Application of 3D Printing in Healthcare

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Acceleration | Value | Technology

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Abstract:

3D printing plays a small but rapidly expanding role in medical and dental device manufacturing. According to the 2013 Wohler's report, the 3D Printing industry had combined revenue of $2.204 billion in 2012. Medical and dental applications were responsible for roughly a sixth of it at $361 million. Overall 3D Printing Industry is projected to be $8.4 billion in 2020.

Applications in medical devices include rapid prototyping, VOC, printing medical device components and surgical & dental guides. Hospitals are starting to use it for creating 3D models of surgical areas to assist planning of complicated maneuvers like skull base tumor removal. Other frontier applications in the medical field which are still in research stage include printing the scaffold for complex organs, organ systems, blood vessels & heart. It is being tested to print skin for burn victims, print cartilage and bone for orthopedic implants.

Like any new technology, 3D printing also faces a lot of moral, religious, regulatory, and legal issues particularly considering the sensitive nature of the healthcare industry. Its cost, accuracy and effectiveness of large scale manufacturing also has a long way to go before it matches traditional high volume manufacturing. Therefore, while 3D printing in healthcare is interesting, it is likely to be somewhat controversial being confined to low volume lesser regulated areas in the near future. However it could evolve into a complex, interdependent eco-system of biotechnology firms, device OEM's, regulators, insurers, patients, care givers, government and others.

Abbreviations:

Sl. No.	Acronyms	Full form
1	3D	3 Dimension
2	FDA	Food and Drug Administration
3	VoC	Voice Of Customer
4	OEM	Original Equipment Manufacturer
5	CAD	Computer Aided Designing
6	CAM	Computer Aided Manufacturing
7	CNC	Computer Numerical Control
8	IP	Intellectual Property

Introduction:

3D printing is a process for making a physical object from a three-dimensional digital model. Additive manufacturing, usually used synonymously with 3D printing is a manufacturing technique where solid objects are manufactured by adding one or more specific material in successive layers [1]. Although the term additive manufacturing is used interchangeably with 3D printing, it is not the only process involved. Even though 3D printing is predominantly additive, subtractive manufacturing process like cutting, drilling, polishing, chiseling can also be used in 3D printing processes [2].

3D printing is done by a 3D printer using a computer designed digital model. In additive manufacturing, the material/s is delivered by one or more nozzles on a moving platform. This result in patterns laid one above the other, resulting in 3D objects. The digital model gives the inputs to the printer regarding the materials used, mobility of the platform and the quantity dispensed [3].

The materials used may be plastics like ABS or acrylic, metals including stainless steel, sterling silver, glass, ceramics, resins, sandstone or rubber [4]. Most low cost 3D printers are filament printers where the extruder is heated up to melt plastics. The extruder then squirts out a thin string of molten plastic onto the moving platform’s surface. More expensive 3D printers use a resin, and the most-expensive models use a powder that is melted or liquefied to bind to the layer below it [3].

3D printing has emerged from a niche process or a hobby to a level where it has created interest among mainstream manufacturers and OEMs. Use cases are now sprouting in many industries including aerospace, defense, medical, automotive, architecture, consumer products among others. The growing importance of 3D printing processes can also be gauged by the fact that the latest version of operating systems like Windows 8.1 offers support to 3D printing [5]. 3D Builder is a free 3D printing app which is bundled with Windows 8.1.

3D printing also plays a small but rapidly expanding role in medical and dental manufacturing. It is now seeing its first commercial use in areas like orthopedics, dermatology, disposables, surgicals and in the manufacturing process of medical and dental devices. In this white paper, we will see the additive manufacturing market landscape and applications especially with respect to the healthcare domain, solutions that can be of interest to service organizations in this space along with the best practices applicable, and the common problems faced in this domain.

Market:

According to the 2013 Wohler's report, the 3D Printing industry had combined revenue of $2.204 billion in 2012. Medical and dental applications were responsible for roughly a sixth of it at $361 million [6]. Overall 3D Printing Industry is projected to be $8.4 billion in 2020.

Applications in Organ Growth:

- Assist planning of complicated surgical maneuvers like skull base tumor removal
- **Precise arrangement of human embryonic stem cells** – 3D printers can be used to squirt nano liters of stem cell culture which contains as little as 4 or 5 cells in precise arrangement over a scaffold to make complex organs and organ systems [7]
- **Organs and Organ Systems** – There is potential for 3D printing of organs like liver and kidney [8] [9]. A firm named Organovo now expects to unveil a printed human liver of 500 micron thickness next year
- **Printing blood vessels & heart tissue** – The same process can be used to make blood vessels to be used for grafting purposes [10]
- **Printing skin** – Printing skin involves designing a scaffold using collagen like material and applying pluripotent stem cells over the scaffold [10]

Application in Orthopedics:

- **Printing cartilage & bone** – To print this type of bone replacement, the 3D bio-printer creates a scaffold in the bone shape and coats it with adult human stem cells, which can develop into many different tissue types. The printer's "ink" consists of a polymer called polylactic acid and a gel-like substance called alginate. This delivers the hard, mechanical strength of bone, along with a cushioning material for the cells [10]

Applications in Medical Devices:

- **Rapid prototyping** – Application of 3D printing techniques in the development of prototypes decreases the time to market and improves the quality of the final product. Using 3D printing also improves the synergy between various teams like industrial design team, hardware team, and software team thereby improving the likelihood of finding the best fit.
- **VOC** – 3D printing enables companies to get valuable user input at an early stage in design
- Manufacturing medical devices and components
- Manufacturing surgical guides – These are the “compasses” that surgeons uses to identify skin surface markings over which incisions can be made to access inner organs

Solutions:

Rapid Prototyping:

HCL offers rapid prototyping and low cost development solutions for a large group of manufacturing industries including medical OEMs. The capabilities include creation of design data, modeling, and manufacturing using CAD-CAM. It also includes software for CNC which are linked to 3D printers, VOC services linked to rapid prototyping.

These services make sure that the time to market is reduced and the product is closer to what the customer wants. Rapid prototypes help the industrial design team and the engineering teams agree on an optimized design much more quickly. It also overcomes the supply chain management problem of traditional manufacturing for prototypes.

Rapid prototyping using 3D printing also enables faster launch times for the product by enabling concurrent engineering as the whole product is not needed for a large portion of test cases.

Design Templates for various devices:

Apart from the above mentioned services, HCL actively pursues the development of frameworks and solutions to provide design template solutions for various common devices including disposables and surgical instruments. Using these templates, the creation of designs of these instruments can be much faster than starting from scratch.

Other possible solutions

1. Development of softwares to identify bony defects by a 3D scan whose dimensions can be used to design a replacement
2. Software for 3-D–printed surgical guides which surgeons place over the surface of the body to guide their drills and knives as they bore and cut into flesh and bone.

By incorporating innovative solutions around 3D printing, HCL brings flexibility in the new product development workflow.

Limitations and Common Issues with 3D Printing

It would have been clear by now that 3D printing has some obvious advantages. However, sensitivity to a number of considerations is needed when new boundaries are broken using science and engineering. Following are the common issues that arises out of the emergence of 3D printing

Cost and Time

3D printing can’t compete with mainstream manufacturing technologies with respect to cost and time for manufacturing. It may take anywhere between a few minutes to several hours to manufacture a product using 3D printing depending upon the material used, size and complexity. It is also possible that 3D printing companies might lock in consumers through a proprietary supply chain channel which might increase the cost of ownership.

Limitations of Material and Size

Today 3D printing is commonly done with only limited materials like plastics, resins and a few metals. Usage of other materials while technically possible, can be very costly and/or time consuming. In healthcare domain, care should be taken while creating implantable Usage of bio compatible materials which would avoid allergic reactions while creating tissues or other implantables is limited right now to labs and proof of concepts. Further, it is extremely difficult and expensive to build something which has more than one material in it. The size of the printer also limits the size of the product and it may be very difficult to produce parts of large industrial machines.

Competing Technologies

Competing technologies are now being introduced which challenge 3D printing in at least some areas. One of the main threats is “Laser Origami” which is claimed to be significantly faster and precise compared to 3D printing. According to bitrebels.com, “The laser uses a combination of cuts and heating in order to separate and bend the plastic sheet into what the user wants to create.” [11]

Ethical and IP Considerations

The capability of synthetically manufacturing human organs and other body parts using 3D printing will raise ethical, moral and religious questions about the role of man in manipulating the nature’s own selection process – again!

"Most people do not yet realize that research is underway which involves not only printing non-human cells, but also merging human cells with non-human cells. We think that once folks begin to realize, depending on their backgrounds, there will be some who will be concerned about this possibility," Gartner research director Pete Basiliere says [12]

The rapid emergence of 3D printing will also create major challenges in relation to intellectual property (IP) theft. Gartner predicts that by 2018, 3D printing will result in the loss of at least $100 billion per year in IP globally [13]

Insurance Considerations

Since 3D printing is a disruptive industry, it is not easy to understand the future implications beyond educated guesses. Since insurance industry typically needs historical data to calculate claims, they have their work cut out with respect to calculating the claims that may arise out of this industry category.

The potential claims can be a product liability including accidental injury/damage due to the 3D printed product or legal liability due to IP issues [14].

With a supply chain which may not involve any physical products as designs and manufacturing processes can be sent electronically, traceability becomes a problem too. This calls for professional indemnity cover

There could also be an employer’s liability angle, as the raw materials used are sometimes powder based, so there is potential for respiratory issues for employees operating the machines to long-tail employers’ liability

Regulatory Considerations

The FDA currently treats 3D-printed devices the same way it treats conventionally made medical devices. In order for a new device to receive FDA approval, its creators must either prove the device is equivalent to one already marketed for the same use, or the device must undergo the process of attaining premarket approval

Since 3D-printed products are made using a different manufacturing method than traditional medical devices use, they could require additional or different forms of testing. Two FDA laboratories are looking into ways 3D printing could affect the way medical devices are manufactured [15]

The FDA's **Functional Performance and Device Use Laboratory** uses computer-modeling methods to determine how tweaks to a medical product's design could affect its safety and performance in various patient populations

The FDA's **Laboratory for Solid Mechanics** focuses on how different printing methods affect the strength and durability of the materials used to make the devices

The lab's findings "will help us to develop standards and set parameters for scale, materials, and other critical aspects that contribute to product safety and innovation," FDA scientists wrote in a recent blog post

Conclusion:

3D printing technology is beginning to disrupt traditional manufacturing practices. Although it still cannot beat the cost and scale advantage of traditional manufacturing which is supported by huge supply chains and just in time practices, it has started to make sense in certain niche areas particularly small scale manufacturing and prototyping.

Not surprisingly, it has found application in healthcare too. There is now buzz about 3D printing of organs, organ systems, blood vessels etc. While these applications are at the cutting edge and have not yet reached the stage of commercialization, 3D printing is increasingly being used commercially in new product development of medical and dental devices. This is possible because of its ease of use and flexibility in rapid prototyping and obtaining VoC if there is an in-house manufacturing facility which can produce prototypes inexpensively. It also promotes collaboration between the industrial design and engineering teams which usually work in tandem during the initial phases of new product development.

Therefore, companies which provide designing solutions as a service to OEMs can leverage the advantages provided by 3D manufacturing in its new product development and sustenance workflow. These companies can give specific services to medical device OEMs by providing design templates of various commonly used medical devices like disposables and surgical instruments. The service firms can also actively pursue development of software services for 3D OEM's so that they can support medical functions like identifying bony defects by a 3D scan whose dimensions can be fed into the computer to design a replacement.

Like any other new disruptive technology, 3D printing applications in healthcare also brings with it a unique set of challenges and considerations. These include challenges on ethical, moral and religious grounds and considerations with respect to insurance, intellectual property and regulatory issues. Good faith and thought therefore needs to be applied when such technology is applied to a field as sensitive as healthcare. While the intentions are noble, proper frameworks and guidelines should be evolved which makes sure that the considerations are addressed while not stifling innovation.

While 3D printing in healthcare is interesting, it is likely to be somewhat controversial being confined to low volume lesser regulated areas like prototyping, training, research and VoC in the near future. However it could evolve into a complex, interdependent eco-system of biotechnology firms, device OEM's, regulators, insurers, patients, care givers, government and others.

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