

Research Article

Patient-Specific Orthopaedic Surgery: An Economic Analysis on 3D Printing Devices

Kevin Rezzadeh, MD^{1a}, Lukasz Witek, Msci, PhD^{2b}, Jacques Hacquebord, MD^{3c}

¹ Orthopaedic Surgery, New York University Langone Medical Center, ² Department of Biomaterials, NYU, ³ Department of Orthopaedic Surgery, New York University Langone Medical Center

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3D printed (3DP) devices are an exciting option for clinical use by orthopaedic surgeons. This study is an economic analysis with a specific focus on personalized surgery. Specifically, we survey the existing landscape of 3DP devices in orthopaedic surgery and explore the benefits of 3DP in preoperative planning and intraoperative instrumentation. We conclude that 3DP is both a financially viable and clinically beneficial aid to the practice of orthopaedic surgeons, provided medical practices and hospitals can overcome potentially high upfront fixed costs and initial delays in clinical adoption.

INTRODUCTION

Orthopaedic surgeons are tasked with correcting various musculoskeletal pathologies. Given the variation in musculoskeletal anatomy, personalized operative planning and devices are a plausible means of improving surgical outcomes. Additive manufacturing (AM) more commonly known as 3D printing (3DP) has the potential to provide customized, patient specific devices (Mulford, Babazadeh, and Mackay 2016). 3DP technology uses a pre-defined digital tool path to fabricate a solid object in three-dimensions using computer aided/designed digital file, stacking layers in the z-axis, of finite thickness until the device is built. While the technology has been widely utilized in research and development, it has not yet made its way to the clinical applications level. This economic analysis review explores potential barriers to its incorporation and benefits to its implementation, with a focus on personalized surgical instrumentation.

BARRIERS TO INCORPORATION

MANUFACTURING

Most, if not all, orthopaedic devices are fabricated in manufacturing facilities offsite from clinical centers. These devices are produced in bulk and ultimately distributed to hospitals and surgical facilities. Device representatives may relay feedback from surgeons to engineers, but there is in some instances a disconnect between surgeon needs and the products device manufacturer deliver. As surgeries become more complex and the standards for success rise, there may open a need for more personalized surgical instrumentation. With the advancement of 3D printing, medical implants fabricated by additive manufacturing (AM) technology can be produced in small batches. The fabrication of these custom patient and surgery specific devices may be time consuming and often requires multiple iterations of between the manufacturing facility and surgeons, lending to increased pricing in comparison to the "off-the-shelf" devices. However, with advancements in technology

^a [Conflicts of Interest Statement for Dr. Rezzadeh](#)

^b Information About Lukasz Witek
[Visit Lukasz Witek's Profile Page on NYU/Langone Site](#)
[Connect With This Author on LinkedIn](#)
[Conflicts of Interest Statement for this author](#)

^c Information About Jacques Hacquebord
[Visit Jacques Hacquebord's Profile Page on NYU/Langone Site](#)
[Connect With This Author on LinkedIn](#)
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and collaboration, 3D printing (3DP) has evolved to make the manufacturing of medical devices closer to the final desired product, ultimately changing the dynamic amongst suppliers, providers, and patients. With the advancements made, there has been an increased demand by hospitals and physicians to have implant production capabilities in house. 3D printed medical implants made at point-of-care facilities allow for maximum customization based on the patient's anatomy, age, and activity level to ensure best fit. Additionally, through innovation labs within the institutions or partnerships with medical 3D printing leaders and vertical integration of the supply chain, hospitals can build out hardware and software infrastructure tailored to the clinical practice of their surgeons.

One of the primary difficulties in implementing 3D printing of devices in hospitals and private surgical centers is that many do not have the proper facilities, equipment, and personnel. Due to these shortcomings, clinicians and technicians may currently focus on outsourcing printing and sterilization procedures to 3rd party vendors (*i.e.*, General Electric Additive, 3M). Additionally, there are safety and environmental requirements for every device manufacturing facility with respect to materials and storage. On average the processing steps to fabricate the device are as follows: manufacturing, sterilization, and delivery, which may have extended lead times, in turn yielding increased lag times between scheduling of surgery to actual date/time of surgery (Abdullah and Reed 2018). While this delay may be acceptable for patients undergoing elective orthopaedic procedures, it may be problematic for urgent surgeries. Hospitals and/or private practices incorporating 3D printers into their facilities or alternatively partnering with local 3D printing centers have the potential to help minimize lead time.

Aside from the lack of infrastructure, another hurdle for the adaptation of 3D printing at the point of care is access to materials and associated testing infrastructure for the creation of 3DP medical devices. For example, some vendors utilize as many as eight different materials to 3D print a single knee prosthesis (Lin et al. 2019). The chemical characteristics of these materials such as purity and toxicity must be considered prior to beginning the fabrication process (US Food and Drug Administration 2013). The standardization of raw materials specifications and the processes around manufacturing could minimize the possibility of adverse patient reactions, although this practice could limit device customizability at individual centers (Christensen and Rybicki 2017).

An additional challenge at times is access to the 3D printing technology. 3D printing patient specific, custom devices requires volumetric data acquisition from imaging modalities such as computed tomography (CT) or magnetic resonance imaging (MRI). The volumetric data helps model the object to match region of interest, and is then exported to the printer for fabrication (Abdullah and Reed 2018). Imaging modalities such as CT or MRI are readily available at most hospitals and medical centers, while there are various digital file formats available, choosing an incorrect file type or conversion has the potential to lead to technical is-

suces that may impact the 3D printing process and efficacy, and ultimately the quality/safety of the device. Interdisciplinary efforts to improve both surgeon familiarity and access to 3D printing technology are likely to further improve clinical adoption.

CLINICAL EVIDENCE

The lack of long-term clinical outcomes regarding personalized surgery is potentially one of the largest contributing factors making surgeons hesitant to incorporate 3D printing into their practice (Lin et al. 2019). Prior to any novel procedures, surgeons commonly look to peer-reviewed literature in addition to peer experience. Due to its novelty in the field, 3DP orthopaedic device literature is primarily comprised of case reports and case series, which tends to be low quality evidence and not confidence-inspiring for hospitals or surgical centers contemplating implementation of such technology. In a preliminary randomized controlled trial, 3DP templates have appeared to outperform the existing standard of care, “*off-the-shelf*” templates. However, the generalization of these studies to the field of orthopaedics is lacking, given the limited clinical scenarios with 3D printed devices. Lastly, aside the need for better assessing clinical benefits, to date there has been no cost-effectiveness analysis to justify additional fixed costs that may be incurred as a result of orthopaedic device customization or long-term cost savings as a result of in-house device manufacturing and/or better patient outcomes.

REGULATORY HURDLES

Like other innovations in healthcare, the implementation of 3D printing is associated with significant regulatory hurdles. The Food and Drug Administration (FDA) follows the Quality System Regulation (QSR) with additional technical considerations for 3D printers and 3D printed devices. Therefore, the FDA evaluates the manufacturing processes, software, and ecosystem around 3D printing. Manufacturers are encouraged to collaborate with consultants who will provide guidance with the submission of the petition to the FDA, prolonging the approval process (Christensen and Rybicki 2017).

The Center for Device and Radiological Health (CDRH) at the FDA is responsible for providing device manufacturers with guidance related to each aspect of the manufacturing process, including design, production, labeling, and testing (US Food and Drug Administration 2013). Ultimately, the CDRH reviews and approves 3D printed medical devices (Christensen and Rybicki 2017). Manufacturers are required to abide by quality systems to ensure that their products achieve the acceptable standards, known as the current good manufacturing practices (CGMPs) (Food and Drug Administration 2018). The development of new devices constantly pushes the boundaries of current guidelines and recommendations requiring the FDA to remain up to date in terms of new regulatory challenges with the technical guidelines made readily available on its site (US Food and Drug Administration 2017). As utilization of additive manufactured devices increases, policy guidance from the

FDA will adapt along the way. Regulatory control over these devices once they become better adopted has the capacity to improve both the safety and tracking of adverse events related to the use of 3DP devices. Ultimately, future success of 3D printing will pose regulatory challenges as there may not be appropriate predicate devices for proposed customized patient and site-specific devices/implants.

BENEFITS

EFFICIENCY AND EFFICACY

Questions that arise from patients regarding the potential use of 3D fabricated devices during surgery surround its efficacy, safety, and cost. Currently, studies have reported the benefit to utilizing 3D printed models in the planning of surgical procedures. A recent literature review, indicated that employing this technology has shown to aid in surgical procedures as a both a visual-tactile model for planning or mock operations and preadaptation of surgical instruments to patient anatomy before ever stepping foot in the operating room (Shilo et al. 2018). Additionally, shorter operative times have been correlated with decreasing patient's risk of infection as well as allowing for speedier post-op recoveries.

The benefits of 3D printing do not only effect operative planning and surgical tools, as this technology offers the capacity in customization of both the device morphology and device finish. The process of 3D printing with layers of materials forms complex geometrical shapes and surfaces that previously were not feasible through traditional, subtractive manufacturing (milling), practices (Cai 2015). It is anticipated that the initial benefits of this customizability to be utilized in complex orthopaedic cases such as orthopaedic polytrauma, oncologic bone resections, as well as in more challenging revision surgeries. Increased demand in mainstream orthopaedic 3D printing may occur concurrently, where procedures utilizing 3D printed device have shown a reduction in the time patients spend in the operating room, under anesthesia, or undergoing recovery. With such positive advantages, this technology can gain a foothold in academic centers to further quantify these benefits. Furthermore, improvement in these types of procedures can positively influence the accuracy of the procedure itself, determined by how well the device fits within the patient's body, both in the short and long term, as the patient regains functionality. As the use of patient-specific implants within orthopaedic procedures is very recent, no long-term benefits have been measured.

As an experimental technology, the cost burden of preliminary 3D printed orthopaedic devices will likely fall upon hospitals and manufacturers rather than individual patients. Last year, category III CPT codes, temporary five-year codes for emerging technologies, have been issued for 3D printed instruments and devices. Factors that are used

to establish permanency of CPT codes to category I CPT codes include widespread physician use and clinical evidence. In preliminary uses of 3D printed objects, hospitals and device manufacturers will need to subsidize patient costs in exchange for the potential added risk to the patient undergoing a relatively untested technology along with the lack of insurance coverage for such procedures. Academic medical centers may be encouraged to use these products at an initial financial loss to be perceived at the forefront of using cutting-edge and gain future expertise in increasingly competitive healthcare markets. As clinical evidence emerges touting the benefits of 3D printed technology in both economic and health outcomes, insurance companies could also be incentivized to cover these devices. Additionally, even in situations where insurance may not cover the custom devices, sufficient surgeon demand could prompt hospitals to negotiate contracts with 3D printing manufacturers for these devices as "physician preference items."

DELIVERY

Orthopaedics is a field ripe with partnerships – with major healthcare brands partnering with technology companies, healthcare systems, and government systems partnering with private companies.¹ Ambulatory surgical centers and hospital systems seeking credibility and expertise may benefit from entering into partnerships with large device manufacturing companies or smaller 3D printing companies. This could be one of the reasons that existing 3D printing providers have partnered with companies like GE Healthcare on bringing technology for model printing to physicians (Shilo et al. 2018). Direct partnerships between 3D printing companies and hospitals to open centers may be a natural evolution in the surgical 3D printing industry. Last year LimaCorporate, an Italian orthopaedic device company and long-time vendor of New York's Hospital for Special Surgery (HSS), officially partnered with the orthopaedic hospital to open their own additive manufacturing center. The impetus for this partnership was HSS's desire to cut down on production and wait times for printed materials, so clearly the need for more efficient production is actively being considered by physicians and hospital systems (Cai 2015). Offering this kind of exclusive partnership is not only attractive from a business perspective, but would also provide a platform for continued product innovation. The ability to ideate and then experiment and implement directly with patients at the hospital allows for quicker solutions to complex patient cases.

However, 3D printing technology may be logistically difficult to adopt given existing hospital-manufacturer relationships and high initial costs associated with personalized 3D printing. As hospital margins become tighter and the use of orthopaedic device sales have increased, there are incentives for hospitals to partner with device manufac-

¹ [3D Printing Partnerships Take Physician Resources, Patient Care to the Next Level](#)

turers in exchange for rebates (Healy 2006). These agreements may be threatened by clinical adoption of new 3D printed devices. Anticipating a potential shift in orthopaedic device manufacturing in the years to come, some major orthopaedic device companies may offer expertise and materials in 3D printing to hospitals in exchange for licensing fees.

If customized devices ever become mainstream enough to compete with standard orthopaedic devices, established device manufacturers may find it easier to price their universal devices more competitively relative to patient-specific 3D printed devices due to economies of scale. Depending on the extent of clinical benefit demonstrated after 3D printing implementation, there may be difficulty in justifying additional costs associated with device customization to patients, hospital systems, and insurance companies. Additionally, the production of 3D printed implants may be cumbersome at first, though manufacturing times could shorten considerably as utilization increases.

CONCLUSION

In summary, partnerships between hospitals and recognizable orthopaedic manufacturers may offer both clinical and

economic benefits to orthopaedic surgery services. Early fixed costs and slow clinical adoption of 3D printing may dissuade hospitals from adopting this technology. However, if 3D printing technology establishes its theoretical benefits clinically, there may be benefits to the expertise gained by early adoption, particularly in urban markets, in which large hospital systems compete to attract patients looking for the latest in surgical treatment. Vertical integration of device manufacturing within hospitals themselves could also promote a culture of innovation, with greater collaboration between surgeons and engineers in producing devices to meet patient needs. As new technologies emerge, software can be upgraded and new plans offered to facilities, preventing obsolescence of currently used tools. Additionally, standard update or upgrade packages could be offered to hospitals based on a subscription or contract. Though still in its infancy, 3D printing in orthopaedic surgery has the potential to emerge as a great way to facilitate positive change in patient outcomes through the creation of personalized medical equipment.

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