CRIMSON PUBLISHERS
Wings to the Research

Orthopedic Research Online Journal

ISSN: 2576-8875

Review Article

Advances in Modern Medicine: Is 3D printing the way ahead?

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Submission: May 05, 2018; **Published:** August 17, 2018

Abstract

It is said that necessity is the mother of invention and rightly so. The innovation of 3D printing which arose from the creative minds of science fiction authors is fast becoming a vital reality in nearly every industry on the planet. The sector where its impact can be tremendous and is breaking grounds is healthcare industry. The technological advances are escalating at a speed which is causing difficulty to the providers to keep up. Surgeons and physicians are using 3D technology to cause a remarkable transformation in providing "individualized healthcare" in this era of "personalized medicine". 3D technology is currently being used across the world for patient treatment, from cutting-edge prosthetics, to dental and facial implants, to organ models and tracheal splints [1,2].

Introduction

Traditional manufacturing techniques work on a "subtractive" process where excessive material is carved away from a rough part that was cast or forged. 3D printing, which is also called "additive manufacturing", works on the principle of creating objects which are built up in successive layers using a variety of materials, with the ink serving both as a substrate and substance [3]. With progressing years since its inception, 3D printers have reduced both in their size and cost, enabling its widespread use in different industries. The technology dates back about 30 years, so it is not new. What makes it exciting, however, is that costs have come down drastically making it much more accessible to the public.

Uses of 3D printing

1. Producing custom-shape components

A. Patient-specific implant manufacturing like hip and knee joints,

B. Precontoured plates,

C. Scaffolds such as vertebral cages as well as meniscus

D. Prosthetic implants for ear ossicles

E. Cranial prosthesis meant to replace lost bone in the skull.

F. New faces and earlobe for trauma victims

G. For spine surgery and spine cages [4,5]

H. Custom polymeric and metallic implants for complex reconstructions, such as tumor surgery

I. Craniomaxillofacial surgery [6,7]

J. Patient specific antibiotic impregnated articulating cement spacer.

2. Patient-specific jigs/ instrumentation: to improve the precision and clinical outcome of surgical procedures.

3. Bio printing & tissue engineering:

A. Dermal skin grafts substitutes printed on 3-D printers into host recipients [8]

B. Cartilage defects 3D printing [9]

4. Anatomical models and simulation tools:

A. Practice models for difficult-to-visualize fractures and deformities to help explain the patients or students the details of the surgery.

B. For presurgical planning or

C. Can sterilize and use it in the operating room (OR) for intraoperative guidance.

D. A "negative" mold of the implant could be made to guide the surgeon in shaping bone grafts during surgery if so desired.

E. Other surgeons are designing their own prototypes of new surgical tools or bone replacement options.

5. Prosthetic limbs for amputees.

6. 3-D printed exoskeleton-like cast that is light-weight, strong and breathable.

7. Imagine losing or breaking a part of an instrument during surgery: simply print it from a data file directly at the hospital, sterilize it, and use it immediately.

8. Surgical planning: site, number and orientation of osteotomies in deformity correction-hopefully to reduce surgical time, improve outcomes and eventually optimize benefit risk ratios.

The possibilities are endless.

Method of 3D Printing

A 3-D printer successively lays down fine layers of the chosen material in a way that is dictated by a sophisticated computer-aided design (CAD) program [10]. Patient specific medical imaging (MRI, CT scans, X-rays etc) -->treatment planning-patient communication-->implant design-->digital 3D printing of a personalized implant and instrumentation. An idea for an indigenous implant/instrument-->modelled using computer-aided design (CAD) software-->printed using desktop 3D printer to fabricate first conceptual models-->refine and make changes as required-->metal 3D printing. One of the pros of 3D printing in designing implants is the amount of freedom it allows in manufacturing more customized anatomical shapes along with the possibility of easily forming porous bone substituting scaffolds. Adding porosity is very difficult in a machining application, because it relies on a laser taking material away from a solid part or a secondary material being applied. But with 3D printing, porosity can be built into the design and accurately output by the printer. These porous scaffolds allow for bone ingrowth, ensuring bio integration and greater stability as well as longevity. A direct relationship between the surgeon and the prosthesis designer must be established, and mutual trust must be created, for a customized approach to deliver optimal results. The 3D printers of today also can create objects in different materials, including but not limited to metals, plastics, silicone, silver, gold, titanium, ceramics, and wax. Several grades of titanium (Grade CP1/2, Ti6Al4V ELI), alloys of cobalt-chrome (e.g., ASTM F75) and alloys of stainless steel (e.g. 316L) are available commercially.

Concerns of 3D Printing

Non-legal

One of the concerns is that many of the 3D implants that companies claim to be customized are not truly "custom" according to FDA. These in fact cover a wide range of size and design parameters which is known as "Envelope submission". After appropriate patient imaging (CT or MRI), they are matched with several computational combinations of finite number of sizes of different parts to create the 3D printed device. This is not the same as creating the exact matching part as required for the patient. Another concern of the shape freedom in 3-D printing is the cleaning requirements of the instruments and implant in the designing and manufacturing phase. Other common concerns are the high image dependency (quality of CT and MRI scans), 3D printing being a time-consuming process with high surgeon dependency in designing part. All the deformities in 3D printing applications are dealt with in a static manner with no accurate measure to test accuracy intraoperatively. Historically, 3D printing including the software's has been expensive, however this is fast changing. The material used, and the final manufactured product needs careful regulation to ensure safety and efficacy. What remains unanswered is whether such inexpensive technology will derange the complicated, computer-guided surgery systems currently doing the rounds in market.

Legal

Several uncharted legal issues arise in the use of 3D printing in modern medicine. The use of 3D technology in the healthcare sector is privy to the fact that modern technology often moves more rapidly than the law itself. Key legal issues include the regulatory landscape, intellectual property, tort liability, environmental effects, health risks in the workplace, and insurance risks and recovery (reimbursement). With the Medical Devices Rules, 2017 coming into force recently, India is introduced to a new medical device regulatory framework. This regulatory framework, however, is devoid of provisions apropos 3D printed medical devices. Whether medical devices are printed in a central location or on-site at hospitals, university medical centers, or doctors' offices, environmental issues and employee health risks may merit attention given that plastic filaments, combustible powders, and high temperatures all may be part of the 3D printing process. Moreover, 3D printing in healthcare attracts privacy concerns. CADs and replicas might contain personal data, especially in cases where 3D printers are often used to test surgeries. In such cases, doctors often get manufactured a perfect copy of the patient's organ to see whether during the surgery the patient will encounter any issue. But do hospitals require patients for a privacy consent to the 3D printing of their organs? And what happens to that 3D printed organ after the tested surgery? The precise effect of modern technologies such as 3D printing on traditional product liability law is difficult to predict, especially when it isn't certain who is to be made liable for any wrongful service/defects. But it is abundantly clear, that as 3D printing continues to unsettle traditional manufacturing, products liability law will likely evolve to accommodate the new, and ever-growing technology. As access to the technology expands, so do concerns of legal issues surrounding regulation and product liability [11].

Conclusion and Future of 3D Printing

3-D printing is already causing a revolution in industry with its benefits being huge. The greatest advantage achievable would

How to cite this article: Kunal A, Alisha A, Kashish A, Pankaj A, Kavita A. Advances in Modern Medicine: Is 3D printing the way ahead?.Ortho Res Online J. 4(1). OPROJ.000579.2018. DOI: 10.31031/OPROJ.2018.04.000579

be bioprinting of tissues resulting in greater possibilities of joint preservation, deformity corrections and management of trauma. The market forces might shape how much popularity 3-D printing achieves. Hopefully in future 3D printing would be quicker, more economical and easily manufacturable, even in OT. With better imaging and processing algorithms, surgeon dependency may be reduced, and the result would be a product meeting exact patient requirement. 3D printing can provide patient care that is customized, patient oriented, and caregiver-inclusive that may prove to be superior to current standard of care. Moreover, 3D printing could even potentially enable patients to print their own medicines at home. The pharmaceutical industry could eventually witness a transition from prescriptions to algorithms. Doctors could hand off an algorithm for patients to go print at home on a 3D printer rather than jotting down "take 2 and call me in the morning" on a sheet of paper. Ultimately, regardless of the promises of any new technology, cautious research is warranted to prove safety, clinical efficacy and value for money for patients and healthcare providers alike. The way ahead is fraught with scientific, ethical, legal and regulatory hurdles; however, the time is right for 3D printing to emerge as a new paradigm in healthcare industry.

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