3-D Bio-Printing

By Sue Coatney(NetApp), Biren Gandhi (Cisco), Beom Soo Park (AMAT), Dmitry Dzilno (AMAT), Emmanuel Munguia Tapia (Samsung), Gowri Kamarthy (Lam)

Abstract

3D printing is the process of creating a 3D object from a digital model by using additive manufacturing, in which an object is made by adding material layer by layer and fusing it together. This approach contrasts with traditional manufacturing, in which an object is formed by removing excess material. This report will focus on 3D printing in the medical field and discuss the current state of technology, disruptive changes, societal impacts, affected industries, the value net analysis and the opportunities for new businesses.

Currently, 3D printing is being used for dental fabrication and prosthetics manufacturing. In addition, researchers are actively exploring the potential of printing bones, tissues and organs for replacement. It is projected that in the next decade there will be significant advancements in this area, which will result in adoption and commercialization of these technologies. According to the United Network for Organ Sharing (UNOS), more than 113,000 patients in the U.S. are currently waiting for an organ transplant. As a result of this technology, there will be fewer number of people waiting for organ replacement and the mortality rate for organ replacements either from the wait time or from issues relating to recipient's compatibility with transplanted organ will be greatly reduced.

As these technologies advance, several regulatory and societal factors will need to be addressed. For example, since the tissue or organ will have to be matched to the recipient, FDA approvals will be necessary. Societal factors, such as athletes enhancing their performance with additional 3D-printed muscle tissue, would have to be considered and regulated. Another major shift would be longer life expectancy, which would impact retirement, savings, social security, and Medicare.

The industries that will be impacted positively with this technology include computer-aided design companies, hospitals and insurance companies saving on expenses related to transplant logistics, stem cell storage and harvesting. The industries that will be negatively impacted include dialysis centers, companies that manufacture pacemakers and heart valves, organ-replacement logistics and transportation.

In summary, 3D bio-printing will have a huge impact on society and people's lives, along with tremendous business opportunities.

Introduction of 3-D Bio-Printing

A 3D printed object is printed in layers, and then the layers are joined or fused together. 3D printing is currently prohibitively expensive, so it is not yet a viable replacement for high-yield manufacturing. However, 3-D printing is very effective for designing prototypes or replacing custom parts. For example, BMW is currently creating car part prototypes using 3D printing. 3D printing is also being used for rapid prototyping in research labs and industries as well as in industrial design, engineering, architecture, construction, automotive, jewelry, dentistry, medicine, civil engineering, automotive, aerospace, and education.

Hypothesis

3D printing is evolving quickly from rapid prototyping to having wider industrial application, particularly for custom or unique parts. In the medical field, this will have a disruptive impact on bone, tissue, and organ replacement, as they are bio-printed instead of sought for in compatible donors. As a result, there will be a drastic positive shift in quality of life with corresponding impacts in business, government, and society.

We emphasize that 3D printing is likely to affect many facets of society, but this paper focuses primarily on the medical field.

3D Bio-Printing Technology [17]

This chapter was completely removed from the original paper due to potential copyright or inadequate citation issue. The pertinent 3D Bio-Printing Technology overview information is still available from the original source (please see the reference [17]) . Authors encourage the curious readers to take a detour from this paper at this point and familiarize themselves with the state of technology and progression of thereof by browsing the site [17]. Authors would like to extend sincere apologies to the readers for the inconvenience and extend apologies to the site author Christopher Barnatt for possible, but clearly involuntary, violation of his rights.

Signed by Dmitry Dzilno personally and for the Authors team

Technology Progression

3D printing technology for medical applications is presently an active topic of research. For instance, there are early stage laboratory prototypes demonstrating on how to print medication, new skin, cartilage and bones (like skull fragments), replacement tissue (such as blood vessels and heart tissue), and even complete replacement organs (such as kidneys and embryonic stem cells.) The subsections below briefly describe practical progress made in each of these areas.

Printing medication. A team of researchers at the University of Glasgow, led by Cronin Lee [13] created a 3D printing application that prints laboratory equipment specific to the experiment they wish to run. Cronin indicates that this technology is the first step towards technology that could allow people print their own medicine at home. With a custom-built 3D printer and chemical inks, users would download the appropriate molecules to perform molecular assembly on the fly.

Printing skin. The last 25 years have seen great advances in creating tissue-engineered skin, which could replace skin damaged from burns, skin diseases and other causes. Recently, scientists have added 3D printed skin to their repertoire. Lothar Koch [5] of the Laser Center Hannover in Germany and colleagues laser-printed skin cells, as reported September 2010 in the journal "Tissue Engineering Part C: Methods."

Printing cartilages and bones. 3D cell-printing efforts have also begun focusing on reproducing the skeletal system. In 2011, researchers in Washington State University [8] used a 3D printer to create a bone-like material and structure that acts as a scaffold upon which new bone can grow. Similarly, Lothar Koch [5] of the Laser Center Hannover in Germany and colleagues have developed laser printing to create grafts from stem cells that could develop into bone and cartilage. Their work was published in January 2011 in the journal "Tissue Engineering Part C: Methods." In May of this year, CNET reported that 75 percent of an American patient's skull was surgically replaced with a custom-made implant produced by a 3D printer from Oxford Performance Materials [7].

Printing replacement tissue. Printing replacement tissue to "patch" or fix existing organs is another active area of research. For example, researchers developed a "heart patch" made of 3D-printed cells that could repair damaged hearts. Ralf Gaebel of the University of Rostock, Germany, and his colleagues [10] made such a patch using a computerized laser-based printing technique. They implanted these heart patches into the hearts of rats that had suffered heart attacks. The patched hearts showed improvement in function, the scientists reported in December 2011 in the journal "Biomaterials." Gabor Forgacs from the University of Missouri in Columbia and colleagues [12] printed blood vessels and sheets of cardiac tissue that "beat" like a real heart. Their work was published in March 2008 in the journal "Tissue Engineering." Forgacs and others started a company called Organovo to bring these products to market. A group at the German Fraunhofer Institute [11] created blood vessels by printing artificial biological molecules with a 3D inkjet printer and zapping them into shape with a laser.

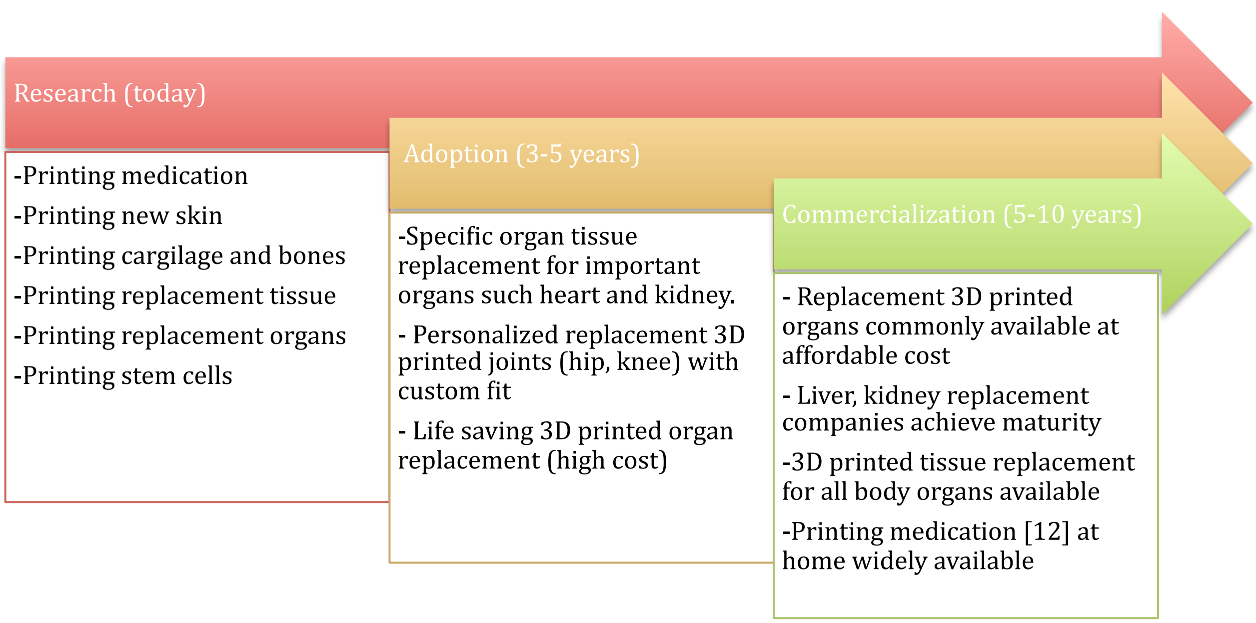
Printing replacement organs. In a stirring talk from TED2011, Anthony Atala [6] described his research in the development of an organ-printing 3D printer. Atala introduced a product of a similar technology — a bladder grown by borrowed cells. He believes this technology could be a solution to the present crisis of the shortages in donated organs.

Printing human embryonic stem cells. Stem cells can now be printed, at least in the lab. In a study published February 5, 2013 in the journal "Science," researchers from the University of Edinburgh [9] describe a valve-based cell printer that prints living human embryonic stem cells. The cells could be used to create tissue upon which to test drugs or grow replacement organs, the scientists report.

Studying cancer with printed cells. Printing cells could lead to better ways of studying diseases in the lab. Researchers are already using automated systems to print ovarian cancer cells onto a gel in a lab dish where the cells could be grown and studied. The printing approach could enable scientists to study cancerous cells in a more systematic environment, and use them to test treatments. The study, led by biomedical engineer Utkan Demirci of Harvard University Medical School and Brigham and Women's Hospital, was published February 2011 in "Biotechnology Journal."

Research into 3D bio printing is still in its early stages, but it is occurring today in laboratories around the world. We believe, by analyzing existing trends, that some of these technologies will be adopted within the next three to five years. Namely, (1) specific organ tissue replacement for important organs such heart and kidney, (2) personalized replacement 3D printed joints with custom fit, and (3) 3D printed organ replacement will become available. For the next five to 10 years, technological adoption will become widespread and commercialized as the technology continues to mature. 3D technology may become commercialized in this order: (1) Replacement 3D printed organs commonly available at affordable cost, (2) Liver, Kidney replacement companies achieve maturity, (3) 3D printed tissue replacement for all body organs available, and (4) 3D printed medicine [12] widely available.

The diagram below summarizes our beliefs in how 3D printing technology will evolve from today's laboratory research and early prototypes into adoption (within three to five years), and eventually into widespread commercialization as the technology matures (in five to 10 years).



Regulatory and Societal Factors

The ability to 3D bio-print bones, tissue and organs will inevitably have regulatory and societal impacts. The FDA, which has the charter of both promoting and protecting the public's health, will play a critical role in how 3D bio-printing is used within the United States. The FDA will need to approve the process of 3D bio-printing for any bone, tissue, or organ transplants, as well as the process of implanting these replacement parts into humans and any follow-up care. As every person has unique DNA and consequently will have unique bone, tissue and organs, there may be additional regulatory approvals required. These additional hoops every patient will be subject to could stifle the adoption of the technology.

Another societal factor to consider is performance-enhancing tissue augmentations. Should a marathon runner, for example, be allowed to have additional muscles bio-printed to enhance their performance? Should a swimmer be permitted to artificially improve his or her lung capacity? Should athletes who do so be banned from competing, and how should we detect it? This is also an issue for soldiers since a superior army could be engineered using bio-printing technology.

These potential enhancements, enabled by 3D bio-printing, could gradually become accepted as normal as time goes on. One must ask whether bio-printing needs to be regulated or controlled, and how a "good" body modification differs from a "bad" one. Otherwise, society might let technology move forward without regulation down a path towards potentially irreversible and adverse societal impacts.

There are also end-of-life issues that need consideration. If body parts can be easily replaced, will people opt to stay perpetually young through replacement instead of aging normally? Such a choice could have dire consequences on population growth, Social Security, and retirement planning. Furthermore, although it sounds far-fetched now, it may soon be possible to replace the brains of people who have suffered from strokes or Alzheimer's.

One must also inquire after the affordability of 3D bio-printing procedures. If only those who can afford these procedures receive them, it could lead to significant magnification of the social divide between those who can and cannot afford the procedures.

Finally, if or when the technology for printing medications at home becomes available, there will be a need to regulate what types of medications users are allowed to print. People could easily print recreational or illegal drugs, or misuse prescription drugs that are not intended for them.

Industries Impacted

Numerous industries will feel the effects of 3D bio-printing technology. While some industries will benefit, others will be negatively impacted.

Positively-Impacted Industries

Ultimately, the patients who are cured by 3D bio-printing technology are the big winners. However, several industry segments, described in this section, will see significant benefit as well.

Health insurance companies and government-funded health assistance services (like Medicare or British Healthcare) will save on recurring costs for chronic health issues. Dialysis treatment costs $55,000-$75,000 per patient per year. In 2007, Medicare spent $8.6 billion in dialysis costs for 335,000 patients [2]. Likewise, treatments for diabetes costs around $6,000 per year per patient, for a total cost of $245 billion per year in the United States [1].

Hospitals and insurance companies will also benefit financially from 3D bio-printing as they will no longer need to spend money on transplant logistics. In addition, both hospitals and surgical supply companies will benefit as customers flock to the hospitals that have organ transplant capabilities.

Since organ printing relies on the patients' stem cells, stem-cell harvesting and storage businesses will experience a positive boost. Even people who are concerned about what the future might bring will have stem cells harvested and banked so that they are ready to meet a future potential need. Computer-assisted design (CAD) software companies such as Rhino and AutoCAD [14] will benefit from this new expanding market, since designs for replacement organs will need to be created digitally. Likewise, companies that provide secure storage and movement of the large CAD designs will also benefit. For example, AutoDesk currently has revenues of $2B. Assuming a 10 percent jump due to an increased demand for images of replacement organs, AutoDesk will experience a revenue increase of $200 million annually.

Negatively-Impacted Industries

The kidney dialysis industry will be significantly affected once replacement kidneys can be 3-D printed. There are currently two major players in the United States dialysis industry: Fresenius, with revenues of $3.4B/quarter, and DaVita, with revenues of $2.3B/quarter. The total revenues of this industry are $22.8B/year. When replacement kidneys become readily available, both companies will see a significant drop in their revenues.

Diabetes supply companies currently have a market of patients buying blood sugar testing supplies, insulin, pills and insulin pumps. Were 3D bio-printing to become a commercialized reality, patients could get a replacement pancreas printed instead. Companies like OneTouch, which is a leading manufacturer of blood sugar monitors and testing supplies, are at risk. OneTouch is owned by Johnson & Johnson, which had annual revenue of $2.7B in 2011.

Companies that sell pacemakers and new heart valves are also at risk as replacement hearts become readily available. For example, Medtronic's Cardiac and Vascular Group had annual revenue of $8.48B and Medtronic Pacing Systems contributed $1.97B to that total. While not all patients would opt for a bio-printed heart replacement, there is still considerable risk to their revenue stream. [3]

The final industry segment that will be negatively impacted is organ replacement logistics (UNOS) and transportation.

Value Net Analysis

The products of 3D bio-printing will ultimately be sold not only to patients, but also to hospitals, medical practices and medical insurance companies. Hospitals that offer bio-printing will see an influx of patients in their facilities. Health insurance companies are also included in the customer segment, as they will need to make cost tradeoffs between ongoing patient expenses and the one-time cost of replacing whatever organ is unhealthy.

Suppliers of the 3D bio-printing industry are inkjet printer manufacturers, including Cube, HP, Cannon, and Stratasys. It is important to note that all of today's inkjet printers will continue to work as is. They only require that the print nozzles be modified for the new bio-material. The creation of a new kind of printer designed specifically for 3D bio-printing is an opportunity area.

Partners include current companies that are engaging in 3D printing (not bio-printing), like Cubify, Cimatron, Perception, 3D Systems, and Stratasys.

The only company that is currently engaging in 3D bio-printing as a business is Organovo, which is currently operating at a loss despite increasing revenues [4].

Opportunities

As a rapidly growing ecosystem full of life-saving applications, 3D bio-printing presents unprecedented business opportunities. Foundational elements of 3D printing technology are the design model, the printer and the material. Each one of the foundational elements offers a wide array of business opportunities.

Autodesk Inc.'s AutoCAD and similar software companies are championing creation of software design models compatible for use in 3D printing [14]. At the same time, many medical equipment makers in the areas of MRI scanning and X-rays are playing close attention to body scans and generating custom organ design models for bio-printing. Dentists could start utilizing patients' unique teeth layout and bone scans to create friendlier implants and prosthetics. Scanning and securely storing such scans and making them available at a later stage could itself become an industry.

A wide majority of today's research in 3D printing repurposes the printing heads and nozzles of traditional printers. Affordable, medical-grade and reliable 3D printers would surely be a new dimension for incumbent printer manufactures and could bring out new opportunities for niche players. A whole new outsourcing industry could emerge based on 3D printing of customized prosthetics, dentistry and other less-sensitive body parts that can be tailor-made for individual patients, similar to today's plastic and metal manufacturing industry.

Plastic and metal have been initial materials for rapid prototyping of 3D printing technology in industrial and automotive verticals. However, 3D bio-printing presents unique challenges as it requires a variety of synthetic materials suitable for manufacturing tissues, bones, cartilage and organs. A great deal of research in materials is either attempting to identify such elements, or using stem cells in conjunction with other synthetic materials. Organovo's MMX bio-printer has already discovered a way of printing live tissue from silicon gel base and stem cells [14]. Other companies are trying other approaches, including harvesting small batches of stem cells to serve as organic material. With this approach, researchers hope to minimize or eliminate the rejection rate of organ implants.

Along with these foundational elements of design, printing and material, there are many affiliated ecosystems that offer new business opportunities. For example, human organs may be printed in advance in case of an emergency. There may be opportunities for "organ lockers," a system that provides secure storage and transportation for customers' organs. When the cost of 3D scanners and printers become affordable for personal use, customers might want "scanning kiosks."

Summary

3D printing technology is quickly maturing, evolving and expanding beyond the industrial rapid prototyping stage. It is no longer restricted to lab or research projects –a commercial ecosystem is growing around various domains of application. Healthcare and surgical fields are especially crucial sectors in the future of 3D printing technology.

The possibility of printing medication [13], new skin, cartilage or bones [15,16] is only the start. Soon, numerous other bio-printing capabilities will emerge, all the way to printing tissue and replacement organs. Providing customized hip or knee joints fitting individual needs is no longer a dream. Producing tissues or organs from stem cells has already become a reality in labs. It is not unrealistic to imagine a time in which a majority of people's organs can be customized and printed in advance, stored in secure facilities and installed on demand at a later stage.

These advances in 3D printing technology bring out some critical social and regulatory challenges as well. How far one can go in replacing body parts to increase life span? What is the fine line separating organ replacement and cloning? How will government benefits and insurance agencies react to increased longevity? And what are the effects of social divide created through availability of technology at an affordable cost? All of these questions will soon become critical.

Of course, along with these challenges come tremendous business opportunities. The basic premise of 3D printing technology relies upon three foundational elements – the design, the printer and the material. Companies that have an early lead in any of those areas could very well set the future direction and growth of the 3D print ecosystem. In addition to tools and process-related companies, companies will jump at the chance to fill the demand for body part scanning, secure storage and transport of organs, surgical procedures for installing organs, and etc. These industries will provide exponential growth opportunities as a result of the 3D bio-printing technology evolution.

To summarize, 3D bio printing is going to have a huge impact on society and will offer unprecedented business opportunities in an exploding ecosystem.

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Biographies

Biren Gandhi:
Currently working as a Principal Architect with Cisco, Biren is spearheading crucial web/mobile technology initiatives for WebEx Social – an Enterprise Collaboration Software offered both on-premise and in the cloud to Fortune 1000 customers. Driven by his passion for practical innovation, Biren has led a series of Workplace Innovation Network (WIN) initiatives at Cisco to cultivate grassroots technical leadership. Prior to joining Cisco, he was divisional CTO of several gaming studios at Zynga and a Sr. Architect at Facebook before that. In between his roles at Facebook and Zynga, Biren co-founded a startup called AdMunity, a highly engaging collaborative social platform for the advertising community. He loves sharing interesting, action-oriented articles on innovation, leadership and organizational culture at http://thoughts.birengandhi.com/. Biren is actively engaged with a number of nonprofit initiatives in San Francisco and the Bay Area, and regularly participates in their annual Walk-a-thons.

LinkedIn: linkedin.com/in/birengandhi
Facebook: facebook.com/birengandhi
Twitter: twitter.com/birengandhi

Emmanuel Munguia Tapia: Dr. Emmanuel Munguia Tapia is the leader of the context awareness project at the advanced software platforms lab in Samsung Research America in San Jose, California. He directs a group of 15 researchers and four software engineers who focus on developing algorithms to infer human activity, location and context from sensory, social, location, and interaction data collected by mobile devices applying data mining, machine learning, and pattern classification techniques. Dr. Munguia Tapia previously worked for Nokia Research, Oracle America, Mitsubishi Electric Research, and Intel Research. Dr. Munguia Tapia received his PhD and MS degrees from the Massachusetts Institute of Technology (MIT) for his work on context awareness, and ubiquitous and wearable computing. His BS degree (with honors) is from the Instituto Politecnico Nacional (IPN), Mexico. He was named one of the best graduating engineers by the Mexican National Association of Schools of Engineering (ANFEI) and received the Presea Lazaro Cardenas Award, one of the highest recognitions of academic excellence given by the President of Mexico.

Sue Coatney: Sue Coatney is the Technical Director in the Data Protection Group at NetApp. Sue has architectural responsibility for Synchronous Data Replication where data is replicated to a backup site. Sue has also worked extensively in High Availability and Clustering solutions on Data ONTAP at NetApp. Prior to NetApp, Sue worked at Hewlett-Packard on the MPE-XL on device drivers and backup solutions, and on the HP-ServiceGuard solution, which provided High Availability solutions for the HP-UX operating system.

Beom Soo Park: Beom Soo Park has a master's degree in laser applications and a Ph.D in the study of synthetic diamond manufacturing and application using a CVD process. He works on PECVD systems and processes at Applied Materials.

Gowri Kamarthy: Gowri has a Ph.D in Chemical Engineering from the University of California at Berkeley, CA. She currently works at Lam in the Etch Product Group.

Dmitry Dzilno: Dmitry is the Senior Director of Engineering Managing Applied Controls Engineering (ACE) organization at Applied Materials, Inc. ACE's primary charter is to provide Control System, Electrical Interconnect and AC power distribution solutions to the company products for the Silicon Systems Group. Dmitry joined Applied Materials in 1996 as Technical Support Supervisor and has held positions of increasing responsibility in Common Software Organization and Foundation Engineering. Throughout his career at Applied Materials, Dmitry helped to drive the innovation agenda by introducing and adopting cutting-edge industrial control system architecture and technologies for process control. In 2004, Dmitry completed the Applied System Engineering course with credits from the Cornell University AGU program. Prior to Applied Materials, Dmitry founded and successfully ran two small companies that operated in the area of service and medical electronics.