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3D Printing's Future in Orthopedics: The Who, What, When, Where, and Why

Who will Produce them?	What are the Key Drivers?	When will this Happen?	Where will they be Made?	Which Products are Right for 3DP?

By Paula Ness Speers, Masha Dumanis, Brandon Wade, Matthew Barnes, and Aenor Sawyer, MD

Growing experience with the use of 3D printing in orthopedics, plus declining cost differences between 3DP and traditionally manufactured implants, are enabling device manufacturers to expand the applications of 3DP in the musculoskeletal sector.

KEY POINTS

- While early adopter-surgeons have readily embraced 3D for pre-surgical planning, anatomical modeling, and printing of instrumentation and/or patient-specific implants in complex CMF and ortho-oncology cases, more manufacturers, as well as more providers, now are realizing its potential in higher-volume and/or standardized orthopedic implants.

- Technological advances continue to improve the economics of production, enabling more flexibility in choosing between 3DP vs. traditional manufacturing technologies when designing and making new implants and instruments.

- Leading academic medical centers are starting to engage with major implant manufacturers in novel partnerships that seek to leverage the unique ability of 3DP to create patient-specific implants for key applications.

- Early positive clinical data, gleaned from the UK national registry and case series, are providing some of the first insights into the value of patient-specific implants to enable enhanced patient outcomes.

3D printing (3DP, also known as additive manufacturing) is making notable strides in penetrating the musculoskeletal device industry. It is no longer only being used for anatomical models to aid in surgical planning and the one-off custom implant for revisions with significant bone loss. It is now being applied to a surprisingly large percentage of off-the-shelf (OTS) implants, and early adopters see growing potential with this technology to enable more real-time or short-lead time printing of patient-specific implants across a broader range of procedures, from trauma fixation to joint replacement solutions.

The consulting firm Health Advances and the University of California, San Francisco Department of Orthopaedic Surgery convened a forum of thought leaders on March 14, during the annual meeting of the American Academy of Orthopedic Surgeons (AAOS), to examine the future for 3DP in the musculoskeletal sector. The panel, titled "*From Printer to Patient: How Will 3DP Reshape Musculoskeletal OEM, CMO, and Provider Roles?*" was moderated by Paula Ness Speers, co-founder and managing director of Health Advances LLC, and Aenor Sawyer, MD, Chief Health Innovation Officer, Translational Research Institute for Space Health, Director UCSF Skeletal Health Service, Department of Orthopaedic Surgery, and Co-Director, UCSF Center for Advanced 3D+ Technologies. Lisa Lattanza, MD, Professor and Vice Chair of the Department of Orthopaedic Surgery and Chief of the Division of Hand and Upper Extremity Surgery at UCSF (Lattanza is moving as of September 1 to Yale School of Medicine/Yale New Haven Hospital to become Chair of the Department of Orthopaedics and Rehabilitation);

Douglas Leach, Managing Director, Biomechanical Innovation, HSS Global Innovation Institute at the Hospital for Special Surgery (HSS); Alan Dang, MD, a Health Sciences Associate Clinical Professor of Orthopaedic Surgery at UCSF and a staff spine surgeon at the San Francisco VA Health Center, along with Yarmela Pavlovic, a partner in Hogan Lovells' FDA Medical Device Group, participated as panelists.

There is now early clinical evidence stemming from a **Conformis Inc.** registry study that patient-specific implants can lead to better clinical outcomes (*see sidebar, "Clinical and Economic Value of Patient-Specific Implants: Conformis as a Case Study."*). And when all the supply chain economics of traditional implant manufacturing, inventory build and shipping logistics are considered, 3DP-produced implants are rapidly approaching cost parity for all but the highest-volume implants. These developments led to discussion among the panelists of the potential to manufacture implants onsite or near hospitals and the identification of two examples where this is already unfolding, as well as the expansion of 3DP beyond patient-specific-implants to off-the-shelf applications.

The adoption curve illustrated in *Figure 1* shows that additive manufacturing has proven its value in dental implants and other MSK (muscoloskeletal) applications are following close behind. While 3D anatomical models have not been a part of routine surgical workflow historically—due in part to early concerns about cost and the lack of expertise with the technical skills and software required to translate 2D images into manipulatable and printable 3DP images and objects—their value in improving pre-operative planning that enables intraoperative efficiencies and improved post-operative outcomes is becoming clearer, setting up the technology for broader adoption. 3DP of patient-specific and OTS implants are close behind, and will likely see rapid growth through the next five years. As manufacturers and surgeons adjust to these new technologies and associated applications, there is no doubt additive manufacturing will be a strong force in musculoskeletal care in the coming years.

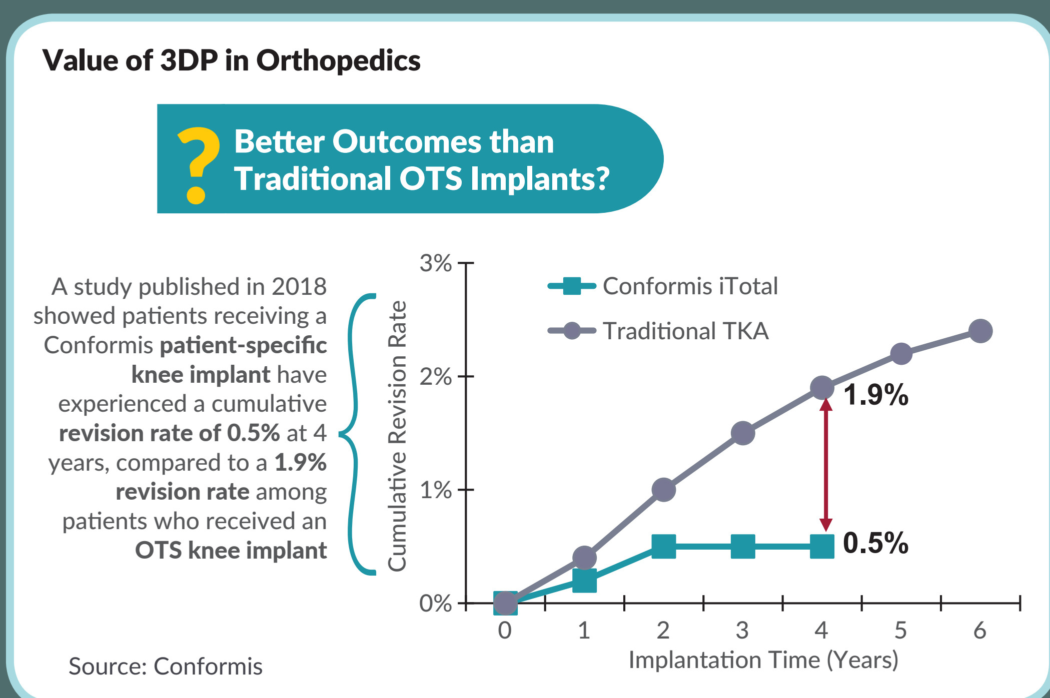
Which Products are Ripe for 3DP?

3DP has been employed selectively in orthopedics since the mid-2000s.

Clinical and Economic Value of Patient-Specific Implants: Conformis as a Case Study

Conformis Inc. has been producing and selling patient-specific knee implants for 10 years, and recently launched a patient-specific hip arthroplasty implant. It uses 3DP to create patient-specific cutting guides, as well as the molds for manufacturing its patient-specific knees.

Although, for a variety of reasons, the company has struggled over its commercial history to gain a more robust foothold in the surgeon suite, last year, it published encouraging 4-year outcomes data from the UK National Total Joint Registry, demonstrating that its patient-specific *iTotal CR knee* implant achieved statistically better clinical outcomes than standard OTS total knee implants, as measured by fewer revision surgeries. The company also published a study indicating a net savings of more than $900/patient when netting out the added cost of a CT-scan versus savings in hospital and post-acute care costs, risk adjusted, for the patients in the study.



Early applications focused on non-implant applications, such as anatomical models for pre-surgical planning, custom cutting guides, and jigs for more accurate bone cuts.

Over time, the technology has penetrated into various musculoskeletal implants, as additive manufacturing has afforded enhanced design elements, such as truss/strut or latticed designs for spinal implants and highly porous surfaces integrally printed for acetabular hip cups. In addition, customized implants addressing patient-specific needs are increasingly relying on 3DP, such as complex craniomaxillofacial (CMF) cases in which matching the patient's bone structure is essential for cosmetic reasons, and in ortho-oncology indications where there is a need to replace irregular and unpredictable bone loss in tumor resections. Previously, surgeons had poor implant options and largely relied on shaving and bending standard parts to meet their needs.

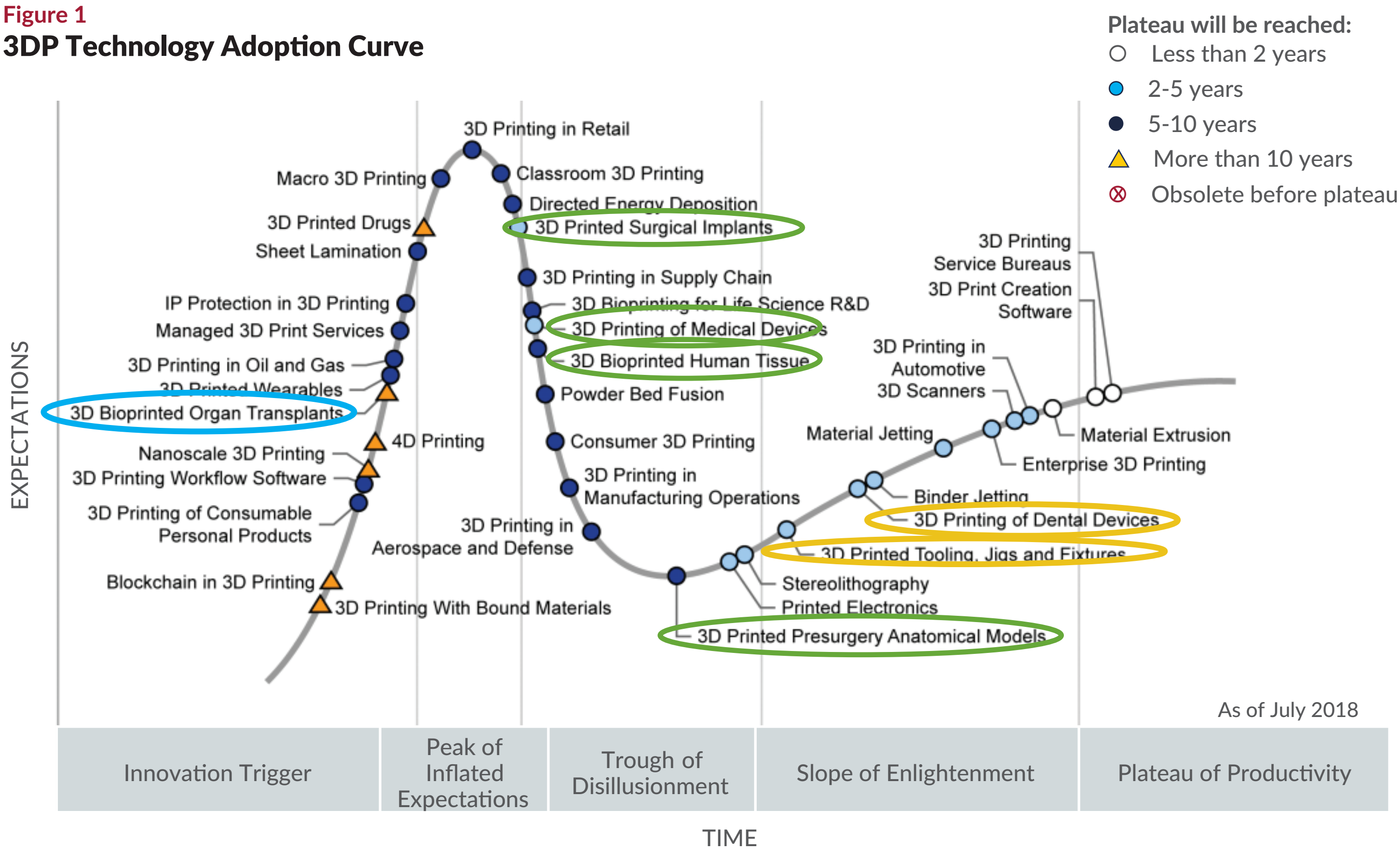
The rate of growth of 3DP implants across all orthopedic implants is clearly accelerating, providing manufacturers with more experience, which is, in turn, helping drive down costs and improve designs and production guidelines.

Estimates suggest that approximately 15% of spine and 5% of large joint implants used in Europe in 2018 were manufactured using 3DP technology.

While similar statistics in the US are not readily available, major orthopedic OEMs are incorporating 3DP manufacturing across product lines, and the number of FDA approvals of 3DP medical devices grew 400% from 2014 to 2017 (*see Figure 2*).

We also see the impact of this trend in the growing number of higher volume and OTS implant designs moving to additive manufacturing. **LimaCorporate**, an Italian-based orthopedic manufacturing firm, has been producing OTS implant designs using 3DP for more than 10 years. It is now relatively indifferent from a COGS (cost of goods sold) point of view on whether it uses traditional or 3DP manufacturing techniques for some of its OTS implants, one of its executives said at the Health Advances/UCSF forum. While an important new initiative for LimaCorporate is to be a leader in custom orthopedic implants for complex cases, working closely with HSS, the fact that it finds additive manufacturing to be cost neutral to traditional

Figure 1
3DP Technology Adoption Curve



Sources: Gartner research & analysis (December 2018); Health Advances research manufacturing technologies for some of its standard implant designs is notable and suggests that the cost curves are starting to converge.

Historically, 3DP resulted in higher manufacturing costs than traditional manufacturing for most orthopedic devices. From a COGS standpoint, 3DP only made sense in low-volume devices due to limitations of the technology (*see Figure 3).*

As Lima's 3DP of OTS implants demonstrates, the 3DP cost curve for the industry has shifted down. As a result, additive manufacturing is becoming cost-effective for all but the highest volume implants (*see Figure 4*). Furthermore, 3DP has enabled advances in OTS implant design/geometries, such as latticing of spinal implants for better bony in-growth/through-growth, which can only be manufactured using 3DP.

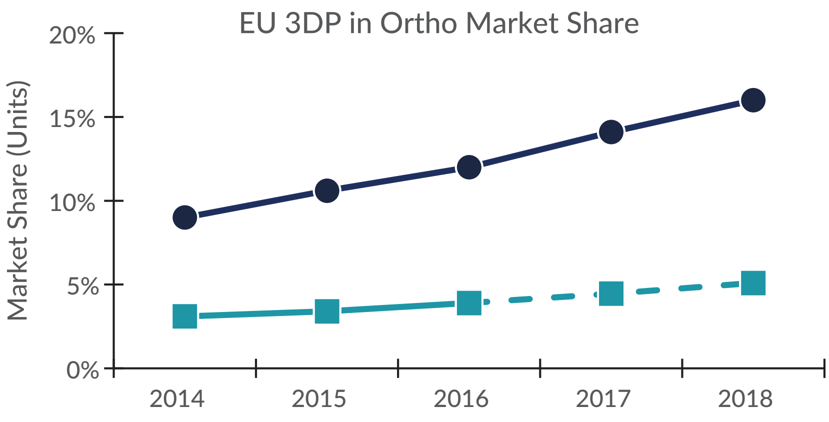
OEM Vs. CMO: Who Will Produce 3DP Products in Ortho?

As additive manufacturing technologies have penetrated the orthopedics sector, the traditional manufacturing business model has also been evolving. Several of the major orthopedics OEM companies—such as **Stryker Corp.** and **Johnson & Johnson/ DePuy**—have purchased additive capital equipment and started to build in-house manufacturing capabilities, leveraging 3DP equipment from the larger additive equipment manufacturers such as **EOS** (30-year-old German supplier of additive manufacturing equipment) and **GE Additive** (founded in 2016, and aquired Arcam EBM and Concept Laser). While many of the large MSK OEMs have historically leaned toward traditional, in-house manufacturing, their investments in mastering additive technologies and product design have been noteworthy in recent years.

Orthopedic contract manufacturing organizations (CMOs) at the same time are paying attention to the actions of major OEMs. Some—Tecomet and Orchid, for example—have already invested in building in-house experience with 3DP capabilities and are offering this to their customers. Others, however, remain bearish about the future of 3DP in orthopedics and are cautiously watching and listening to their customers for signals of if, when and for what, they want to employ 3DP technology in the orthopedics sector. This is, of course, typical of the way many OEMs and CMOs have worked together for decades—with OEMs driving the design decisions and required specs for implants they want manufactured, and then CMOs responding to those designs and competitively bidding to win outsourced manufacturing volumes.

Figure 2

Market Opportunity and Growth

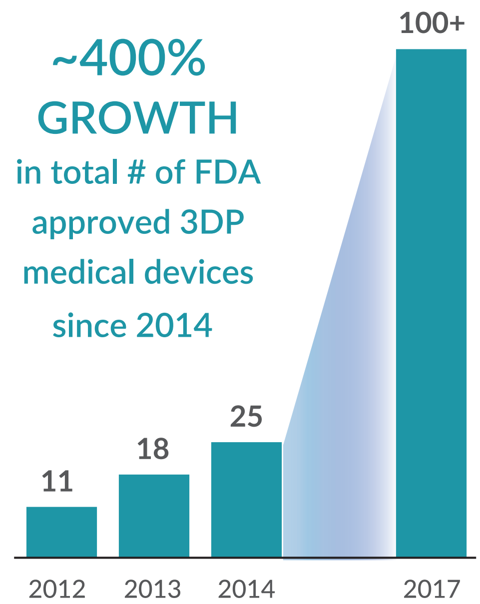


2014 – 2018 CAGR

Spine Cages	15.5%
Joint Replacement	14.2%

Note: Joint Replacement data extrapolated from 2012-2016 data.

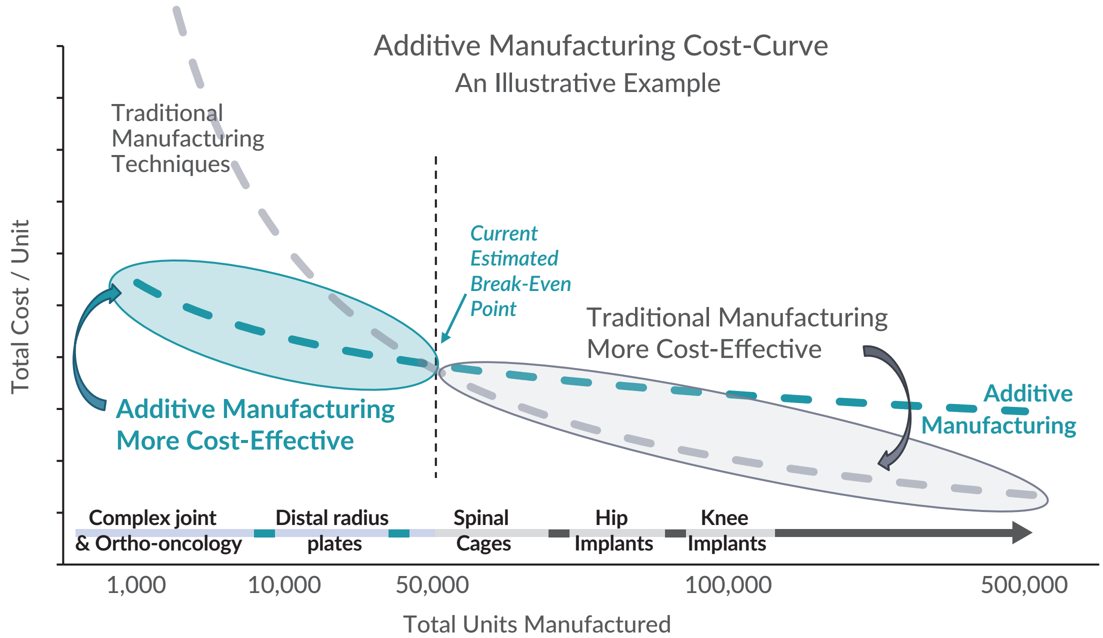
Sources: Health Advances analysis; Avicenne



Sources: Health Advances analysis, Ricles 2014 Rapid, FDA 2017

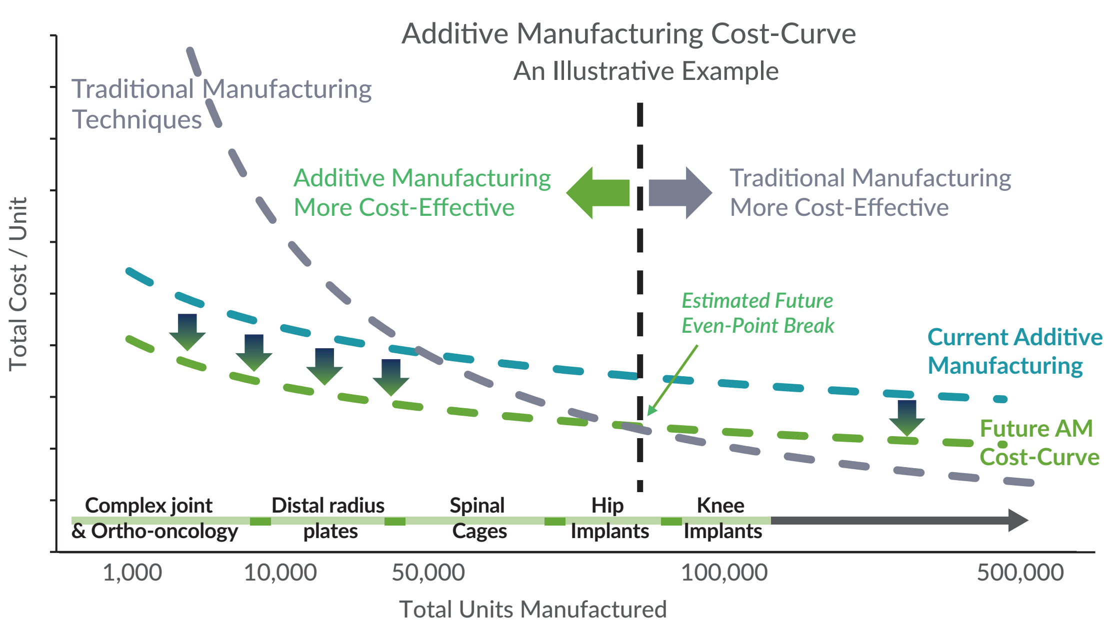
While CMOs seek to enter into more collaborative design and development relationships with their OEM customers, this is often only feasible with the mid-to-smaller OEMs. The majors, on the other hand, have large in-house design and engineering departments to drive product development, plus they want to retain the intellectual property in-house and not have that sit at the CMOs, so they can retain more negotiating leverage on purchases and pricing of those products.

Figure 3
Current Additive Manufacturing Cost Curve



Sources: Health Advances analysis; Advanced Manufacturing

Figure 4
Future Additive Manufacturing Cost Curve



Sources: Health Advances analysis; Advanced Manufacturing

Yet, like any new manufacturing technology or material use, it takes practice to progress down the learning curve to ensure both top quality and affordability. Therefore, when OEMs are evaluating partners to help with additive manufacturing for new implants or instrumentation, they are looking for those with proven experience in design, production scale, and quality control within additive manufacturing. Most manufacturers can produce one-off prototypes, but it takes time and direct experience to become an expert in commercial additive manufacturing. The CMOs that lag in building this expertise risk being leap-frogged by their peers who are investing in the space, and/or by new entrants to the medical field that bring long histories of additive manufacturing in non-medical applications, such as in aerospace or automotive parts manufacturing.

Where Will 3DP be Performed for Ortho Implants and Instruments?

As various entities gain more experience with additive manufacturing and develop more evidence supporting clinical and economic value, the traditional, more centralized manufacturing model is being challenged. With the ability to print only what you need, when you need it, and with manufacturing efficiencies at smaller scale production (i.e. production lots from one to many implants), the potential for a more disseminated manufacturing model is feasible. This opportunity has not been lost on academic medical centers or their vendors and has led to new kinds of collaborations (*see box, "San Francisco VA Health Center's Experience"*).

Academic medical centers associated with leading universities that have programming, materials and manufacturing expertise are natural early innovation centers that can advance these new approaches. UCSF is one of the pioneers incorporating 3DP into production of patient-specific implants to enhance the clinical ease and speed of the procedure, as well as to improve patient satisfaction due to better fit in applications such as trauma fixation. To-date, UCSF has ordered the actual 3DP implants from manufacturers operating outside of its facilities, but it is forming new kinds of industry collaborations to advance its goals of incorporating 3DP more fully into its MSK practices moving forward.

In complex upper extremity reconstruction and deformity correction, the use of 3D planning software and patient-specific 3DP guides can be the difference between a single surgery with great outcomes, or repeat surgeries with inferior outcomes, Lattanza stated during the Health Advances/UCSF forum. "The reality is that currently most of my patients with complex deformities can and do benefit from these technologies—I see a future where we use 3DP implants routinely in all trauma and other skeletal reconstruction procedures," she stated.

Since 2011, Lattanza has been partnering with engineers at **Materialise** to create detailed 3D images of her patients' deformities matched against images of the healthy side of the patients' anatomy. By overlaying the two in 3D, she and the engineers are able to develop a surgical plan, along with custom guides and, in the future, custom implants to ideally match the patient's natural anatomy. She has done more than 120 cases using this technology and trained more than a dozen fellows on its use, based on the belief that this approach enables a faster operation, with less time under anesthesia for the patient, less blood loss, faster recovery, and better functional and cosmetic outcomes.

UCSF has had an early leadership role in embedding 3D technology within its healthcare system, and one of the university's leading proponents has been Aenor Sawyer, who co-moderated the forum with Health Advances' Paula Ness Speers. Over the past decade, Sawyer, an orthopedic surgeon and health-tech innovator, has leveraged 3DP to prototype devices, and she presented examples of those experiences. In 2017 she co-hosted the 3DHEALS/UCSF conference convening industry and academic leaders and highlighted 3DP contributions to healthcare including education, surgical planning, prototyping and testing, guide and implant fabrication, and bioprinting. Subsequently, she and UCSF collaborators realized the importance of establishing onsite capabilities for 3DP at UCSF and thus established EDGE Labs in the department of orthopaedic surgery. Her role in space health innovation also drives her interest in this technology, she noted.

These initiatives led to communication with other 3D investigators on campus, and in 2018, Sawyer teamed up with some of them to launch the Center for Advanced 3D+ Technologies (CA3D+). A multidisciplinary initiative,

San Francisco VA Health Center's Experience with 3DP Models

Hospitals across the country, in particular academic medical centers and thought-leading institutions like UCSF and HSS, have been using on-site or near-site 3DP of anatomic models for pre-surgical planning for several years. Alan Dang, MD, staff surgeon at the San Francisco VA Health Center, gave several examples of in hospital printing of 3D anatomical models in orthopedics and spine surgery at the hospital during the Health Advances/UCSF forum. On-site printing has allowed the hospital to "provide rapid turnaround on clinical timeframes, reduce shipping costs and associated logistics, and lower costs to iterate and help educate the patient," he said.

In one case, an anatomical model of the complexity of a fracture helped convince a patient that a fusion of the ankle was a better clinical decision than the patient's originally desired open reduction and fixation. In a different situation, the hospital saved $13,000 in direct costs by avoiding the need for a custom shoulder implant. The printed model allowed the surgeon "to target his screw fixation for the glenoid component" and turn to an OTS product by matching the 3D physical model of the patient's anatomy with OTS implants offered by various manufacturers to find the best-matched OTS implant. 3DP models are also a "fantastic training tool for residents as they prepare to help in cases," Dang pointed out. His colleagues have seen such immense benefits "that any time a CT scan is obtained at the SF VA, a 3D print is considered," he said.

the center's founding partners are from the departments of orthopaedic surgery, cardiology and radiology, and collaborators come from neurosurgery, ENT and other surgical specialties. The center provides inhouse end-to-end capability for producing precision anatomic models and visualizations (in VR/AR/or flatscreen) from clinically indicated CT scans, Sawyer said. Investigation is also underway in the complex areas of on-site cutting guide and implant fabrication, as well as bioprinting. "In addition to enhancing surgical planning, CA3D+ is improving rapid prototyping, trainee and patient education and supports research initiatives in the effectiveness (in cost and care) of 3D+ capability on the frontlines of healthcare. This knowledge is essential to ensure sustainable, responsible implementation of these new technologies and advance them from novelty to standard of care in the healthcare system," she added.

Dang, who is also on faculty at UCSF and a participant in these programs, shared additional examples supporting his view of 3DP's ability to improve the performance of spinal fusion devices by creating more open and porous cage structures that facilitate bony ingrowth faster and more completely. These benefits can only occur through additive manufacturing and distinguish spine surgery from other common uses of 3DP in that the benefits are independent of patient-specific and patient-matched sizing of devices. His enthusiasm led to the founding a year ago of **PrinterPrezz Inc.**, a 3DP contract manufacturing company, that enables partnerships with local hospitals and collaborative agreements to accelerate product development and manufacturing in the field. The company has four co-founders, including Dang's brother, Alexis, who is an orthopedic sports medicine surgeon, also at UCSF. They share chief medical officer responsibilities. The company also just announced that 3DP aerospace pioneer Greg Morris, who retired from GE last year, is joining its board of advisors—an indication, Dang says, of top talent's interest in the field's medical applications.

PrinterPrezz also has a new partnership with **SI-Bone Inc.**, a manufacturer of implants for MIS sacroiliac joint fusion, in which the manufacturer can access PrinterPrezz's customized development and build services for potential future 3DP advanced devices and implants. *iFuse-3D*, Si-Bone's second-generation, additively manufactured implant, was introduced in 2017 and has come to represent a significant share of the company's US implant sales among its *iFuse* product line.

UCSF is far from alone in leading the integration of 3DP into MSK. In January, HSS and Lima announced an expansion of their 5-year relationship focused on 3DP of implants for complex cases (*See box, "HSS and LimaCorp"*). While historically Lima has produced 3DP implants for HSS's most complex ortho cases in Italy, the company is now building out a design and manufacturing facility on the HSS campus in mid-town Manhattan to provide the hospital with even faster design-to-patient turnaround time. The proximity to HSS's large internal engineering and design team should enable both parties to work more closely together to ensure the best solution for each patient, Leach said.

To date, 3DP has focused largely on pre-operative planning and surgical instruments, and OTS porous structure implants—such as spinal cages and custom implants for unique anatomies or revision surgeries that require longer lead times. But what about "just in time" implants that are made on-site for each patient in real-time as they are undergoing surgery? It may seem that this is the making of a science fiction movie, but a 5-year research collaboration between Stryker and St. Vincent's Hospital in Melbourne, Australia (announced in 2017) is bringing this closer to reality. While this is essentially a proof of concept study, and focused on bone cancer patients, it demonstrates the potential of printing patient-specific implants in real-time by combining the digital navigation capabilities inherent in a surgical robot with 3DP (*see Figure 5*).

HSS and LimaCorp: Bringing the Implant Product Closer to Bedside

The agreement between HSS (Hospital for Special Surgery), and LimaCorporate to build and operate an additive manufacturing facility on a teaching hospital campus is the first of its kind and will focus on creation of custom implants for highly complex surgical cases. The facility will be operated by Lima and will leverage HSS's expertise in clinical care and its engineering team. Speaking at the Health Advances/ UCSF forum, Douglas Leach, Managing Director, Biomechanical Innovation at HSS' Global Innovation Institute, highlighted that by putting manufacturing near the hospital, the collaboration between surgeons and engineers can improve exponentially, and the speed at which implants get to patients may be similarly improved. The relationship is geared to enable research, training, and rapid product innovation. While it will initially focus on supplying the metro NYC area, this facility will have the potential to service other clinical locations in the region.

When and Why Will 3DP in Ortho Become Manufacturers' Preferred Approach?

As outlined above, not only is 3DP being integrated into the commercial manufacturing capabilities of traditional orthopedic OEMs and CMOs for OTS and patient-specific implant production, but various experiments are active in more local and non-traditional settings and relationships.

So the question is not "Will 3DP become more mainstream as a core manufacturing technology for ortho and spine implants?" but "How quickly will 3DP penetrate and become one of the core manufacturing techniques for ortho and spine implants?"

The rationale for the increased penetration of 3DP into orthopedic implants is driven by both clinical and economic benefits. Clinically, 3DP is enabling better outcomes through applying its technical capabilties of printing integrated high-porosity surfaces on hip implants to enable enhanced fusion, as well as the "open architectural struts" designs in spine implants which permit greater ingrowth of bone, and are only manufacturable with 3DP technology.

It is also enabling cost-effective printing of patient-specific implants, which lead to better fit, easier surgical procedures, better clinical outcomes, and better patient satisfaction in CMF and TKA procedures. And, of course, 3DP enables patient-specific implant solutions for complex deformity and revision cases, where previously an assemblage of OTS "parts and pieces" had to suffice.

But 3DP enables much more than improved clinical outcomes—it can enable a reduction in the overall cost of a case through a variety of levers (*see Figure 6*).

In an industry that is beset by pricing pressures and above-average SG&A expenses, compared to the rest of the medical device industry, these economic advantages will become more and more important to manufacturers trying to drive total costs down to remain competitive on price.

In summary, we have already moved past the early application stage of 3DP in the musculoskeletal sector. 3DP is now not only the choice for complex cases in which patient-specific implant needs cannot adequately be met by standard OTS implants made with traditional

Figure 5

Current Just-In-Time and On-Site 3D Printing Pilots

"Just-In-Time" Implants

ST VINCENT'S HOSPITAL MELBOURNE · RMIT UNIVERSITY · stryker

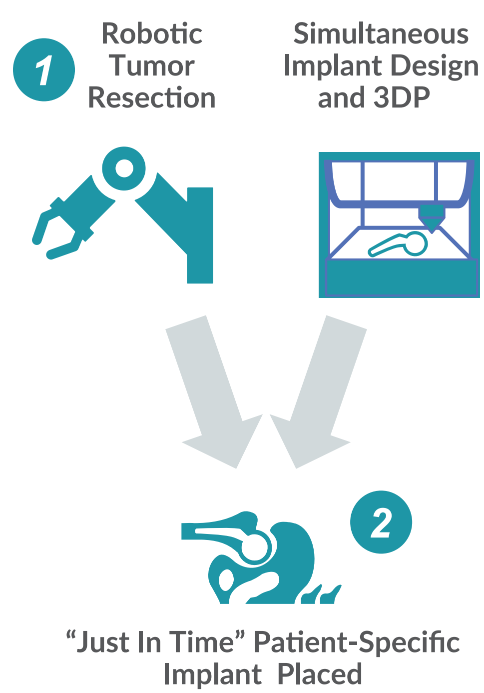
- Real-time 3D printing of orthopedic implants for musculoskeletal tumor resection
- 5-year collaboration between Stryker and St. Vincent's hospital in Melbourne Australia
- Collaboration started in October 2017

FUNDING: Jointly funded, Stryker ($8.7M USD) and IMCRC ($1.7M)

PURPORTED BENEFITS: Maximal bone and soft-tissue retention, reduced LOS

"Our aim is to bring [custom 3DP] to the theatre. While patients are having their cancer removed in the operating theatre, in the next room, we are custom printing an implant to precisely fill the space left after removal of the diseased bone."

– RMIT Professor Milan Brandt, lead researcher on the project



Note: IMCRC=Innovative Manufacturing Cooperative Research Centre; RMIT=RMIT University, Melbourne, Australia.
Sources: Health Advances analysis; Company websites; Press releases; 3D Print

manufacturing technologies, and for CMF cases where cosmesis is highly valued, but its use has broadened to OTS applications, where it is already the manufacturing method of choice in spine implants.

Furthermore, clinicians are increasingly interested in leveraging the technology to move from "good enough" implants to "patient optimized implants" not only for the clinical benefits and improved patient satisfaction benefits, but also to make the surgical procedures easier and faster, as enhanced planning and better patient-matched implants reduce/eliminate device manipulation in the OR. Questions linger over where production will take place and who will control it—the hospital, the OEM, or to some extent the CMO—but those are matters of logistics, not 'ifs.' FDA oversight is another unsettled area, but here too, it is a matter of how to navigate FDA, not if it will be approved. A 2017 proposed guidance lays out what companies submitting 3DP devices for regulatory approval need to consider.

The economic advantages of 3DP will become more important to orthopedic manufacturers trying to drive down total costs to remain competitive on price.

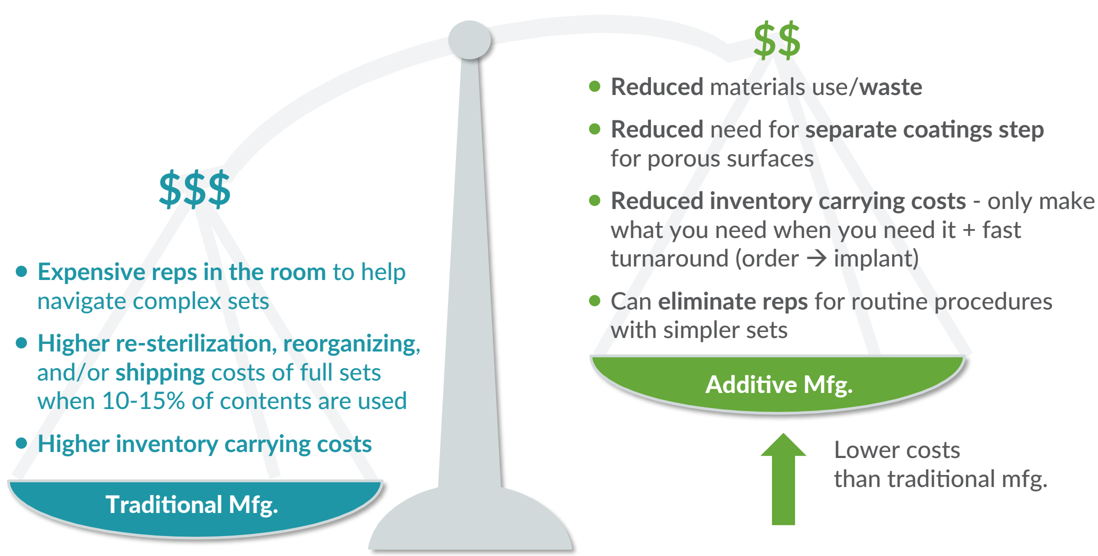
Manufacturers that embrace 3DP technology to the fullest cannot only provide surgeons and patients with better matched implants, but they have the potential to dramatically reduce manufacturers' upfront investment in implant and instrument sets for new product launches by being able to respond in real time to demand with just-in-time production of required implants and instruments. They can also reduce the complexity of instrument sets by providing simplified sets that include the targeted implant size—as determined by pre-op imaging and 3D planning—and associated instruments for the patient-specific procedure. This is already happening regularly in simpler procedures, such as ACDFs (anterior cervical discectomy and fusion), which are often performed in ambulatory surgical centers with simple, single-use instrument sets and targeted implants delivered for each procedure, and we expect to see much more of 3DP in MSK implants and instruments—both patient-specific and OTS versions—in the years to come.

The next horizon for 3DP in orthopedics is bio-printing of soft tissues for tissue repair and replacement solutions, but that's a topic for another day.

Paula Ness Speers (pnspeers@healthadvances.com) is Co-Founder and Managing Director, Masha Dumanis is a Director, Brandon Wade is Engagement Manager, and Matthew Barnes is a Senior Analyst at Health Advances. Aenor Sawyer, MD, is Director, UCSF Skeletal Health Service, Dept Orthopaedic Surgery.

Figure 6
Assessing System-Wide Manufacturing Costs of 3DP vs. Traditional Mfg.

System-Wide Economic Benefits of Additive Manufacturing Must be Fully Evaluated



Source: Health Advances