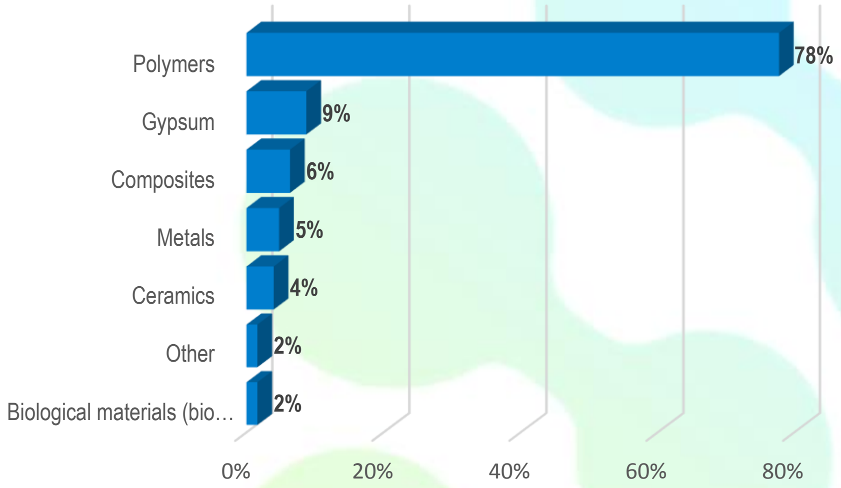
Like prototypes, additive manufacturing has been used for tooling & patterns for more than 30 years. More than 95% expect continued growth for this application area with the largest group expecting 5 to 10% growth.

Anatomical Models



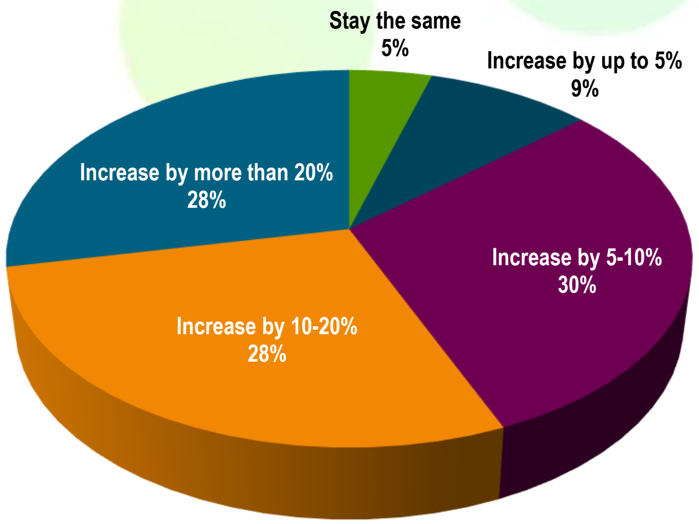
PROCESSES USED

While material extrusion remains the most used, anatomical models represent the second highest usage rate of vat photopolymerization.



MATERIALS USED

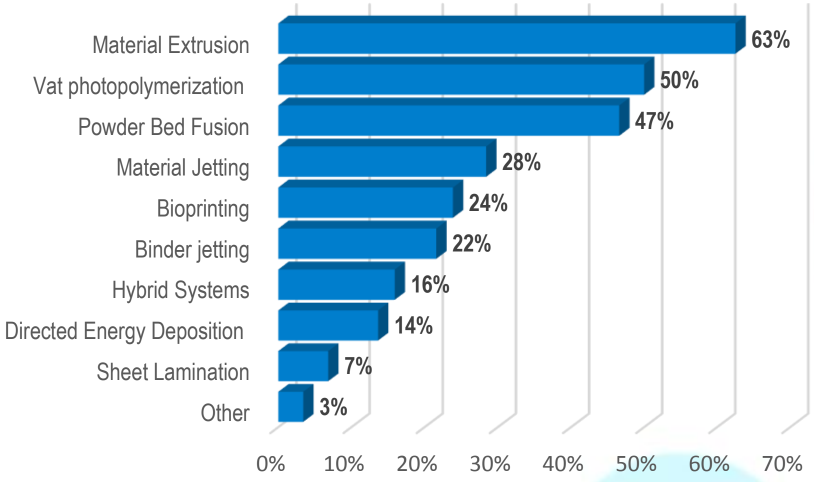
By far, polymers are the most common material used for anatomical models. While not determined in this survey, it is likely that polymers represent a much higher percentage of all anatomical models 3D printed. Although still small usage rates, anatomical rates have the highest usage for gypsum.



EXPECTED GROWTH

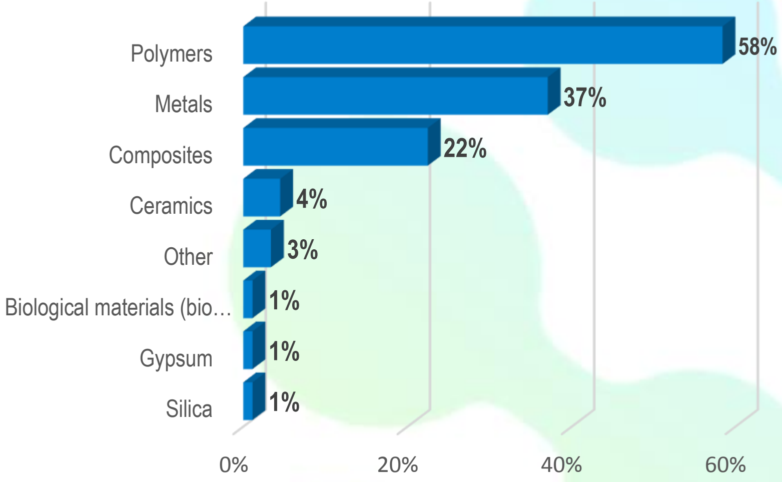
The growth expected for anatomical models is close to that for overall applications growth with a slight increase at the high growth rate of more than 20%.

Prosthetics & Assistive Devices



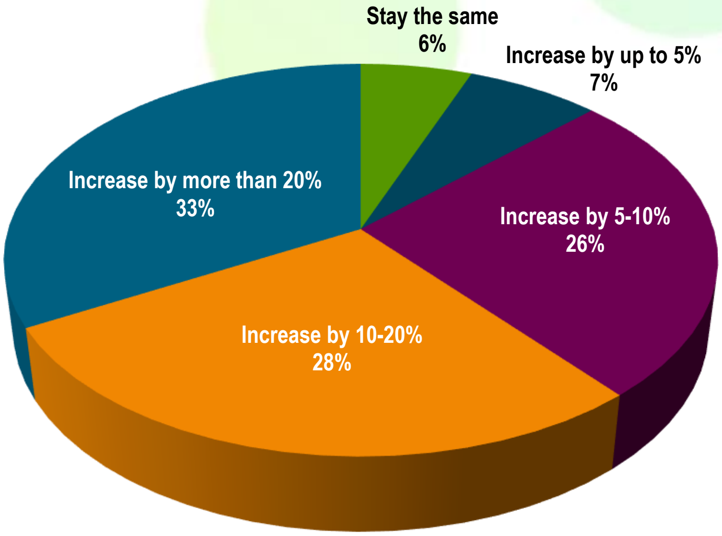
PROCESSES USED

Prosthetics & assistive devices represent the highest usage rate of material extrusion.



MATERIALS USED

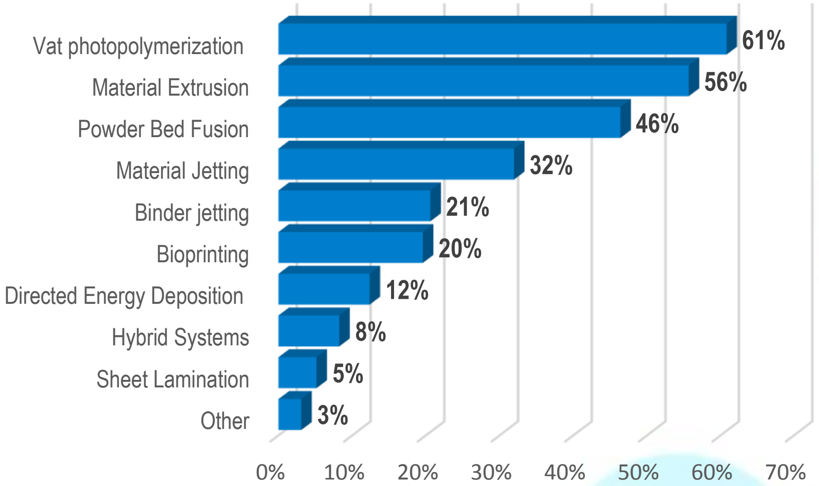
Polymers are again the highest used material for prosthetics & assistive devices in line with the creation of many assistive devices at the point of care.



EXPECTED GROWTH

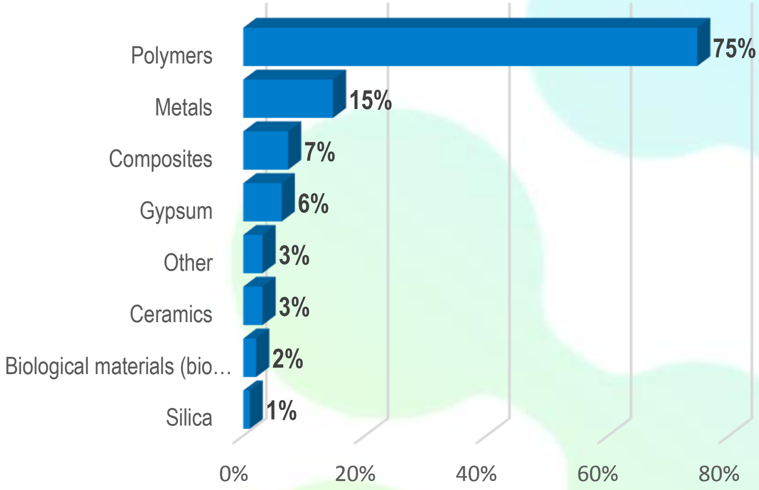
Higher growth rates are expected for prosthetics & assistive devices with nearly 66% expecting more 10% growth, and a third expecting more than 20% growth.

Surgical Planning



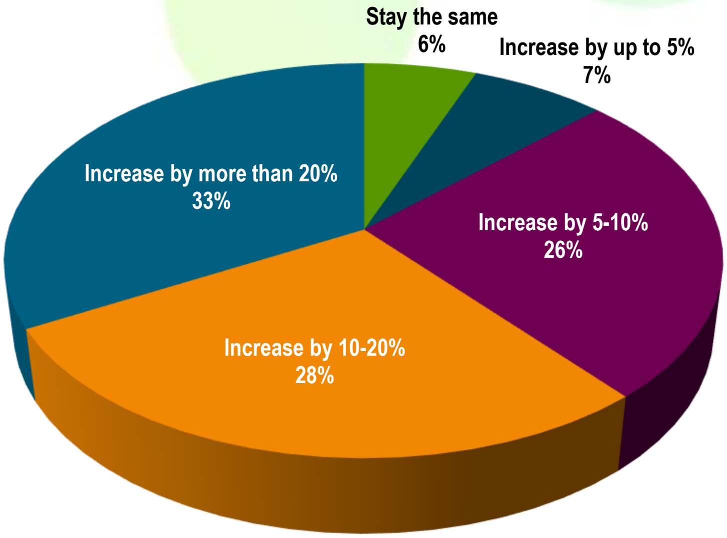
PROCESSES USED

Surgical planning includes both surgical guides and anatomical models. The higher usage rate of vat photopolymerization for surgical planning is consistent with a high need for accuracy and fine features.



MATERIALS USED

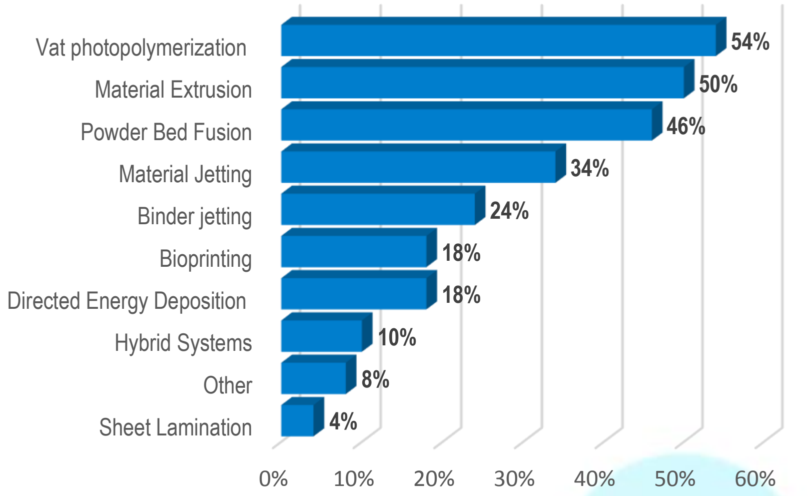
Like all anatomical models, polymers is the most used material. This reflects processes most commonly used at the point of care.



EXPECTED GROWTH

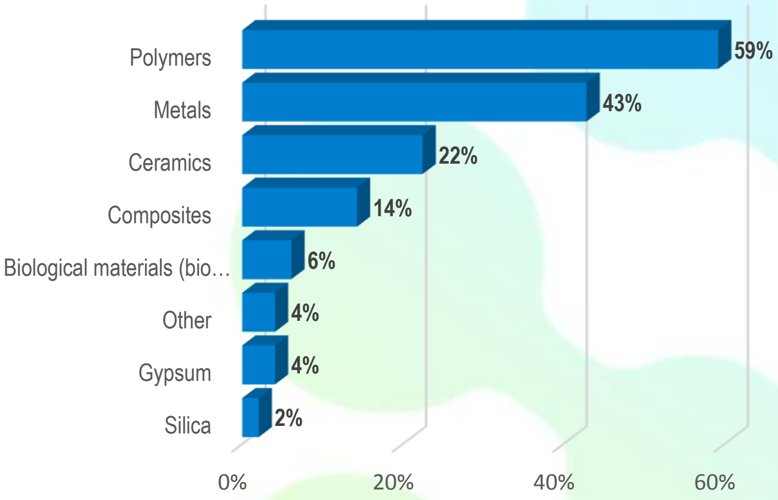
Expectations for growth of surgical planning are on the higher end with more than 60% expecting more than 10%, and a third more than 20%.

Dental



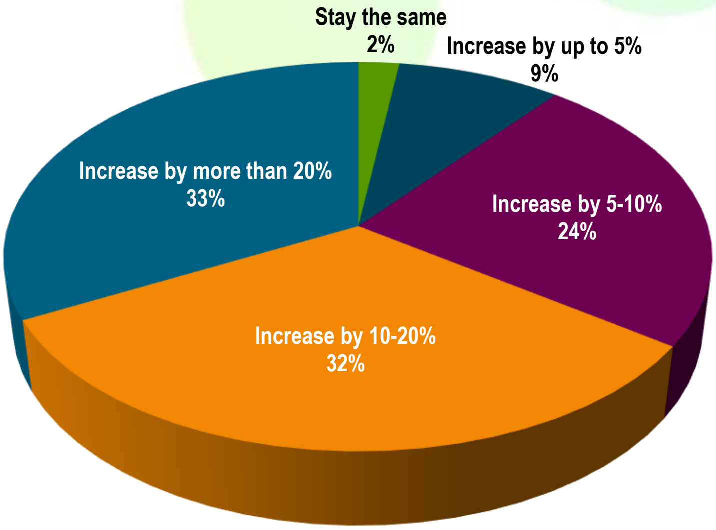
PROCESSES USED

Dental applications include both direct uses and indirect uses such as patterns for creating clear aligners. Vat photopolymerization as the most used process reflects a high need for accuracy and fine features.



MATERIALS USED

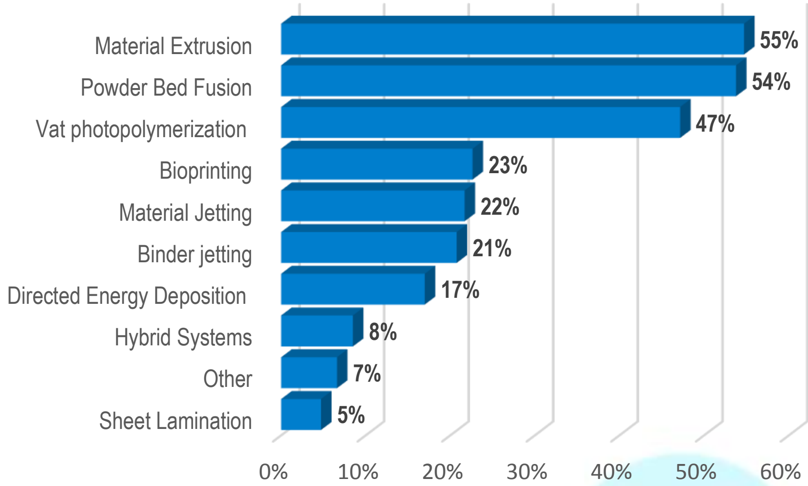
Unlike other applications 3D printed closer to the patient in a hospital setting, dental applications include bridges and other dental prosthetics demonstrated by a higher use of metals.



EXPECTED GROWTH

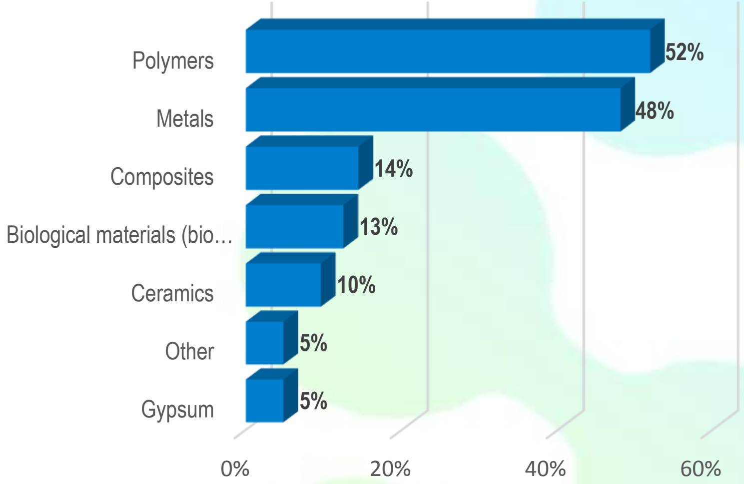
98% expecting growth in dental applications corresponds to the long history of the dental industry in patient-matching or mass customization. 3D printing, particularly when combined with intraoral scanners, represents an efficient process for matching an individual patient. .

Patient-Matched Devices



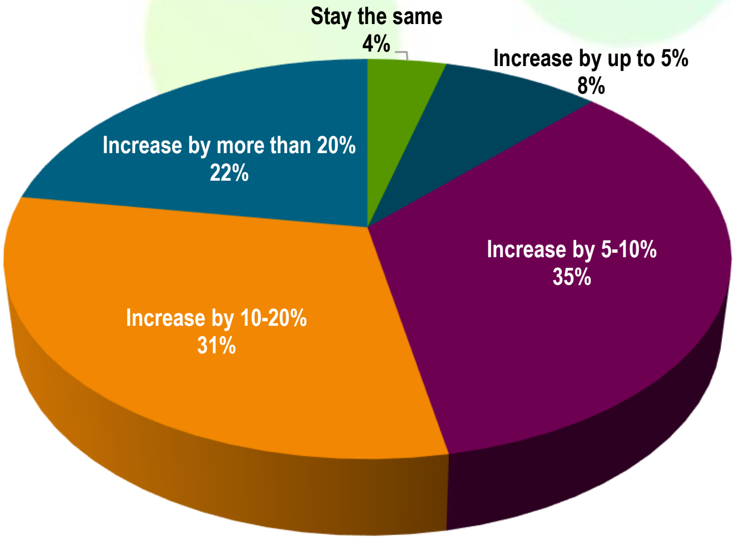
PROCESSES USED

Patient-matched devices can include orthopedic implants (while most are still serialized) as well as assistive devices created at the point of care. The nearly equal use of material extrusion and powder bed fusion is consistent with the variety of applications.



MATERIALS USED

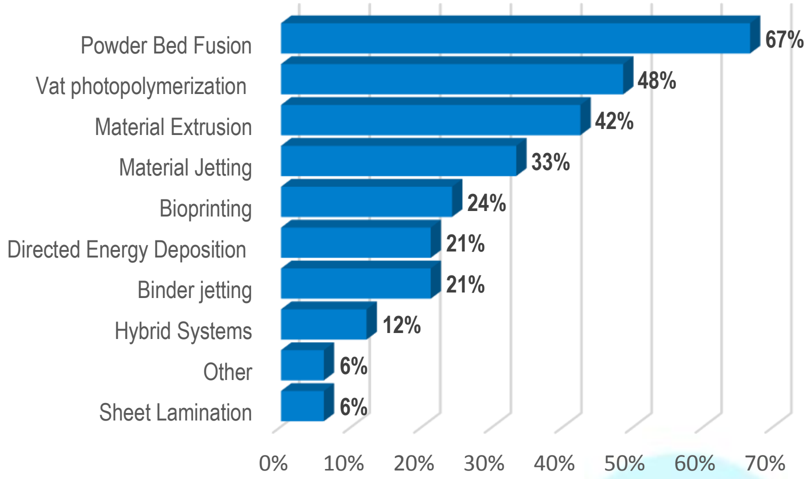
The relatively close usage rates of polymers and metals is in line with orthopedic implants that need to be patient-matched when a serialized implant will not work.



EXPECTED GROWTH

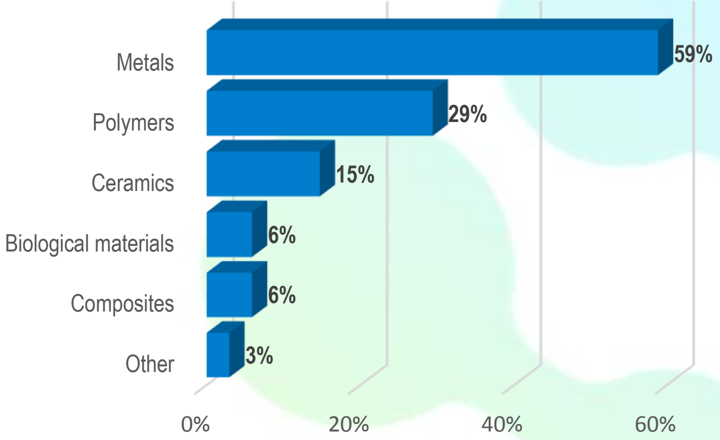
While overall, the largest number (24%) expect the greatest growth in patient-matched devices, specific growth rates closely mimic growth rates for all applications.

Serialized Devices



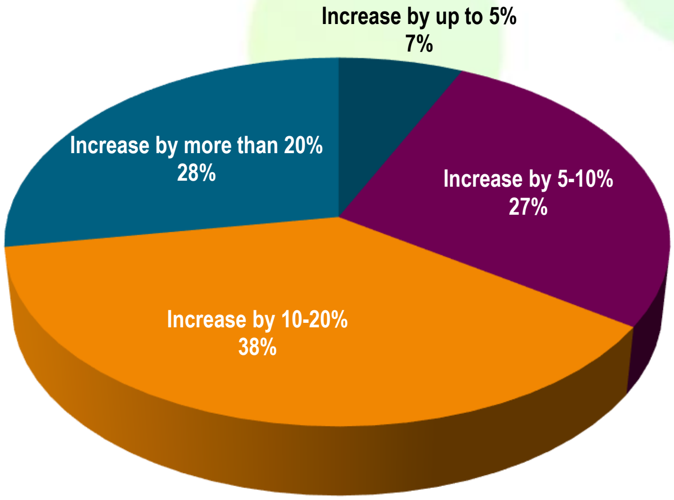
PROCESSES USED

Serialized devices represent the production use of off-the-shelf devices, commonly orthopedic implants available in a series of sizes. Powder bed fusion is the top process for creating these devices with complex structures needed for in-bone growth.



MATERIALS USED

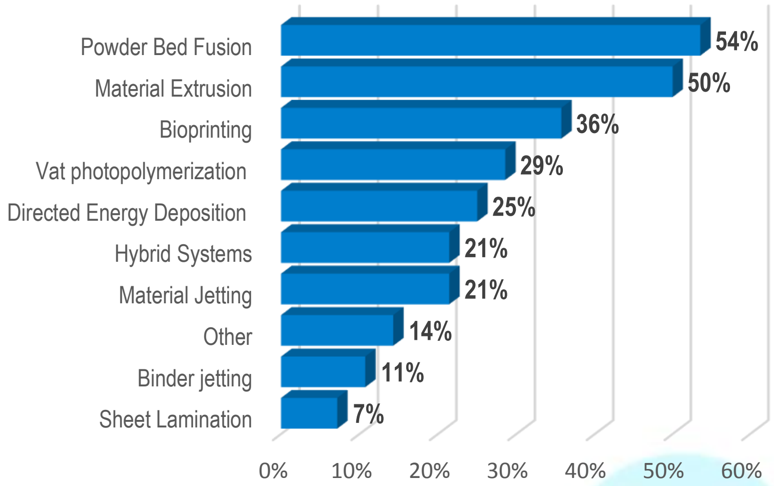
Although an FDA review of devices receiving clearance showed a near equal use of polymers and metals, responders indicated metals is the dominant material used for serialized devices.



EXPECTED GROWTH

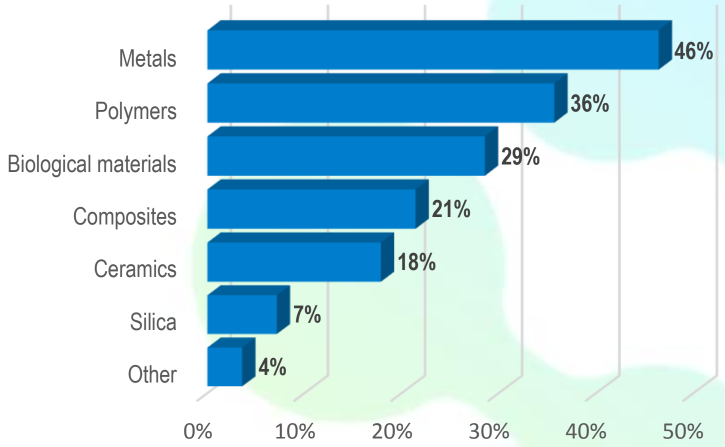
Serialized devices are one of two application areas (active devices being the other) that all responders expect growth with more than 65% expecting more than 10% growth.

Active Devices



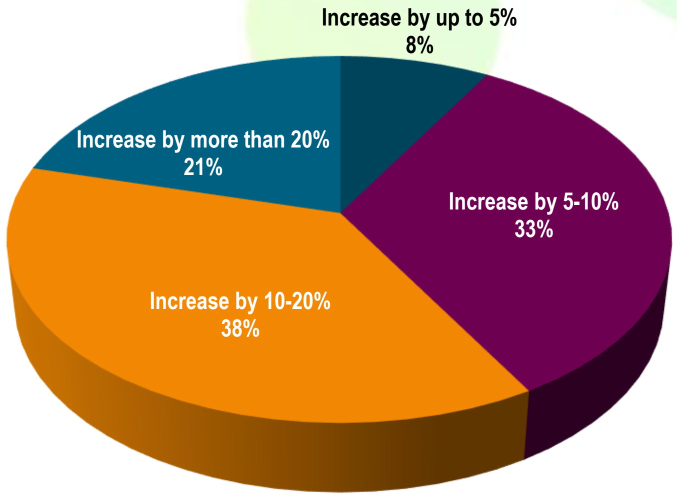
PROCESSES USED

Active devices applications are still being defined, representing a variety of devices that interact with the body using smart materials, sensors, changes over time, or electrical charges. While powder bed fusion is the top process, bioprinting has the highest usage rate outside of tissue fabrication.



MATERIALS USED

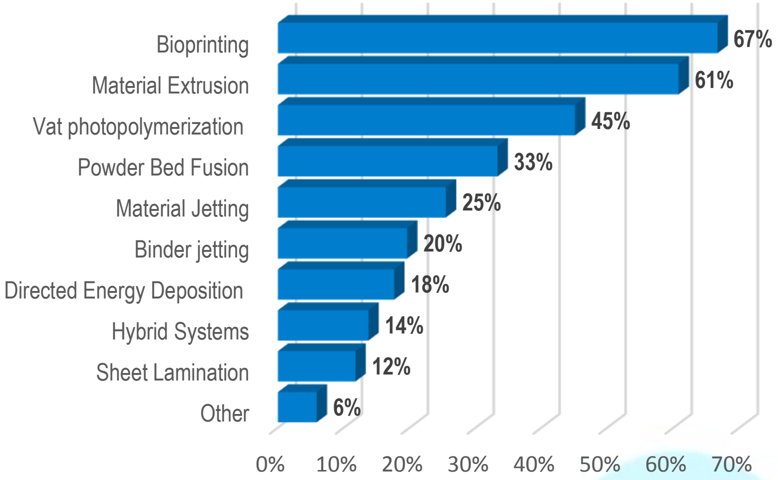
Metals are the top materials used for active devices, with biological materials having the highest usage rate outside of tissue fabrication.



EXPECTED GROWTH

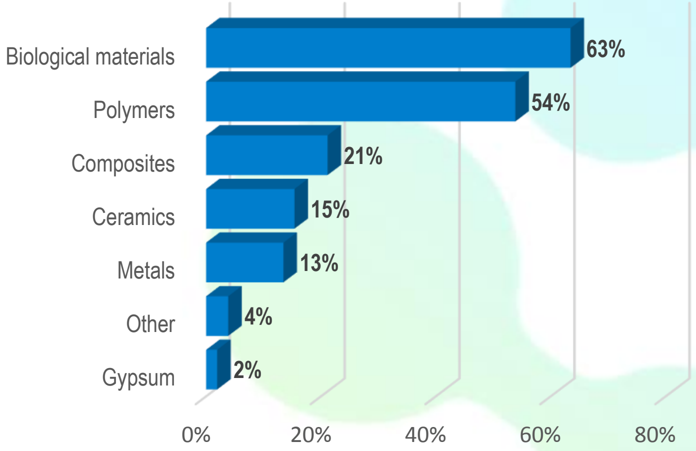
Active devices is the second application area (serialized devices being the first) where all responders expect growth with nearly 60% expecting more than 10% growth.

3D Biofabrication



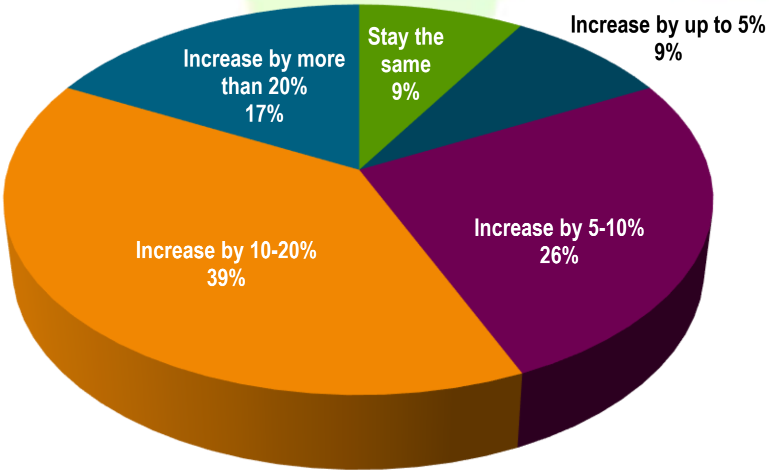
PROCESSES USED

3D biofabrication includes direct printing of tissues and structures to generate tissues. With many bioprinting processes using a material extrusion approach, bioprinting and material extrusion are the top processes.



MATERIALS USED

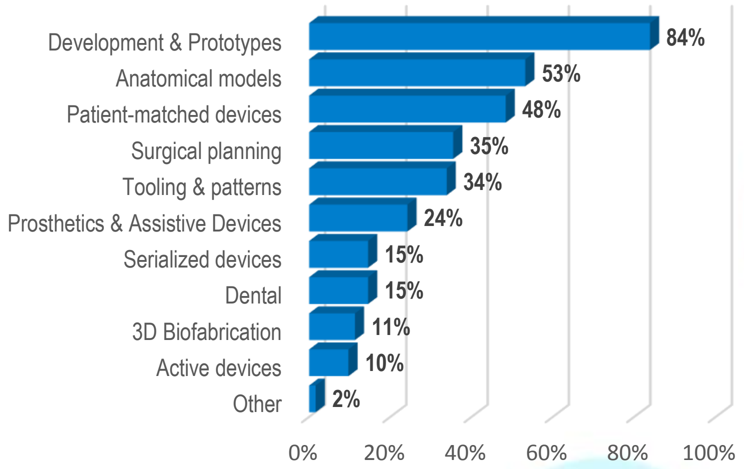
Biological materials are the top material category used to 3D print tissues (direct) followed by polymers often used for scaffold (indirect) to generate tissues.



EXPECTED GROWTH

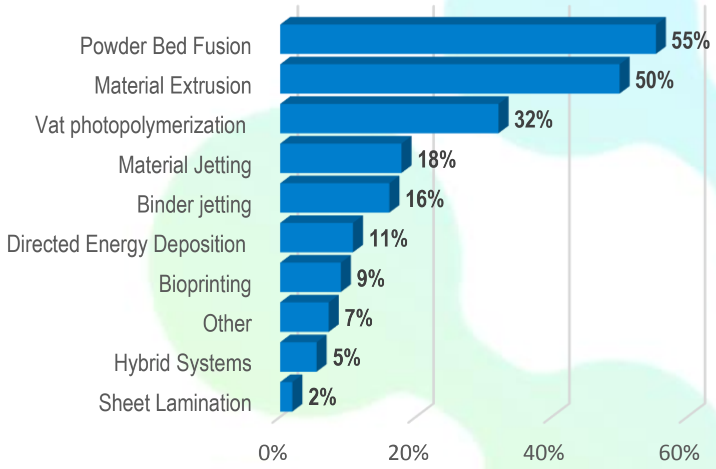
3D biofabrication has the highest response for “stay the same” of all application areas. Although many important developments were seen this year, full clinical use is still some time away.

Medical & Dental Device Manufacturers



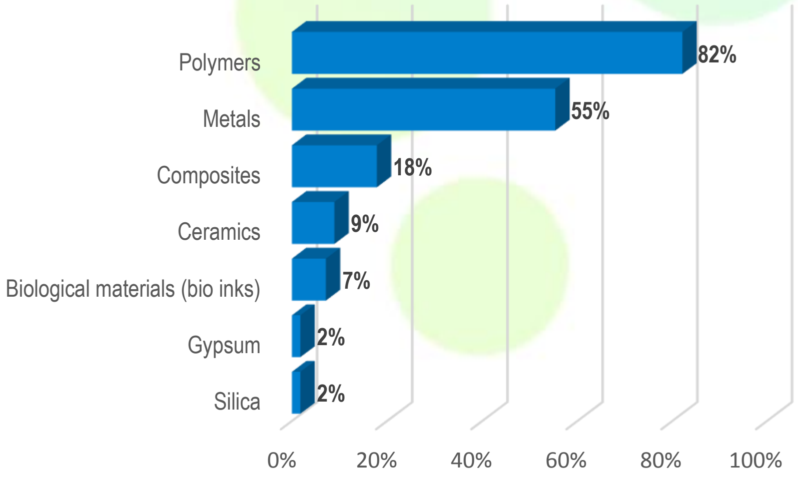
APPLICATIONS

Many device manufacturers were early adopters of AM for prototypes with Baxter Healthcare having one of the first commercially installed machines in December 1988. Development & prototypes continues to be the top application area for device manufacturers. Although anatomical models may be seen as something most often done at the point of care, many device manufacturers also produce anatomical models.



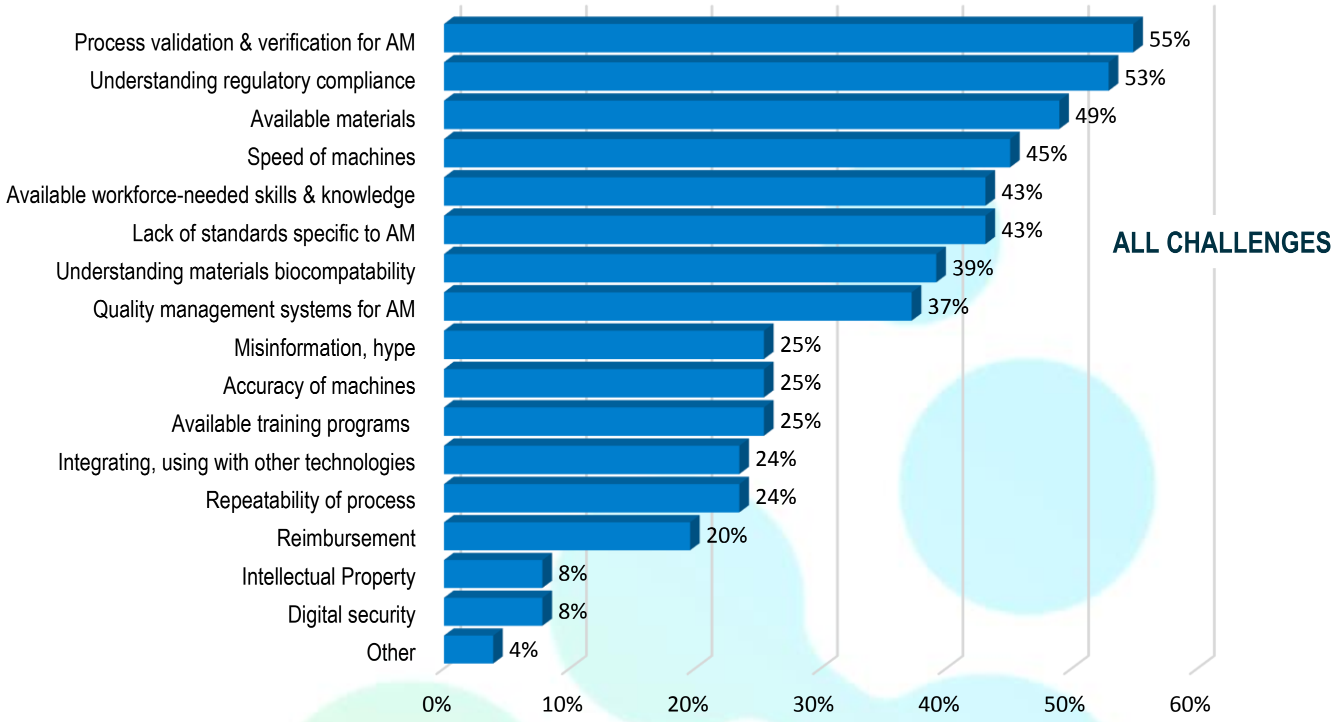
PROCESSES USED

Powder bed fusion is the top process used by device manufacturers reflecting the diverse materials capability of the process.

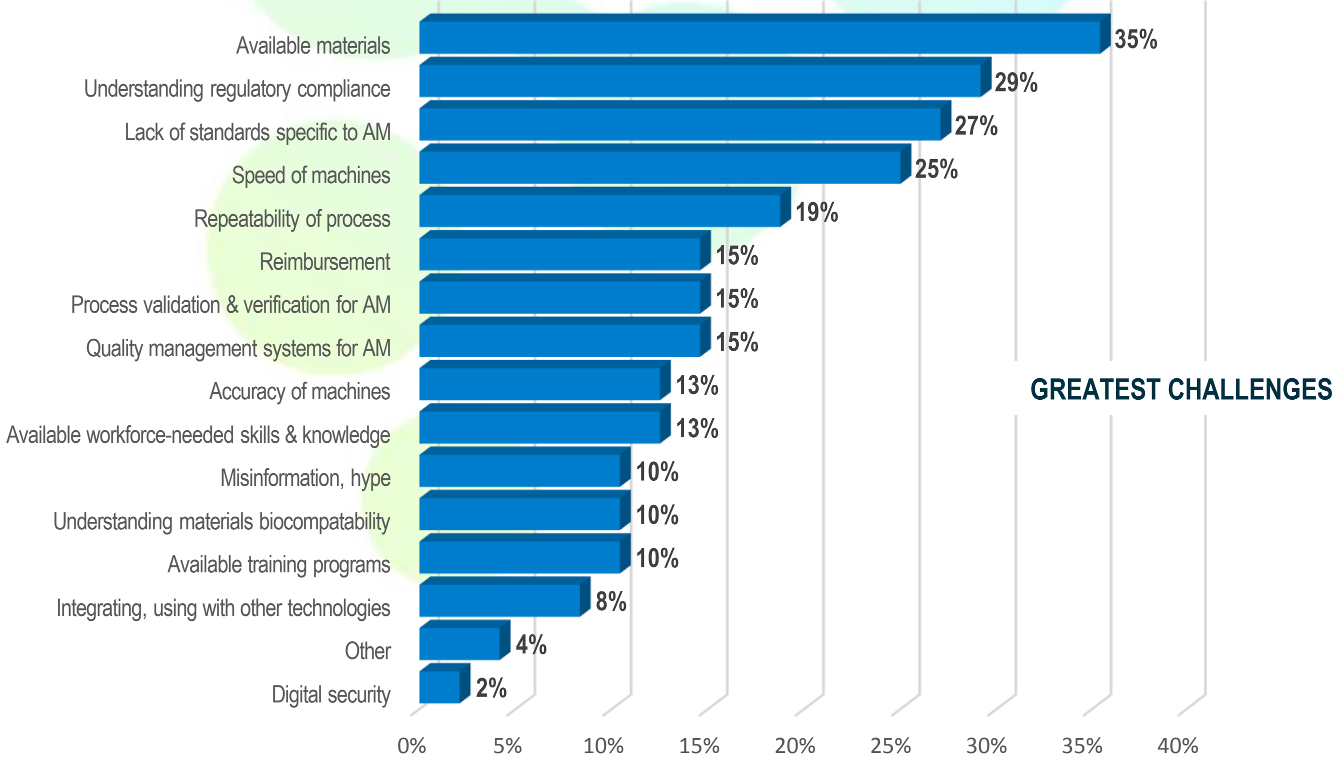


MATERIALS USED

The high rate of polymer use is consistent with prototypes being the highest application area with metals the second material reflecting the production use for many orthopedic implants.

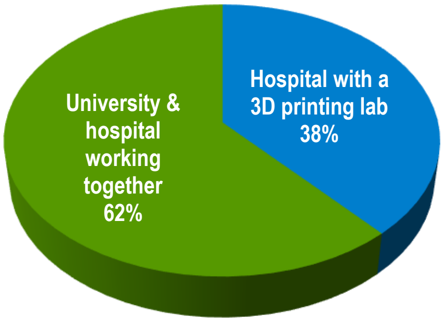


The top challenges for device manufacturers are consistent with the highly regulated and competitive environment in which devices are manufactured including V&V, compliance, standards, materials, and speed of machines.



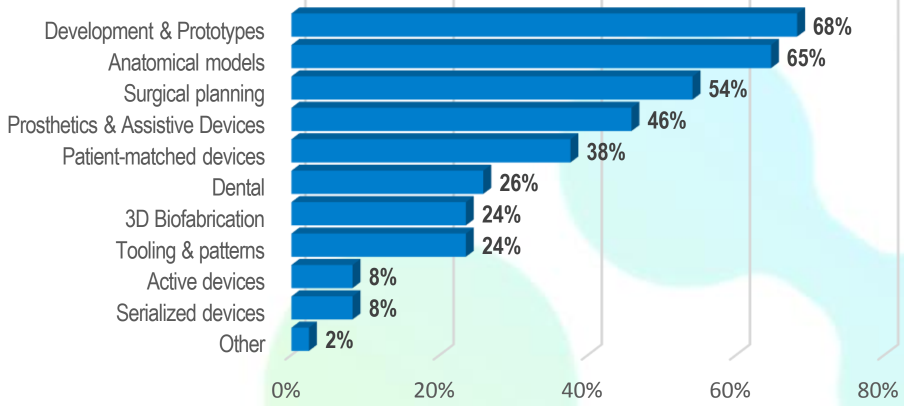
Point-of-care Manufacturers

POINT-OF-CARE SETTING



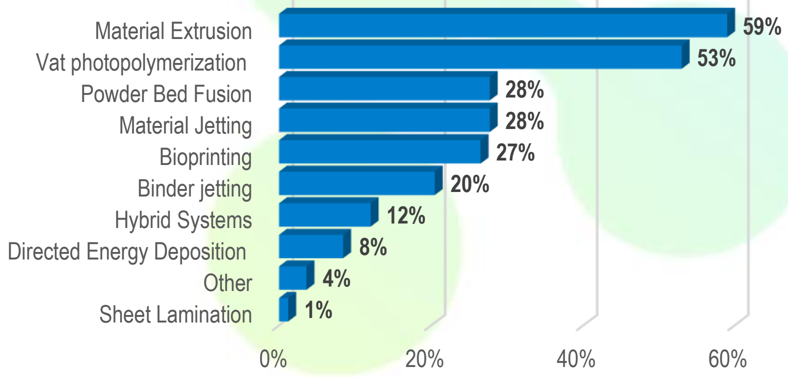
The first point-of-care manufacturers were those connected to a university engineering department. That approach continues with more than 60% of point-of-care manufacturers representing hospitals and universities working together.

APPLICATIONS



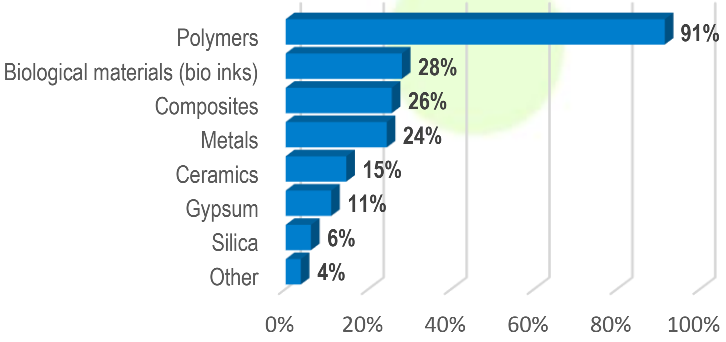
While anatomical models are 3D printed by point-of-care manufacturers (likely the top application within a hospital), prototyping as the top application suggests clinicians and university engineers work together to develop new applications.

PROCESSES USED

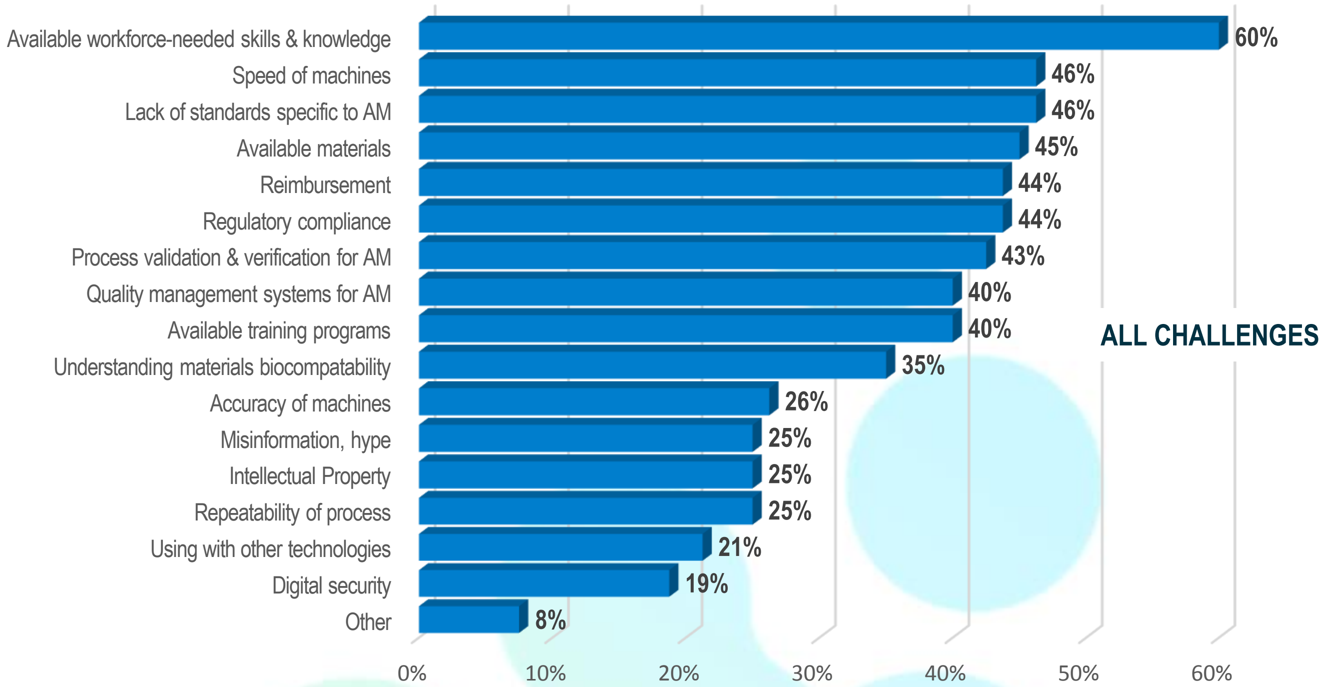


While material extrusion is the top process, vat photpolymerization is the second most popular process at the point-of-care reflecting the challenges of installing a powder-based within a clinical setting. Those in use are likely within the university engineering department or a dedicated engineering department housed in a separate building like that of Mayo Clinic.

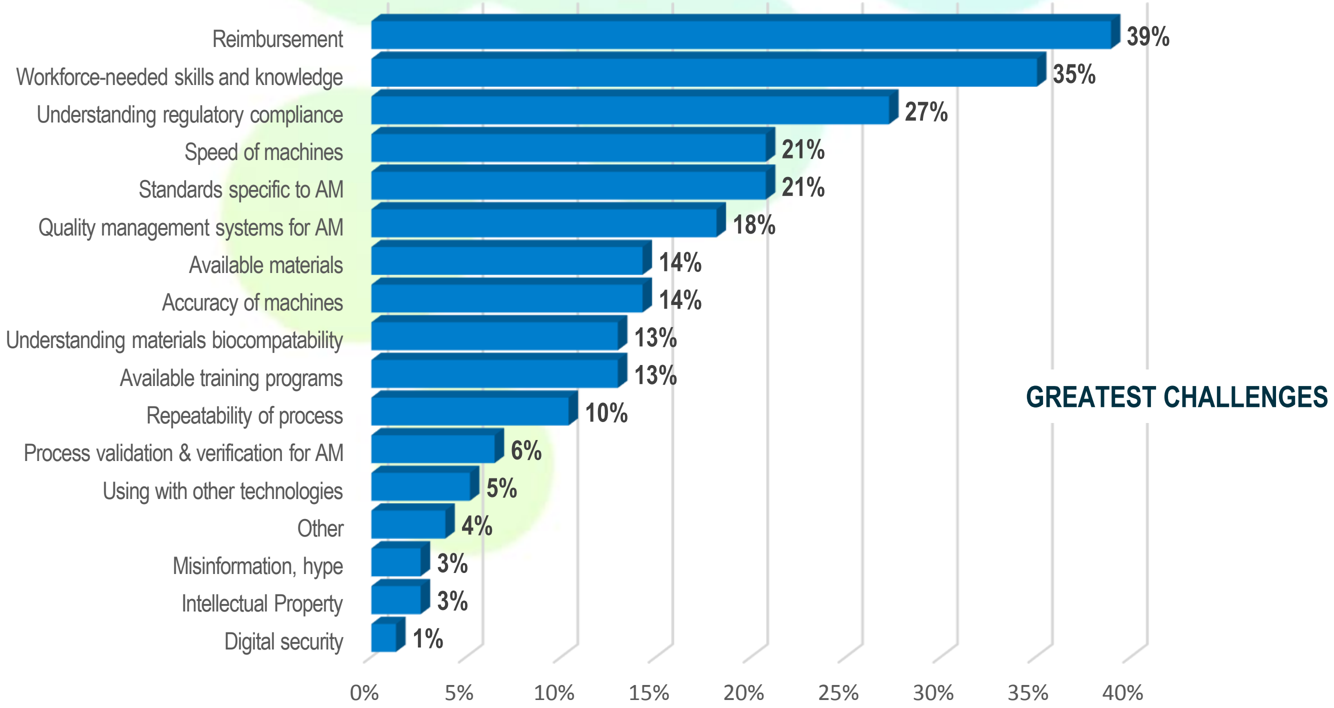
MATERIALS USED



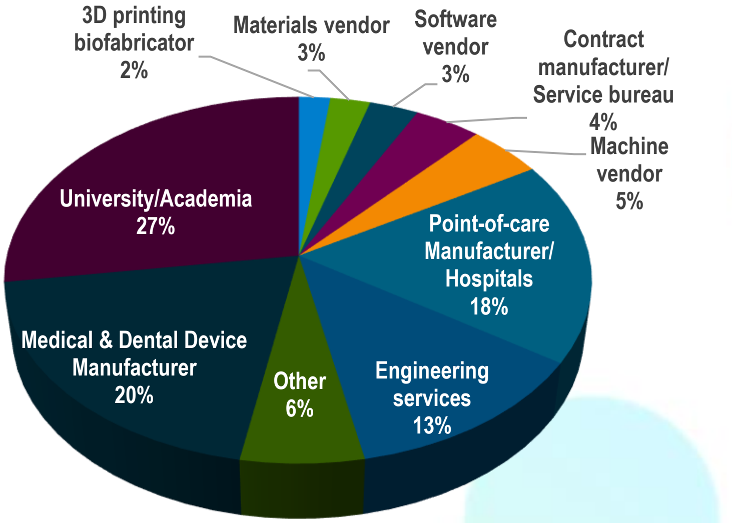
Polymers, by far, are the top material used at the point of care consistent with the top applications of prototypes, anatomical models, and surgical planning.


ALL CHALLENGES

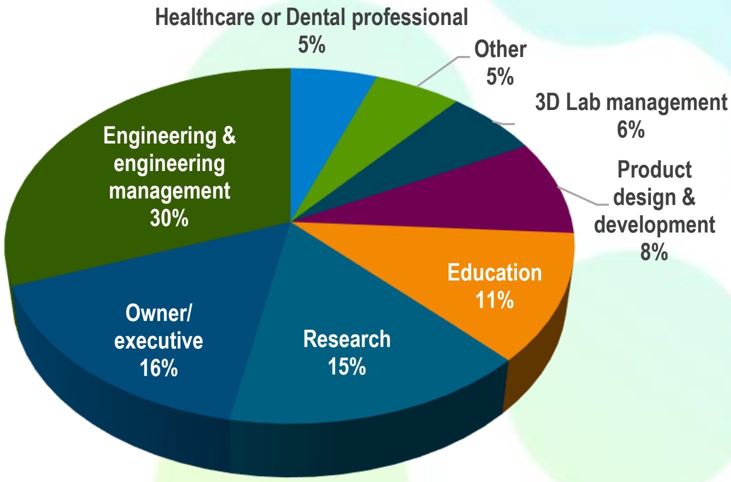
While device manufacturers and point-of-care manufacturers share similar top challenges including workforce, lack of standards, and speed of machines, there are clear differences. Reimbursement becomes the greatest challenge consistent with anatomical models and surgical guides being a new type of medical product, followed closely by workforce requiring a combined knowledge of medicine and engineering.


GREATEST CHALLENGES

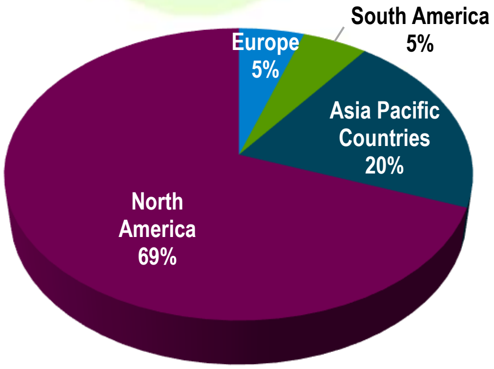
Response Profile



ORGANIZATION TYPE



JOB FUNCTION/ROLE



LOCATION

APPENDIX

RESOURCES

The ASME Medical AM/3DP Advisors find, develop and share resources on a **dedicated web page**.

- AM Medical Event Series
- AM Medical Webinar Series
- 3D Printing of Medical Devices at the Point of Care: Regulatory Concept Framework Series
- Process Verification & Validation for Medical Devices Using Additive Manufacturing
- Medical 3D Printing Applications Infographic
- ASME Medical AM/3DP Advisors
- 3D Bioprinting
- Wearables, Embedded, Bioprinted Sensors
- Video: Designing Medical Devices with Additive Manufacturing
- Medical Additive Manufacturing/3D Printing Publications
- Journal of Medical Devices Special Issue: Three-Dimensional Printing of Medical Device

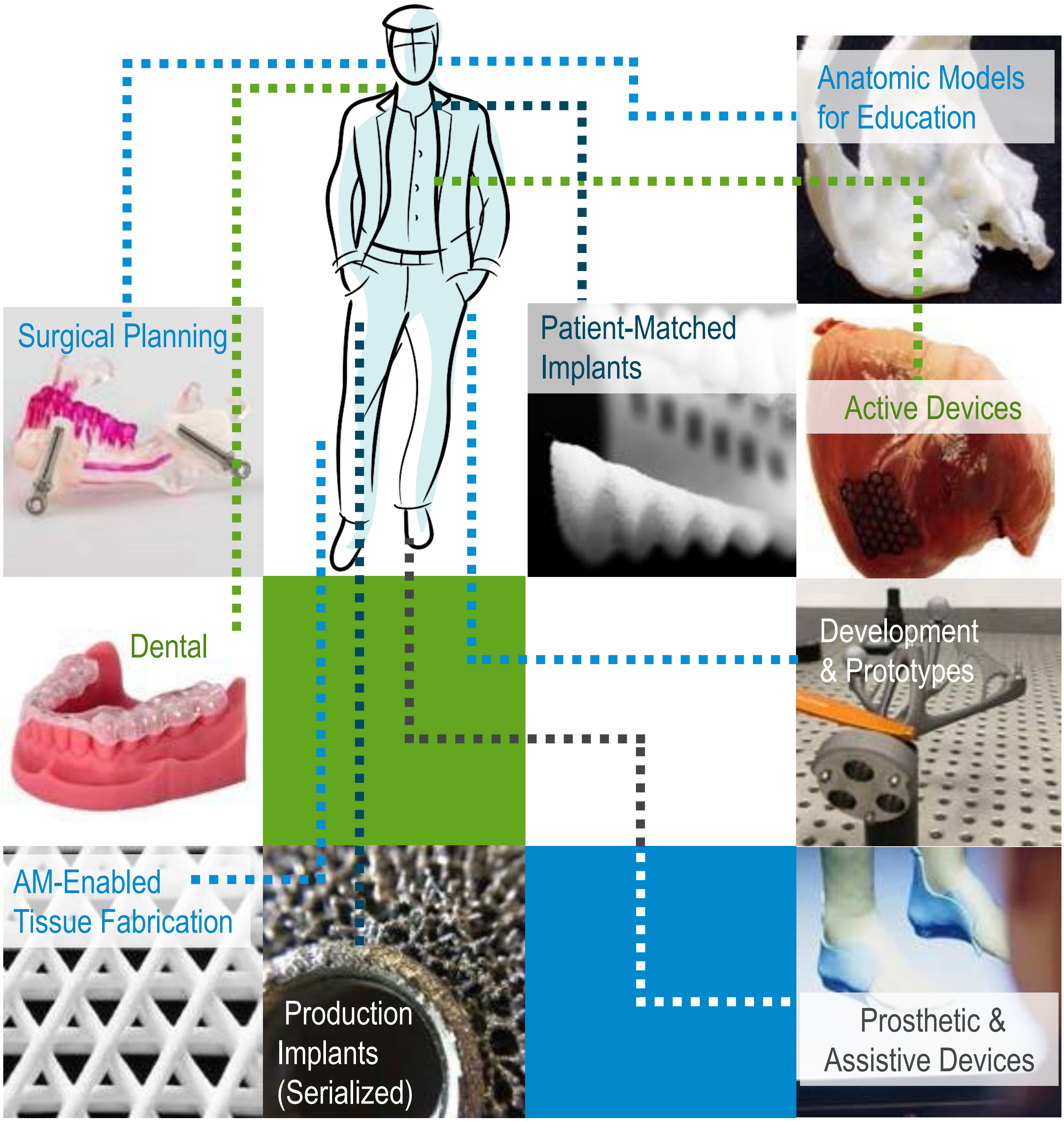
Additional Resources

- FDA Technical Guidance (PDF)
- DICOM Standard (medical imaging files)
- AMSC-Additive Manufacturing Standardization Collaborative & Standardization Roadmap
- JOURNAL: 3D Printing in Medicine
- International Journal of Bioprinting
- NIH (National Institute of Health) 3D Print Exchange
- RSNA 3D Printing Special Interest Group

AM/3DP PROCESSES

Process	Includes…
Binder jetting	CJP, CBJ, SPJ
Bioprinting	Printing with cells
Directed Energy Deposition	LMD, LENS, EBAM, DMD
Hybrid Systems	Combines additive & subtractive
Material Extrusion	FDM, FF
Material Jetting	MJM, MJP
Powder Bed Fusion	SLS, DMLS, SLM, DMO, EBM, MJF
Sheet Lamination	UAM, SLCOM, CBAM
Vat photopolymerization	SL, DLP, CLIP

Medical Applications of Additive Manufacturing



Anatomic Models for Education

Surgical Planning

Patient-Matched Implants

Active Devices

Dental

Development & Prototypes

AM-Enabled Tissue Fabrication

Production Implants (Serialized)

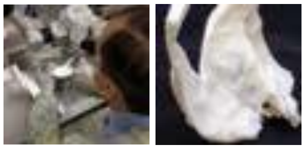
Prosthetic & Assistive Devices

How 3D Printing Impacts Patient Care

Development & Prototypes: Using AM as a prototyping tool to accelerate development has been used by medical manufacturers for about 30 years. One of the first commercial installations of a ma- chine was at Baxter Healthcare in 1988. Today, this lightweight surgical tool concept for tracking hip implant alignment during surgery, took advantage of AM design capabilities including assembly consolidation, topology and surface texture optimization, and ergonomic design features.

Courtesy: Renishaw (Canada) Solution Center, Intellijoint Surgical, and MSAM Labs University of Waterloo.

Anatomic Models for Education: Using medical imaging (MRI. CT) data, anatomical models can be 3D- printed for physicians to use to discuss surgery with patients as well as simulation tools like this acoustic neuroma model that has the nerve canal and membranous labyrinth filled with paint. The surgeon can practice in the lab, causing the model to bleed paint if the structures are damaged.



Courtesy: UPMC 3D Printing Program and Anish Ghodadra, MD

Prosthetics & Assistive Devices: Using surface scanning, patient-matched prosthetics and assistive devices can be made directly or indirectly AM serves as molding pattern to better, fit, mirror, or address unique needs of a patient. One example is this set of custom orthotics that are barely visible inside an ordinary pair of shoes, and successfully stabilized the walking of a young boy with cerebral palsy.

Courtesy: Formlabs

Dental: With the advancement of digital imaging and materials, AM/3DP has become a better way to produce many dental devices that are patient-matched. Accurate bite splints and night guards can be made using the E-Guard material.

Courtesy: EnvisionTEC.

Surgical Planning: Using medical imaging data, anatomical models can be used as surgical planning tools. Having a physical model often provides a surgeon 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. This example shows both a patient's model and the surgeon's cutting guide for an osteotomy to replace the jaw bone.

Courtesy: 3D Systems Healthcare, based on a VSP™ Virtual Surgical Planning) session

Production Implants (Serialized): The design advantages have allowed device manufacturers to use AM as an efficient production method. Orthopedic implant manufacturers in particular, have found the advancements in metal AM have allowed them to efficiently manufacture the porous surfaces needed for in-bone growth. The close up of a titanium acetabular cup (hip implant) shows the complex porosity manufactured with the cup itself.

Courtesy: Lauralyn McDaniel

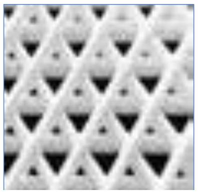
Patient-Matched Implants: Using a patient's medical imaging, devices can be designed and manufactured to match a patient's individual anatomy. AM can enable development of a patient-matched device to treat rare conditions like tracheobronchomalacia (TBM). The trachea splint made of polycaprolactone developed at the University of Michigan is strong enough to hold the trachea open allowing the child to breathe, flexible enough to grow with the patient, and is absorbed by the body when the child's trachea strengthens.

Courtesy: Lauralyn McDaniel

Active Devices: With development of processes to print electronics and with smart materials, new devices that includes sensors that provide feedback or conduct impulses within the body, are considered active devices. This graphene heart patch made with the 3D painting process, is highly electrically conductive and can transfer impulses over an inactive area of the tissue.
The material and process could also be applied to other muscle and nerve repair as well as implantable bioelectronics.

Courtesy: Dimension Inx

AM-Enabled Tissue Fabrication: 3D printing technologies can be used to print biological materials (bioprinting) or structures like scaffolds that can be used to regenerate tissues. This scaffold (closeup image) is made of Hyperelastic Bone® and is intended for off-the-shelf, generic bone void filler use. It can provide a scaffold on which the bone can grow.



Courtesy: Dimension Inx

ASME
SETTING THE STANDARD

ASME is a not-for-profit membership organization that enables collaboration, knowledge sharing, career enrichment, and skills development across all engineering disciplines, toward a goal of helping the global engineering community develop solutions to benefit lives and livelihoods. Founded in 1880 by a small group of leading industrialists, ASME has grown through the decades to include more than 100,000 members in 140+ countries. From college students and early-career engineers to project managers, corporate executives, researchers and academic leaders, ASME's members are as diverse as the engineering community itself. ASME serves this wide-ranging technical community through quality programs in continuing education, training and professional development, codes and standards, research, conferences and publications, government relations and other forms of outreach.

www.asme.org

About AM Medical Powered by ASME

Achieving the growth potential of 3D technologies requires collaboration between the manufacturing and medical communities to enable technology application. The AM Medical series will move this critical collaboration forward by focusing exclusively on 3D innovations in an interactive, collaborative environment for learning and sharing. Participants will see and hear more about the latest advancements in 3D printing, materials, quality processes, scanning and visualization; new software solutions for post-processing, modeling and simulation; and more—all in one place. Professionals and organizations with shared interest in growing applications in medical devices, point-of-care, dental and bioprinting will collaborate to advance human health.

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