

Application of 3D Printing in Medical Devices New Product Development

by

Michael David Sandford

B.S., Mechanical Engineering, Lehigh University, 2010
M. Engineering, Energy Systems, Lehigh University, 2011

Submitted to the MIT Sloan School of Management and the Department of Mechanical Engineering in
Partial Fulfillment of the Requirements for the Degrees of

Master of Business Administration and
Master of Science in Mechanical Engineering

in conjunction with the Leaders for Global Operations Program at the
Massachusetts Institute of Technology

June 2017

© 2017 Michael Sandford. All rights reserved.

The author hereby grants to MIT permission to reproduce and to distribute publicly paper and electronic
copies of this thesis document in whole or in part in any medium now known or hereafter created.

Signature of the Author _____

Signature redacted

MIT Sloan School of Management, Department of Mechanical Engineering

May 12, 2017

Certified by _____

Signature redacted

Steve Spear, Thesis Supervisor

Senior Lecturer, MIT School of Management

Certified by _____

Signature redacted

Brian Anthony, Thesis Supervisor

Principal Research Scientist, MIT Department of Mechanical Engineering

Accepted by _____

Signature redacted

Maura Herson, Director of MIT Sloan MBA Program

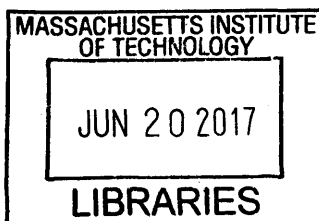
MIT Sloan School of Management

Accepted by _____

Signature redacted

Rohan Abeyaratne, Chairman, Committee on Graduate Students

Department of Mechanical Engineering



ARCHIVES



77 Massachusetts Avenue
Cambridge, MA 02139
<http://libraries.mit.edu/ask>

DISCLAIMER NOTICE

Due to the condition of the original material, there are unavoidable flaws in this reproduction. We have made every effort possible to provide you with the best copy available.

Thank you.

The images contained in this document are of the best quality available.

THIS PAGE INTENTIONALLY LEFT BLANK

Application of 3D Printing in Medical Devices New Product Development

by

Michael David Sandford

Submitted to the MIT Sloan School of Management and the Department of Mechanical Engineering

on May 12, 2017

in Partial Fulfillment of the Requirements for the Degrees of

Master of Business Administration

and

Master of Science in Mechanical Engineering

Abstract

For Johnson & Johnson (J&J), a healthcare industry leader, speed to market is a valuable component of any New Product Development (NPD). This is especially so in its Medical Devices (MD) franchise—increased saleable lifetime, first mover advantage, customer loyalty, and company reputation for innovation are just some of the reasons that accelerating the pace of development is a priority at J&J. Despite the incentives to speed up the development process, a typical MD product introduction takes three years from initial prototyping to full launch. Over this period, the product is repeatedly refined, prototyped, and tested for reliability and safety prior to production at high volume to meet expected demand. Throughout this process, J&J has historically favored proven manufacturing techniques such as machining and injection molding, which are well understood by the company's designers and manufacturing engineers but lead to long development cycles and high costs when used iteratively, as in NPD. Because new products can improve patient care—which is at the core of J&J's Credo—the company is currently investigating methods to accelerate the NPD process. One way to accelerate development that is being explored is enabled by the burgeoning field of additive manufacturing, or 3D Printing. Traditionally used only for early prototyping and development, innovation in 3D Printing over the past decade and recent FDA guidance on the subject opens the opportunity for its use in late-stage development, tooling, and even end production healthcare products. The scope of this effort was to investigate how MD can use 3D Printing to shorten NPD time from early prototyping through launch, with a target of two months acceleration.

Through literature review, expert interviews, and close work with three project teams at J&J over the six-month duration of this effort, a portfolio of technical and organizational improvements were identified to improve New Product Development speed in Medical Devices. The use of 3D Printing was found to have a positive impact on all phases of development, ranging from initial design through high-volume manufacturing, with a cumulative effect of over 8 weeks of project-dependent improvement. An organizational structure was proposed to speed adoption of any new technology by using a twofold approach, which focuses on improving both organizational knowledge and internal processes to optimize

company value. Additional proposals for using 3D Printing to reduce time to market include: using Direct Metal Laser Sintering (DMLS) for improved injection molding tooling; increasing developer access to local 3D Printing technologies; establishing decision rules to determine appropriate investment in new technology; using polymer 3D Printed injection molds for improved prototyping; increasing minor design iterations to minimize major reliability tests; improving availability of cutting-edge high-volume additive manufacturing technologies; and developing Design for Additive Manufacturing (DFAM) guidelines to decrease the learning curve for engineers. In compilation, these proposals show significant potential to increase the rate of organizational learning around 3D Printing and accelerate the pace of NPD in MD. 3D Printing therefore has the ability to benefit not only J&J's financial position, but also the patients it serves through new products and improved clinical outcomes.

Thesis Supervisor: Steven Spear

Title: Senior Lecturer, MIT School of Management

Thesis Supervisor: Brian Anthony

Title: Principal Research Scientist, MIT Department of Mechanical Engineering

THIS PAGE INTENTIONALLY LEFT BLANK

Acknowledgements

This work would not have been possible without the help and support of many individuals along the way.

First and foremost, I would like to thank my lovely fiancée, Samantha, for your love and support over the past two years. You have made my time in the Leaders for Global Operations (LGO) program possible with never-ending encouragement, boundless optimism, and daily selflessness. I especially thank you for your support over our time apart during the bulk of this project—I would not have been able to do it without you.

Next, I'd like to thank my family: Steve, Scott, Mom, Dad, Grandma, and Grandpa (and Donnie). You've been so supportive throughout my life, and have inspired me to take chances and do great things. I feel so blessed to have such an amazing family to come home to.

I'd also like to thank my MIT advisors, Dr. Brian Anthony and Dr. Steven Spear, for their insights, encouragement, and recommendations throughout this project. I appreciate the opportunity to work under both of you, and this project would not have been a success without your help.

Further, I'd like to thank Caleb Dailey, for his invaluable help over the six months I spent at J&J. You provided me direction, treated me as a peer, and offered me time out of your busy schedule from the first day I arrived, and for this, I am grateful. I will miss our thought-provoking daily conversations about not just 3D Printing, but also life in general. Through my time working for you, I learned so much about how to manage a team effectively while navigating a complex business environment. My time at J&J would not have been as educational, fun, and impactful without your guidance.

Next, I'd like to thank Sudhir Patel and Peter Ostiguy for their technical guidance and expert insights. I enjoyed the chance to work together, and I really appreciate the work you both put in to help me find direction. I would not have been as effective without your support, and this project certainly would not have been the same without you.

Lastly, I'd like to thank the countless engineers, project managers, and scientists at J&J who have contributed to this work. Specifically, I'd like to thank Mark Cosimi, Manny Gillio, and Sam Onukuri who helped find excellent projects where I could test my hypotheses. Furthermore, Scott Nield, Dan Luna, and Simon Cohn were great resources who not only connected me with their project teams, but also offered me the opportunity to work among them. I'd also like to thank the Launch Management team, including Anthony Sostre and Rashmeet Sangari, for being so supportive and helping me get my feet on the ground.

Finally, I'd like to thank Filip de Keersmaecker for sponsoring this project—the LGO program would not exist without support like yours. I truly enjoyed working as part of the VCM team.

THIS PAGE INTENTIONALLY LEFT BLANK

Table of Contents

1	INTRODUCTION.....	15
1.1	PURPOSE OF PROJECT	15
1.2	PROBLEM STATEMENT	15
1.3	PROJECT GOALS	16
1.4	PROJECT HISTORY AND APPROACH	16
1.4.1	Understand organization and technology	18
1.4.2	Work within projects to prove value	19
1.4.3	Design structure for implementation strategy	19
1.4.4	Test and refine implementation strategy through simulation	19
1.4.5	Transition process to sustaining organization	19
1.5	THESIS OVERVIEW	20
2	BACKGROUND	21
2.1	INDUSTRY OVERVIEW	21
2.1.1	Typical Product Profile	22
2.1.2	Benefits of Speed to Market in Medical Devices	24
2.2	JOHNSON & JOHNSON	24
2.2.1	New Product Development at J&J Medical Devices	25
3	ADDITIVE MANUFACTURING TECHNOLOGIES AND CAPABILITIES	29
3.1	ADDITIVE MANUFACTURING OVERVIEW	29
3.1.1	Classes of available 3D Printing Technology	30
3.1.2	Available Post-Processing Options to Improve Printed Parts	33
3.1.3	Advantages of Additive Manufacturing	34
3.1.4	Drawbacks and limitations of current technologies	36
3.1.5	Emerging Technologies	37
3.2	USE OF ADDITIVE MANUFACTURING IN MEDICAL DEVICES	39
3.2.1	Industry trends	39
3.2.2	Key competitor behavior	40
3.2.3	Key industry focus area: scan-to-print	41
3.2.4	FDA Guidance	42
3.3	USE OF ADDITIVE MANUFACTURING AT J&J	42
3.3.1	3D Printing Expertise	43

3.3.2	Organizational learning around 3D Printing at J&J	43
3.3.3	Internal Capabilities	44
3.3.4	External Capabilities	46
3.3.5	Current Process for producing 3D Printed parts	46
3.3.6	Business Commitment to 3D Printing	47
3.3.7	Value Generation from AM	47
4	DEVELOPING AN IMPROVED STRATEGY FOR USING 3D PRINTING IN NPD	49
4.1	INTRODUCTION	49
4.2	OPPORTUNITY IDENTIFICATION AND ANALYSIS.....	49
4.3	IMPROVING ORGANIZATIONAL 3D PRINTING KNOWLEDGE TO SPEED NEW PRODUCT DEVELOPMENT	53
4.3.1	Designing an organization to facilitate 3D Printing learning.....	53
4.3.2	Practical implementation of the new organizational structure at J&J	57
4.3.3	Refining Organization Structure through Optimization Model	63
4.3.4	Discussion of Results and Recommendations from Simulation Data.....	72
4.4	IMPROVING ORGANIZATIONAL 3D PRINTING CAPABILITIES TO SPEED NEW PRODUCT DEVELOPMENT	76
4.4.1	3D Printing Technologies, Techniques, or Process Improvements to Enable NPD Acceleration	76
4.4.2	Discussion of Results.....	98
4.5	CULTURAL IMPACTS	102
4.6	APPLICATIONS OF RESEARCH TO OTHER AREAS OF J&J	102
4.6.1	Applications of 3D Printing research.....	102
4.6.2	Applications of organizational structure research.....	103
5	RECOMMENDATIONS AND CONCLUSIONS.....	105
6	APPENDIX.....	106
6.1	3D PRINTING UTILIZATION ASSESSMENT FRAMEWORK	106
6.2	BEST FIT PARAMETERS FOR 3D PRINTED RAPID TOOLING	107
6.3	SIPOC ANALYSIS FOR 3D PRINTING BLITZES	108
6.3.1	High-level diagram	108
6.3.2	Detailed explanation of SIPOC analysis	109
6.4	SIMULATION DETAILS	113
6.4.1	@Risk Model Inputs	113

6.4.2	Non @Risk Model Inputs	114
6.4.3	Calculation Details.....	117
6.4.4	Simulation results.....	124
7	REFERENCES.....	132

List of Figures

Figure 1: Project approach for research and implementation	18
Figure 2: High-level framework for determining 3D Printing capabilities.....	18
Figure 3: DePuy Synthes Corail Hip System [19]	22
Figure 4: Ethicon Enseal for cutting and sealing tissue [20]	23
Figure 5: Ethicon Securestrap Open, for implanting a hernia mesh [21].....	23
Figure 6: New Product Development “Triad” [23].....	26
Figure 7: Development group involvement over the NPD cycle (not necessarily to scale) [23].....	26
Figure 8: Typical Medical Devices NPD critical path (~36 months total)	28
Figure 9: 2015 share of total 3D Printing industry demand by end-use industry [27].....	29
Figure 10: Breakdown of 3D Printing demand by end-use application [27]	30
Figure 11: Production component printed in Ultem [30].....	31
Figure 12: Complex part produced using Stereolithography [34]	32
Figure 13: Overview of 3D Printing categories for metals technologies [28]	33
Figure 14: Overview of 3D Printing categories for polymer technologies [28]	33
Figure 15: Deloitte framework for understanding AM paths and potential value [40].....	35
Figure 16: Basic process of Continuous Liquid Interface Production (CLIP) [48]	38
Figure 17: Quantity of 3D Printed medical devices with FDA approval [53]	40
Figure 18: Process of producing physical models from medical imaging [58]	41
Figure 19: Current relationships of groups influential in use of 3D Printing	44
Figure 20: Orders by operating company for one J&J lab	45
Figure 21: Pathway for internally producing parts at J&J	47
Figure 22: Quotes from various employees at J&J	52
Figure 23: Proposed organizational structure to maximize value from 3D Printing technologies	55
Figure 24: Ascending volume of resources from Pioneers to Developers.....	56
Figure 25: Cascade of industry knowledge between 3D Printing functional groups.....	57
Figure 26: Pathway for internal production of 3D Printed parts under proposed structure	59
Figure 27: Entitlement vs. actual Time-to-Delivery for various 3D Printing technologies in MD	59
Figure 28: Key proposed interactions between Service Providers and Developers during NPD cycle (Contrast to Figure 8 on page 28)	61
Figure 29: Example plots of model outputs from one iteration	64
Figure 30: Impact of Initial Knowledge on Aggregate Benefit of proposed strategy.....	73
Figure 31: Importance of tB with respect to initial knowledge gap.....	74
Figure 32: Extreme case illustrating the importance of the Pioneer Learning Rate over time	75
Figure 33: Cavity, sprue, gate, and runner design for sample part	78
Figure 34: Sample part shown with traditionally machined cooling channels	78
Figure 35: Sample part shown with conformal cooling channels	79
Figure 36: Cooling analysis for conventionally cooled mold (total cooling time 29.4 seconds).....	80
Figure 37: Cooling analysis for conformally cooled mold (total cooling time 23.6 seconds)	80
Figure 38: Warpage analysis for conventionally cooled mold (max deflection 1.87mm).....	81
Figure 39: Warpage analysis for conformally cooled mold (max deflection 1.45mm)	82
Figure 40: Decision process for cultivating value streams	88

Figure 41: Useful life (in units produced) of PolyJet-printed injection molds vs. other molds for various materials [31]	89
Figure 42: Attempt to create 3D Printed injection mold inserts using Carbon's cyanate ester	91
Figure 43: Experimental setup with metal-polymer blend injection-mold inserts	91
Figure 44: Control setup with PolyJet injection-mold inserts	92
Figure 45: Experimental prototype parts for both setups	93
Figure 46: Example part produced using the experimental mold (left) and PolyJet (right)	94
Figure 47: Failure modes of metal-polymer blend mold (left) and PolyJet mold (right)	95
Figure 48: Typical market adoption curve showing potential for 3D Printed limited launch	101
Figure 49: Framework for determining 3D Printing capabilities	106
Figure 50: Best fit parameters for using 3D Printed (PolyJet) Rapid Tooling [83]	107
Figure 51: SIPOC diagram for 3D Printing Blitzes	108
Figure 52: Impact of Initial Knowledge on Aggregate Benefit of proposed strategy	124
Figure 53: Probability distribution of Aggregate Benefit for Simulation 1	125
Figure 54: Sensitivity of Aggregate Benefit to various input ranges for Simulation 1	125
Figure 55: Ranking of input variable impact on program value over specified range for Simulation 1 ...	126
Figure 56: Probability distribution of Aggregate Benefit for Simulation 2	126
Figure 57: Sensitivity of Aggregate Benefit to various input ranges for Simulation 2	127
Figure 58: Ranking of input variable impact on program value over specified range for Simulation 2 ...	128
Figure 59: Probability distribution of Aggregate Benefit for Simulation 3	128
Figure 60: Sensitivity of Aggregate Benefit to various input ranges for Simulation 3	129
Figure 61: Ranking of input variable impact on program value over specified range for Simulation 3 ...	129
Figure 62: Probability distribution of Aggregate Benefit for Simulation 4	130
Figure 63: Sensitivity of Aggregate Benefit to various input ranges for Simulation 4	130
Figure 64: Ranking of input variable impact on program value over specified range for Simulation 4 ...	131

List of Tables

Table 1: Potential benefits of 3D Printing in the healthcare industry	16
Table 2: Top five medical devices companies by 2015 revenue	21
Table 3: Experimental values for Initial Knowledge Levels	71
Table 4: @Risk decision variables.....	113
Table 5: Non-decision variables utilizing @Risk distributions	113
Table 6: Fixed non-@Risk model inputs	116
Table 7: Experimental values for Initial Knowledge Levels	117
Table 8: Abridged calculations page from optimization workbook.....	117
Table 9: Detailed explanation of calculations from optimization model.....	123

THIS PAGE INTENTIONALLY LEFT BLANK

1 Introduction

1.1 Purpose of Project

Speed to market is a critical component for any New Product Development (NPD), but especially so in medical devices—improved product designs delivered with speed can significantly benefit patient outcomes, which is a top priority for Johnson & Johnson (J&J) [1]. Additionally, increased saleable lifetime, first mover advantage, customer loyalty, and company reputation for innovation are some of the other reasons that accelerating the pace of development is important to the company. One possible way to accelerate development is the field of additive manufacturing, or 3D Printing. Initially used only for early prototyping and development, innovation in 3D Printing over the past decade and recent FDA guidance on the subject opens the opportunity for its expanded use in product development [2]. 3D Printing has potential advantages not only for the products themselves, but also for the tooling and fixtures that produce them [3]. This project aims to improve J&J’s strategy for using 3D Printing throughout the development cycle, which minimizes time-to-market. The strategy includes identifying a portfolio of potential technologies and techniques to use in development; recommendations for process improvements enabling teams to better use 3D technologies; an assessment of current internal and external capabilities and potential improvement areas; and recommendations on organizational changes that will facilitate quicker adoption of new technology.

1.2 Problem Statement

Despite J&J’s depth of knowledge and advanced capabilities in the space, there remain widely different ranges of 3D Printing implementation across teams and projects, with potentially millions of dollars in uncaptured value [4]. Interviews show that some pockets within R&D groups have used advanced 3D Printing methods to successfully speed project developments, while others consistently resort to less efficient and more costly traditional methods of prototyping [5]. Additionally, investigative work as part of several project teams has shown sub-optimal utilization of both internal equipment and expertise between J&J franchise companies; where some teams have access to extensive resources, others do not. Uneven distribution of knowledge and capabilities is not unique to 3D Printing among rapidly evolving technologies at J&J—management interviews revealed this to be a widespread challenge when implementing new technology. While the company has had success developing advanced technical expertise in confined “Centers of Excellence”, diffusion of this expertise to the practitioner level is too slow, according to management.

In order to accelerate the time-to-launch of new products, J&J could benefit from a strategy where both technological and organizational changes capture the benefits of 3D Printing. Due to the nature of its

products, which are seen to provide a fertile testbed for additive manufacturing in healthcare, the Medical Devices (MD) segment of J&J was selected to pilot and test an enhanced strategy.

1.3 Project Goals

3D Printing has been studied for a wide variety of applications, and shows promise in many industries. The technology has the potential to drive tremendous value in the healthcare industry, through several mechanisms as outlined in Table 1.

Potential Sources of Value from 3D Printing in Healthcare				
Customization	Improved Design	Reduction in Supply Chain Risk	Improved Part Characteristics	Speed to Market
Ability to easily produce patient-specific products such as orthopedic implants.	Reduced cost of iterations allows for increased design refinement and higher quality end products.	Non-specialized tooling allows for supplier diversification and decentralized manufacturing.	Layer-by-layer production allows designers almost infinite geometric freedom, with fewer manufacturing constraints.	Enhanced prototyping speed and potential to improve capital equipment can accelerate product launches.

Table 1: Potential benefits of 3D Printing in the healthcare industry

The goal of this project was to improve J&J’s processes involving 3D Printing and generate at least two months of time savings in typical 36-month MD NPD cycles. The intended outcome of this project is to maximize the return on investment from any proposed solution—therefore the value of time or project costs saved needs to outweigh the cost of any process improvements or capital expenses.

This project was based on experiences with three different project teams within J&J’s Medical Devices franchise; two with Ethicon Endo-surgery in Cincinnati, OH, and one with Ethicon, Inc., in Somerville, NJ. The success of the effort was based on a comparison between project schedules before and after the improvement process took place.

1.4 Project History and Approach

The original hypothesis that motivated this project was that if NPD teams had access to the latest 3D Printing technologies, they could launch products faster and provide value to J&J. After working within

several project teams, this hypothesis evolved to include not just the access to the technology, but also to the organizational learning required to use it effectively. This was the result of observations showing that despite J&J having an excellent ability to develop knowledge and capabilities in high-level research, these investments are slow to diffuse to the project level where value is captured. For example, if one of the company’s corporate-level research labs works with a 3D Printing company to pilot a new material, it may be several years before an engineer in Medical Devices is made aware of the advancement.

It became clear over the course of this project that organizational structure is equally, if not more important, than access to equipment when predicting the implementation success of a rapidly evolving technology. Using the Value-Capabilities-Assets-Processes (VCAP) operations strategy framework, this idea is expressed in the following equation:

$$Value = Capabilities * (Assets + Processes) \tag{1}$$

In this equation, value is expressed as a function of three organizational characteristics: Capabilities, which are an organization’s ability to manage effectively and accomplish tasks; Assets, which are its physical equipment and human capital; and Processes, which are paths formed by a network of activities that transform inputs to outputs [6]. Applying this methodology to the introduction of a new technology, like 3D Printing, it is clear that value captured depends on more than just capital investment. Developing processes and learning to manage organizational impacts are also critical to an effective implementation strategy. In the past, J&J has had difficulty capturing value from new technology at the project level, despite pockets of advanced internal capabilities—perhaps a lack of focus on process development is the explanation.

Ultimately, the project objective evolved to the following: “Develop a 3D Printing implementation strategy, which provides project teams with enhanced technical knowledge, improved access to 3D Printing capabilities, and streamlined 3D Printing manufacturing processes that significantly accelerates NPD cycles and provides value for J&J.” To meet this objective, an approach was developed that involved five phases, as outlined in Figure 1. Because NPD projects within J&J Medical Devices typically occur over a period of several years, and this project’s duration was roughly six months, this approach was needed to accelerate the learning process. Figure 1 outlines the project phases.

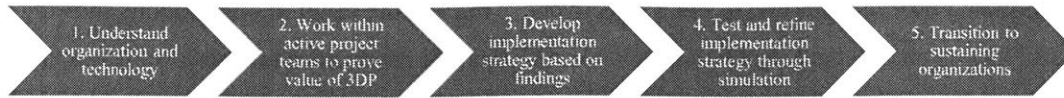


Figure 1: Project approach for research and implementation

1.4.1 Understand organization and technology

The first phase was broken down into two components: technology understanding and organization understanding. Technology research identified new types of 3D Printing and new techniques enabled by it that had not seen widespread use at J&J. This project was conducted by attending a 3D Printing focused convention, interviewing technology experts, benchmarking industry leaders, and completing an extensive literature review. Additionally, trips to several J&J sites provided data on both technologies available to engineers and their current applications in development projects.

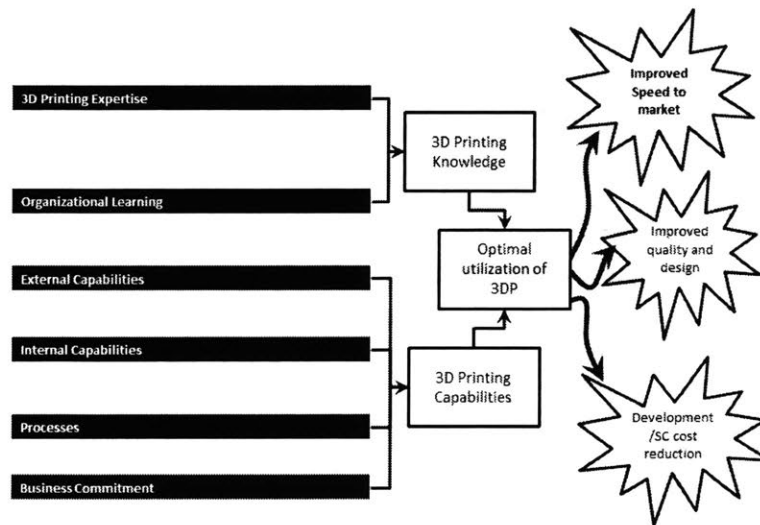


Figure 2: High-level framework for determining 3D Printing capabilities

Throughout this process, data on J&J’s organizational structure was collected—this included learning about the functions of various groups and the relationships between them. To synthesize both the technology and organizational data, the framework shown in Figure 2 and expanded upon in Appendix Section 6.1 was developed to help understand the current and potentially improved states of a 3D Printing strategy. Collecting data on available technologies and the organization’s structure formed an understanding of 3D Printing’s current role in the organization, and helped to identify opportunities where that role may change in the future.

1.4.2 Work within projects to prove value

The second phase shown in Figure 1 was meant to implement many of the immediate opportunities identified in the first phase and test their efficacy. Three projects, which were at various stages but still relatively early in development, were chosen to pilot many of these techniques for practicality. Each New Product Development project team included six to ten members consisting of a product manager, several engineers or designers, and manufacturing experts. Project scope depended largely on how far along it was in the development process; for example, the least developed project had greater input from R&D than the most mature project. Conversely, the most mature project had more input from supply chain than the least developed project. This dynamic is discussed in detail in Section 2.2.1.1. The goal of working with these teams was to identify organizational or technological improvements that could significantly reduce NPD cycle time.

1.4.3 Design structure for implementation strategy

Based on experience with the three pilot projects, the next step shown in Figure 1 was to develop an implementation strategy for use across J&J Medical Devices. This step included refining the techniques used in Phase 2 and designing an organizational structure to ensure an effective rollout of the process. Developing a strategy that would capture benefits from the new technologies required careful consideration of the existing organizational structure of the franchise; details of the developed proposal are outlined in the following sections.

1.4.4 Test and refine implementation strategy through simulation

Because the duration of this project was significantly shorter than the duration of the NPD projects on which were focused, it was impossible to experimentally evaluate the impact of the improvements proposed. For this reason, the next phase involved modelling the proposed structure to determine critical variables and provide recommendations for implementation. This simulation resulted in general recommendations for the implementation strategy and provides a framework for further refinement once the value of 3D Printing in New Product Development is more thoroughly evaluated.

1.4.5 Transition process to sustaining organization

The final step in this project's approach sought to transition the process to an organization within J&J that will be responsible for implementation of the recommendations developed. This involved not only identifying appropriate roles and responsibilities for the organization, but also securing leadership support for the initiative. To capture the potential opportunities identified in this effort, it is important for J&J to transition and sustain the process improvements. Given the value proposition identified in the previous phases, doing so will benefit future NPD projects.

1.5 Thesis Overview

Chapter 2, “Background”, provides context for the project and discusses the relevant industry environment. It discusses the general process of medical device development and the specific process used by J&J.

Chapter 3, “Additive Manufacturing Technologies and Capabilities”, discusses the current state of the 3D Printing industry and its applications within medical devices. This section also highlights the inherent advantages and disadvantages of each technology. It provides a brief description of their use at J&J. Finally, this section discusses emerging technologies that may be useful for product development in the near future.

Chapter 4, “Developing an Improved Strategy for using 3D Printing in NPD”, details the process taken in this project to develop recommendations to improve J&J’s strategy of using the technology. This section also provides frameworks for change based on this project, and discusses a model that can be modified to estimate the value of similar programs in J&J’s Consumer Products and Pharmaceutical franchises.

Chapter 5, “Recommendations and Conclusions”, provides a summary of the findings from this project, and discusses the overall value of an improved 3D Printing strategy.

2 Background

The following chapter provides an overview of the medical devices industry, including some typical products and the several advantages of speed in this market. J&J's Medical Devices franchise and its New Product Development organizational structure are discussed, which provide specific context for this project within the company.

2.1 Industry Overview

The medical devices industry is competitive, fast moving, and strictly regulated. New products are developed every year based on feedback from surgeons and patients that are meant to give an advantage over the competition. The medical devices industry encompasses thousands of products and treatment areas. The products created by medical devices companies also have a wide range of complexity—some are as simple as a contact lens, where others are as complex as a multi-axis surgical robot. Regardless of their form, medical devices are designed to improve patient quality of life, procedural outcomes, or cost-effectiveness.

The estimated global revenue from sales of medical devices was \$330B in 2016, with orthopedics composing the largest share, at 14% of the total. This market is geographically concentrated; roughly 80% of revenues come from just ten countries, with the United States alone accounting for 39% of the total. Despite increasing revenues, new cost and pricing pressures come from a push for value-based care [7]. Table 2 shows the top companies in the medical devices industry, ranked according to their 2015 revenue from devices.

Company	2015 Sales from Medical Devices
J&J	\$25.14B [8]
Medtronic	\$20.26B* [9]
GE Healthcare	\$17.64B [10]
Siemens	\$12.93B [11]
Philips	\$11.60B** [12]

*In 2016, Medtronic merged with Covidien for combined revenues of \$28.8B

**Converted from Euros to Dollars using exchange rate of 1€:\$1.06

Table 2: Top five medical devices companies by 2015 revenue

In the United States, the US Food and Drug Administration (FDA) regulates medical devices companies under Code of Federal Regulation (CFR) 21 Part 807 [13]. This code dictates the process for registering new devices prior to sale. An important characteristic of this code is that it classifies medical devices as

Class I, II, or III based on the level of control deemed necessary to ensure the safety and efficacy of the product. Class I devices, such as a wheelchair or orthodontic bracket, pose the lowest risk to patients and have the least strict filing requirements. Class II products, such as special surgical tools, pose a greater risk to the patient. Class III products, such as replacement heart valves, involve the most risk to the patient and require premarket approval [14]. The products analyzed in this project largely fall under Class II regulations.

The medical devices industry, and more broadly the healthcare industry, is subject to pressure from both payers and legislators to reduce the cost of treatment. Increased attention from these institutions and several highly publicized cases of price increases, such as drug maker Mylan's 2016 price hike of EpiPen, have resulted in a more difficult environment for healthcare companies [15]. Increased pressure on top-line revenue drives a focus on cost cutting, innovation, and new product differentiation to preserve profits.

2.1.1 Typical Product Profile

As discussed previously, medical devices come in a wide range of sizes and functions—in fact, the FDA has classified approximately 1,700 different types of medical devices [16]. Despite this, the vast majority of unit sales in the industry share many characteristics. For example, a device that is implanted or used in surgery needs to undergo a sterilization process. The materials used, therefore, need validation that they can withstand the degrading side effects of gamma radiation, steam, or ethylene oxide. Additionally, there are a limited number of biocompatible materials that can be used in medical devices [17]. Because of these constraints, manufacturers are limited to a certain set of materials that provide both the quality and the durability needed. Common plastics used in the industry include polyethylene, polypropylene, and polycarbonate; common metals include stainless steel and titanium [18]. An example of a medical device that uses several of these materials is shown in Figure 3 below, which uses titanium, stainless steel, and several polymers [19].

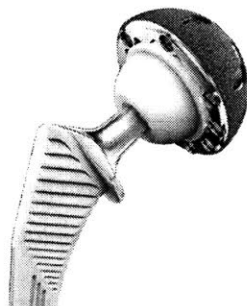


Figure 3: DePuy Synthes Corail Hip System [19]

With this breadth of products in mind, this project focused on narrowing scope to a manageable subset of devices that are representative of a large part of the total industry. The subset chosen was hand-held surgical tools. These products were chosen because they presented significant engineering and scheduling challenges through complex components, high quality requirements, material variety, and manufacturing method diversity. The devices in focus are made of materials such as stainless steel, polycarbonate, or bio-absorbable polymers that are typical in the devices industry.

Examples shown below are J&J products that fall under the description above. Surgeons or patients use these products regularly, with volumes of at least 500,000 per year and ranging up to several million per year. These products are used by hospitals around the world and represent the leading edge of surgical technology. Despite only analyzing a narrow subsection of medical devices, the techniques learned through this project apply to many more products across the industry and J&J's portfolio of businesses.

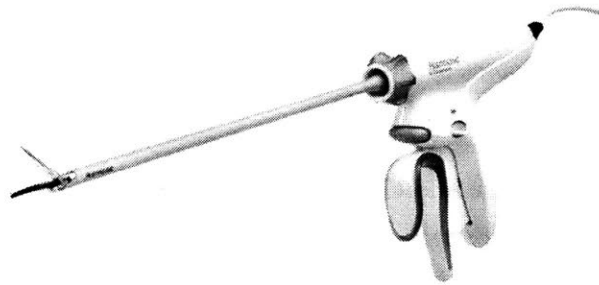


Figure 4: Ethicon Enseal for cutting and sealing tissue [20]

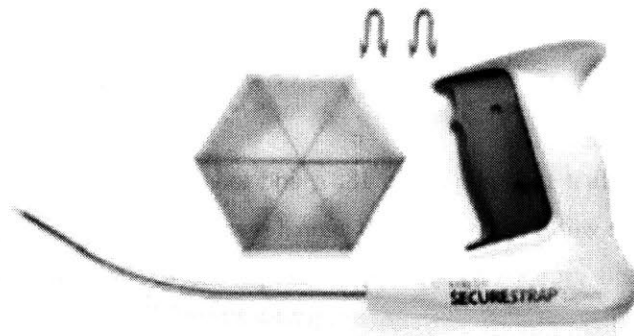


Figure 5: Ethicon Securestrap Open, for implanting a hernia mesh [21]

2.1.2 Benefits of Speed to Market in Medical Devices

Speed to market is critical to the success any company. The ability to market a product sooner can enable increased sales life, surgeon or patient loyalty, and new-treatment pricing power. Additionally, developing and producing products faster gives the manufacturing organization valuable production experience, potentially resulting in reduced costs compared to competitors. When analyzing the opportunity cost of lost revenue alone, one month of development time can easily reach several million dollars for a new medical device based on J&J analysis.

Product development overruns, and conversely development accelerations, can be broken down into three categories: The first case arises when demand for a product is inelastic, and a company's lost value is simply the time value of money over the delay. The second and more severe case involves products with some substitutes, where later market entry results in lower peak sales. The third and worst case, which addresses products that become part of other systems, occurs when a development delay causes severe and continuing reduction in sales over a product's lifetime. Because of extensive training needed for use, surgeon loyalty, and switching costs, medical devices typically fall into the third and most severely affected category [22].

Because it is difficult to quantify the effect of speed on expected sales over time, competitor behavior, and customer loyalty, J&J's finance team recommended excluding these factors from this project's analysis. Doing so led to the conservative approach that values an accelerated project schedule as only the net present value of earlier revenue. In other words, despite medical devices falling into the worst-case scenario described above, any analysis performed in this project treats demand as inelastic, with the value of speed determined only by the time value of revenue of the expected schedule truncation. This choice was based on the relatively small change expected resulting from this work—the finance team determined that truncating a 36-month timeline by two months is not likely to have a significant effect on the shape or amplitude of a sales curve.

2.2 Johnson & Johnson

Johnson & Johnson (J&J) first incorporated in 1887, and today is one of the largest and most diverse healthcare companies in the world with over \$70B annual revenue and 127,000 employees. The company has three different segments grouped by type of product produced: Pharmaceuticals, Medical Devices, and Consumer Products [8].

This project focuses specifically on the Medical Devices (MD) segment, which is further broken down into a portfolio of operating companies that provide orthopedic, surgery, cardiovascular, diabetes, and vision care products. The Medical Devices segment saw revenues decrease by 8.7% from 2014 to 2015,

with sales reduction across each business resulting largely from currency impacts. Spend on R&D within the MD segment remains steady at an average of 6.2% of sales over the past three years [8].

Within the MD segment, this thesis is largely based on work completed with Cincinnati, Ohio based Ethicon Endo-Surgery, Inc. (EES) and Somerville, New Jersey based Ethicon Inc. EES produces a variety of surgical tools, which include advanced harmonic cutters, laparoscopic staplers, and trocars. Ethicon, Inc. focuses largely on wound closure solutions, which include sutures, hemostat patches, topical skin adhesives, and hernia meshes.

2.2.1 New Product Development at J&J Medical Devices

J&J Medical Devices develops new products each year through its surgery, orthopedic, cardiovascular, and specialty businesses. At any time, there are several dozen new products under development across these segments. The following section discusses the structure of J&J's New Product Development (NPD) organization, and follows with a description of the typical process used to bring a product to market.

2.2.1.1 *New Product Development organizational structure*

The structure of J&J's Medical Devices development organization is a "Triad", with Global Strategic Marketing (GSM), Research and Development (R&D), and Product Management (PM) making up the three main groups. GSM is tasked with developing the commercialization strategy, which involves capturing voice of customer, pricing data, expected sales volumes, and regional sales specifics. R&D is responsible for developing a product design which can meet customer requirements, applicable regulations, and cost targets. Finally, PM is tasked with developing a supply chain strategy to ensure adequate customer service, while optimizing costs [23].

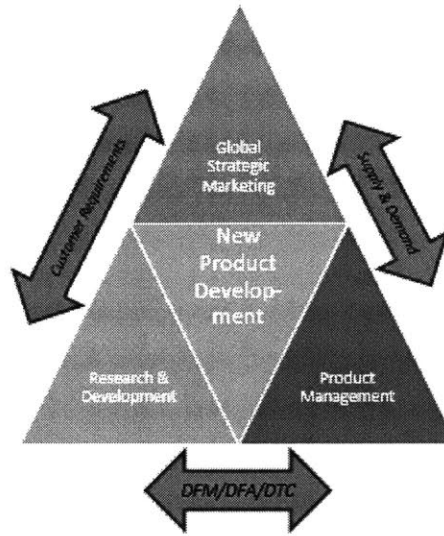


Figure 6: New Product Development “Triad” [23]

Figure 6 also illustrates how the interactions between these groups are critical to a successful new product launch. GSM feeds customer data to R&D, which develops an initial concept. PM and R&D then work closely to develop a final product that optimizes cost and value through Design for Manufacturing (DFM), Design for Assembly (DFA), and Design to Cost (DTC). As PM works to finalize the supply chain for launch, it is working closely with GSM to refine sales volumes and ensure adequate capacity. This process is generically outlined in Figure 7, for a typical Medical Device New Product Development.

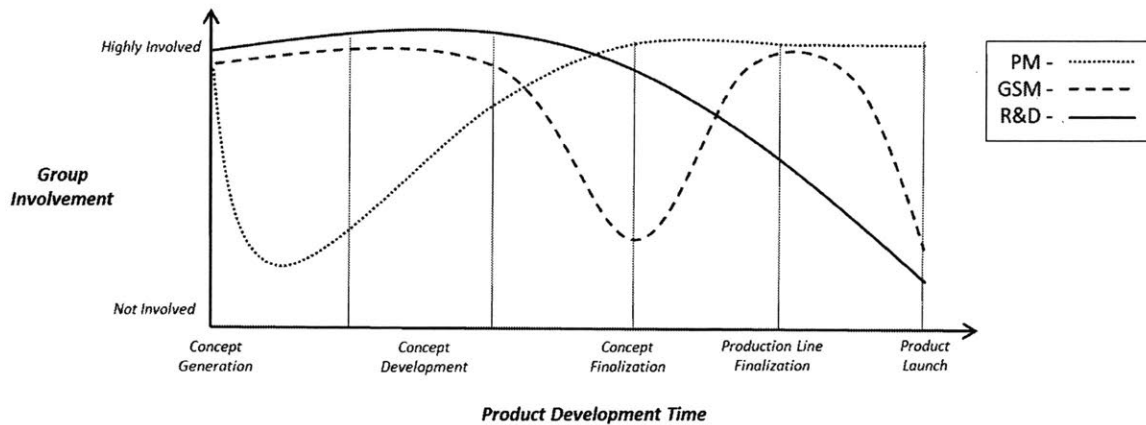


Figure 7: Development group involvement over the NPD cycle (not necessarily to scale) [23]

Housed within the Medical Devices PM group, J&J maintains both Metals and Plastics Centers of Excellence, which are centralized groups of manufacturing experts who provide component-level recommendations to project teams. These groups specialize in traditional high-volume manufacturing techniques, such as injection molding and extruding plastics, or stamping, Metal Injection Molding (MIM), or machining metals. Both groups are routinely involved throughout the NPD process, and have built a strong reputation among the R&D teams and Product Managers for meeting both quality and cost constraints.

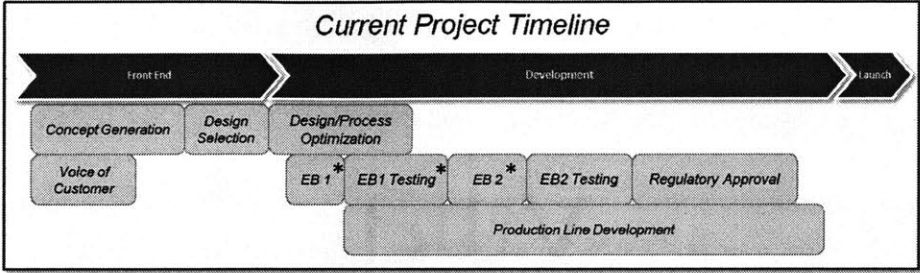
2.2.1.2 Typical New Product Development Process

J&J Medical Devices uses a Stage Gate process for New Product Development. Both R&D and GSM are heavily involved in the first several stages, where a market need is developed into a tangible prototype. During these early stages, several iterations of product concepts are revised based on customer feedback. When the team has reached a viable concept prototype, the business commits to producing it and a manufacturing site is selected. The next several stages involve further refining the product, ensuring supply chain readiness, and regulatory submission. Once a product is ready for sale, it can be marketed in one of two different ways: it can be rolled out via a limited launch or a full launch. A limited launch occurs if there is question to the strategic commercial value of a product. Finally, a product reaches the final stage once all New Product Development activities conclude [24].

A typical product development in the MD segment involves several common tasks that define the project's critical path. The "Front End" of NPD involves Concept Generation and Design Selection; these steps are highly iterative and often use 3D Printing to build both touch-and-feel and functional prototypes. After Design Selection, there are several rounds of "Engineering Builds"; these low-volume production runs build units for reliability testing. The number of Engineering Builds depends on the complexity of the product and the ability of the team to reach a point where it is comfortable with the design's form and function.

Production Line Development, which is the process of preparing the manufacturing line to deliver the expected volume of units, occurs in parallel to the Engineering Builds. Despite not having a finalized design upon starting this process, developing the production line in parallel with product design allows for a significantly shorter critical path, and is common practice at J&J MD. Typically, Production Line Development is completed soon after Regulatory Approval, as shown in Figure 8 below. It is important to note that most Class II NPD projects schedules are structured such that Regulatory Approval does not fall on the critical path. After the team meets these prerequisites, the product is then ready to market.

Figure 8 shows an overview of this process; any given project can vary slightly from this template, but in general, this model is consistent for the focus areas of this thesis.



*EB is an abbreviation for "Engineering Build"

Figure 8: Typical Medical Devices NPD critical path (~36 months total)

3 Additive Manufacturing Technologies and Capabilities

The 3D Printing industry is experiencing exponential growth in both size and available technologies. From the first commercial stereolithography machines pioneered by 3D Systems in 1987, the industry has expanded to many dozens of manufacturers producing a variety of machines with capabilities ranging from desktop prototyping to stainless steel production line work [25]. According to PwC, two out of three companies surveyed in 2014 were using 3D Printing in some capacity [26]. Of those that are using 3D Printing, over 60% reported they were experimenting with using the technology beyond strictly prototyping. Between 2003 and 2015, the industry's Compound Annual Growth Rate of revenue was 21% [10]. Additionally, new technologies include novel capabilities such as printing in carbon fiber composite and ceramic materials. 3D Printing has proven to be a valuable technology that can provide both time and cost savings during development and beyond.

This chapter provides a brief summary of current available technologies and discusses applications to the medical devices industry.

3.1 Additive Manufacturing Overview

Additive manufacturing has applications to many different industries for its ability to produce rapid, low-cost parts. Figure 9 shows the current distribution of total 3D Printing revenue based on industry, with medical and dental applications providing an important part of the total.

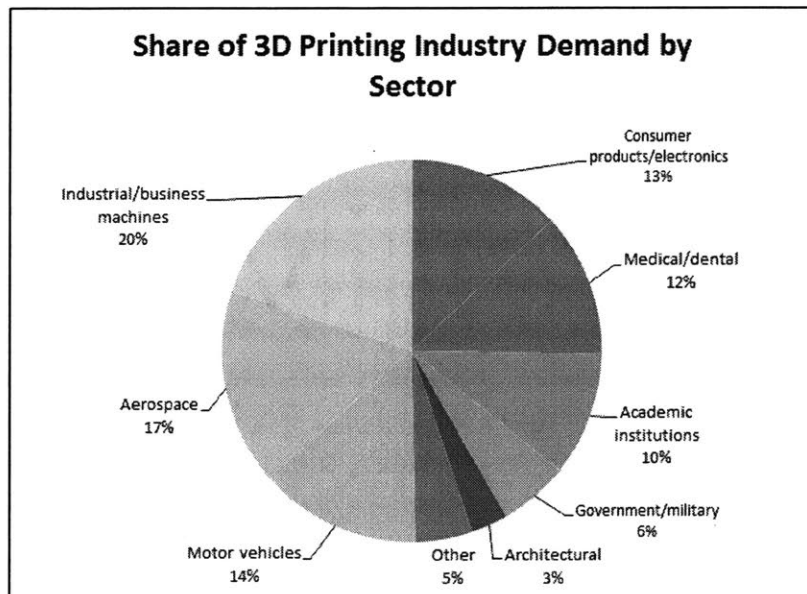


Figure 9: 2015 share of total 3D Printing industry demand by end-use industry [27]

Within the companies that use 3D Printing, there is a wide range of end uses for the technology. The diversity of application shows that 3D Printing is no longer confined to touch-and-feel prototyping—in fact fully one-third of all 3D Printing currently produces functional parts, as shown in Figure 10.

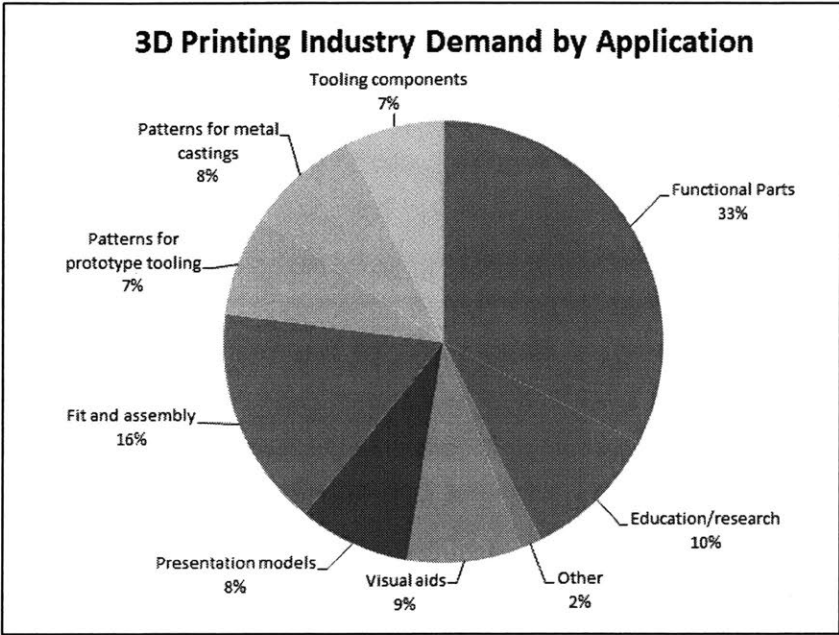


Figure 10: Breakdown of 3D Printing demand by end-use application [27]

3.1.1 Classes of available 3D Printing Technology

The wide range of end-use applications is a result of the diversity of technology options from which to choose. Depending on desired characteristics such as cost, speed, material, strength, and surface finish, part production can be optimized for the specific application. To categorize the various technologies, ISO and ASTM developed several classes through ISO/ASTM 52900, which are used to group by general process [28]. Each class is discussed briefly in the sections below [27].

3.1.1.1 Material Extrusion

Printers in this group of technologies selectively dispense material through a nozzle. Material Extrusion is commonly used because it is inexpensive, relatively easy to operate, and compatible with a wide range of materials. This class of technologies is the most commonly used type of 3D Printing. A specific example technology is Fused Deposition Modeling (FDM) [27]. Because these printers can print in engineering materials such as acrylonitrile butadiene styrene (ABS) or Ultem, as opposed to UV-unstable resins only suitable for prototyping, they can be used to make end-use parts, though there are some

limitations on surface finish [29]. Figure 11 shows a production component that produced using FDM Material Extrusion technology.

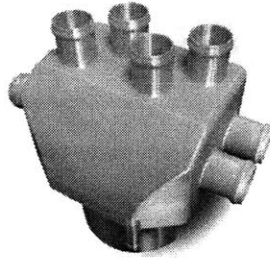


Figure 11: Production component printed in Ultem [30]

3.1.1.2 Material Jetting

This growing segment of printers uses ink-jet nozzles to dispense droplets of photopolymers, which are cured by UV light [27]. These systems can print at high rates of speed and with very high quality surface finishes. Due to UV sensitivity of the parts they create, Material Jetting is often not suitable for long-term end-use parts. An example technology is PolyJet, by Stratasys [31].

3.1.1.3 Binder Jetting

Originally developed at MIT [32], this class of technologies uses alternating layers of powder and liquid bonding agent. This is a versatile technology that can use any powdered material for builds, though post-print sintering may be required. HP's Multi Jet Fusion technology, which promises high quality and very high print speeds, is an example of Binder Jetting and is currently in to process of commercialization.

3.1.1.4 Sheet Lamination

This group of technologies uses sheets of paper or other thin material, cuts each layer to shape, and adheres them together to create a 3D model. This class is not commonly used in the medical devices industry, but has among the lowest material costs of any 3D Printers.

3.1.1.5 Vat Photopolymerization

This class of printers uses light to sequentially cure layers from a vat of liquid photopolymer resin. First commercialized in 1988 as Stereolithography (SLA), Vat Photopolymerization remains a popular choice for engineers because of its large variety of available materials and good surface finish [27]. New technologies in this class, such as Continuous Liquid Interface Production (CLIP), improve on the original concept by delaying the chemical reaction to create fully homogeneous parts [33].

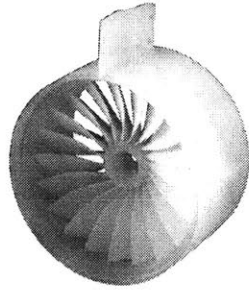


Figure 12: Complex part produced using Stereolithography [34]

3.1.1.6 Powder Bed Fusion

This versatile class of technologies has wide prototyping and production applications, with available materials such as Nylon and stainless steel. In this process, directed thermal energy is used to fuse select regions of a powder bed. Industrial giants such as GE have already used Powder Bed Fusion to reduce weight and increase reliability in several critical jet engine parts [35]. Two popular example technologies in this class are Electron Beam Melting (EBM) and Direct Metal Laser Sintering (DMLS) [27].

3.1.1.7 Directed Energy Deposition

This class of technologies is limited to very large machines that use a laser or an electron beam to melt a continuous stream of powder [36]. These machines are used for industrial-focused applications such as pipe cladding, and typically have multi-material and five-axis capabilities [27].

3.1.1.8 Considerations when choosing a specific technology

Figure 13 and Figure 14 provide a breakdown of each technology based on critical characteristics for metallic and polymer materials, respectively [28]. A basic understanding of available technologies is critical to selecting the best one for a specific application. For example, parts made with a powder bed technique will have significantly different mechanical properties than those made with an extrusion technique, even while using same material. The process steps used by different technologies controls the suitability of parts produced for a particular application, and project teams can use the figures below as a starting point to isolate potential candidate techniques.

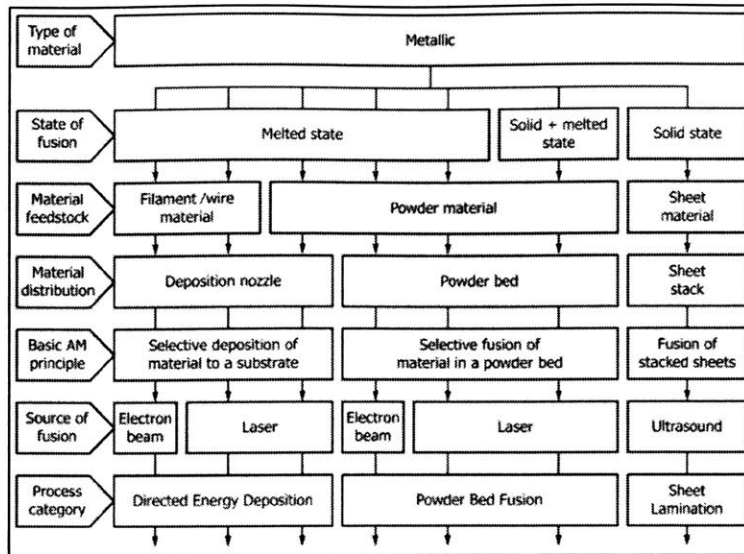


Figure 13: Overview of 3D Printing categories for metals technologies [28]

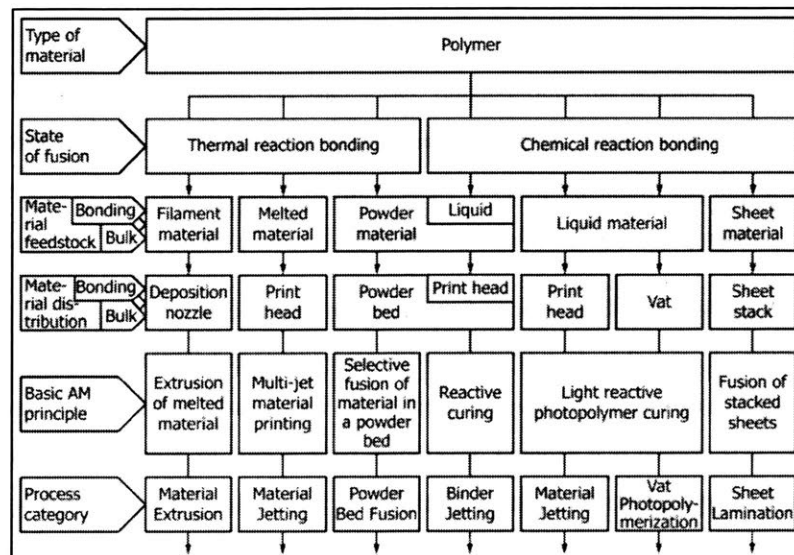


Figure 14: Overview of 3D Printing categories for polymer technologies [28]

3.1.2 Available Post-Processing Options to Improve Printed Parts

In addition to the available 3D Printing technologies, there are a large number of post-processing options that can alter and improve the final properties of a printed part. Despite adding time, complexity, and cost to builds, these processes can greatly enhance the range of practical uses for 3D Printing while still remaining faster and cheaper than alternative manufacturing methods. While this thesis will not discuss

all available post-processing options, several characteristics these processes seek to improve are discussed below [27]:

Surface finish: A limitation of 3D Printers is often that they cannot achieve a comparable surface finish to injection molding, stamping, or other methods. This can be overcome by finish machining, grinding, polishing, coating, micro-machining, or sanding. These processes often involve adding material to the initial model, such that the finishing step brings the part to the specified dimension [27].

Color: Some 3D Printing technologies have limited color options. This drawback can be overcome through computational hydrographic printing, coating, or painting [37].

Material: Innovative techniques have been developed to coat plastic parts with a metal coating, such as Nanovate, which provides for a compelling alternative to Metal Injection Molding (MIM) [38]. Additionally, 3D Printing can be used to make injection molds, as discussed in Section 4.4.1.5.

Strength: The strength of binder-jetted parts can be improved through a process called infiltration, which also makes the parts impermeable to liquids [39]. Metal parts can easily be heat-treated to improve their properties, through a three-step process involving stress relieving, hot isostatic pressing, and precipitation hardening [27].

Understanding the advantages and limitations of each technology is critical to capturing value from it—despite a wide variety of available technologies and post-processing techniques, 3D Printing is not suitable for every application. 3D Printing is a rapidly evolving class of technologies, and it necessitates continuous learning. It is critical that product developers have access to adequate training materials and expertise; this concept is explored in detail in Chapter 4.

3.1.3 Advantages of Additive Manufacturing

3D Printing technologies are fundamentally different than traditional manufacturing technologies, and these differences result in significant opportunities to capture value. Deloitte published a framework for understanding paths to value through 3D Printing, which identifies four key segments where companies can benefit [40]. This framework is shown in Figure 15.

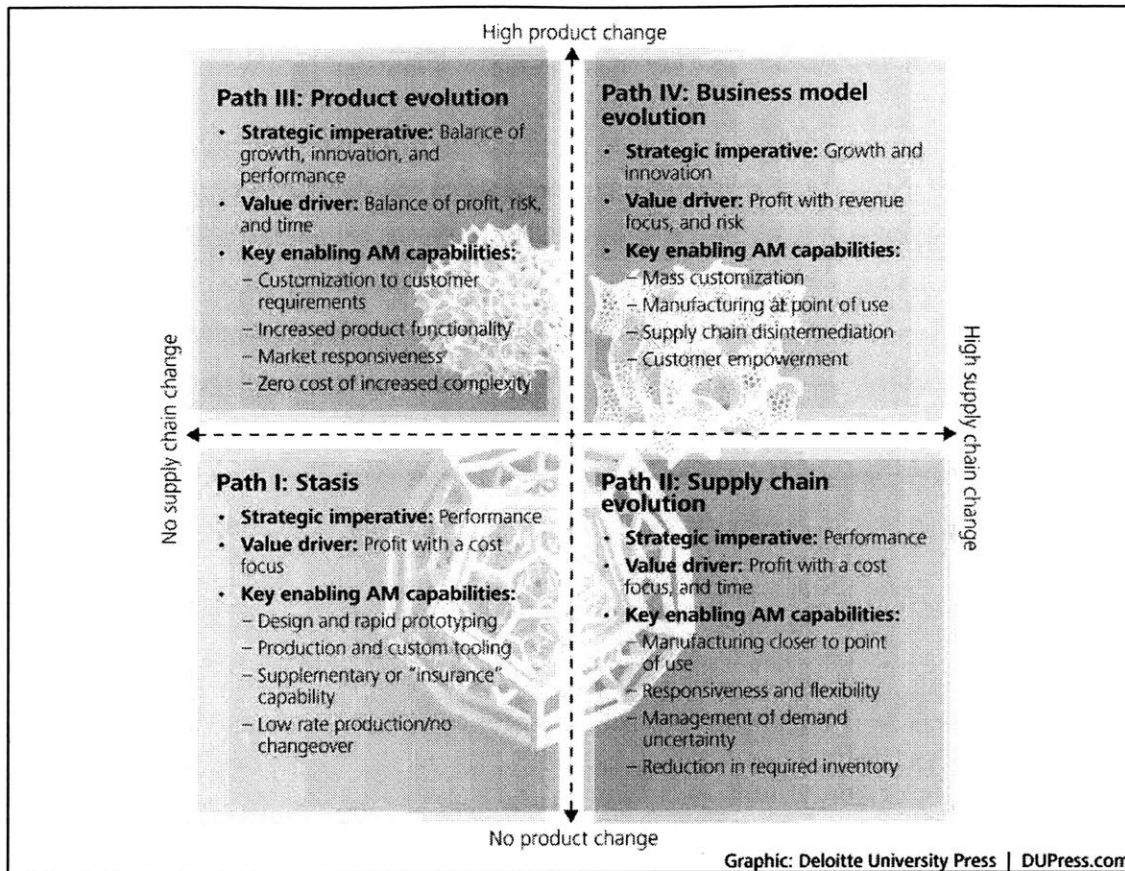


Figure 15: Deloitte framework for understanding AM paths and potential value [40]

The capabilities described in Figure 15 are the result of 3D Printing’s flexibility—the fact that a part is built layer by layer gives a designer geometric freedom to include complex features not possible using subtractive methods [41]. Additionally, 3D Printing requires no tool changes, no part-specific setups, and only a small footprint. Different technologies offer a wide variety of working materials, and post-processing can help to meet even the most strict dimensional specifications.

Several current processes at J&J fall into Paths I and III, which shows that the company has started to see the benefits that 3D Printing can bring to products. In the “Path I” quadrant shown in Figure 15, developers routinely use AM for prototyping, and teams have begun to use it to improve the quality of production tooling. In the “Path III” quadrant, J&J now offers low-volume customized cutting guides for knee replacement surgery through its TruMatch platform; despite requiring manual input to design each guide, this system adds value through time savings in the operating room and more successful surgical

outcomes [42]. These successes are driven by highly valuable applications and have led J&J to develop an excellent 3D Printing knowledge base.

Despite some success with using 3D Printing in products, J&J has not yet developed processes in Path II or Path IV. These quadrants require the company to develop end-to-end processes for mass customization and point-of-use manufacturing. As costs decrease, materials improve, processes are developed, and as-printed quality comes in line with traditional manufacturing, 3D Printing will become more viable for end-use products and J&J will begin to exploit this technology in its supply chain.

3.1.4 Drawbacks and limitations of current technologies

3D Printing technologies continue to improve, but their performance has fallen well short of early expectations across various industries [43]. This is due to limitations of manufacturing products one layer at a time—high material cost, layer stratification, poorly understood mechanical properties, and slow build speed have prevented 3D Printing from having a larger impact on global supply chains [27].

Because each technology is slightly different, 3D Printers often print using proprietary materials. Manufacturers thus far have exploited this fact through a printers-and-ink model; typical 3D Printing polymers range from \$18-114 per pound, where traditional polymers for injection molding fall between \$0.45-0.90 per pound. In addition, despite a more fluid market for metals 3D Printing materials, the large energy requirements for powder production lead to significantly higher costs than traditional materials [27]. Despite costs remaining significantly higher than traditional materials, the average cost of 3D Printed parts has continued to decrease; between 2001 and 2011, the cost of 3D Printing dropped by 51% after adjusting for inflation [44]. Under increasing pressure from payers and regulators to reduce cost of care, medical device companies will be carefully monitoring this trend and assessing cost-saving opportunities as the price of 3D Printing materials continues to fall.

Layer stratification, and more generally poor surface finish, has also been a barrier to adoption for 3D Printing. Despite higher resolutions than ever, many 3D Printed parts still suffer from “steps” in their surface finish from printing finite layers. While these imperfections may be acceptable for prototype parts, they are rarely up to the production standards of a medical devices company like J&J. Another concern resulting from the printing process is that closed geometries often present a significant challenge. Technology classes such as Powder Bed Fusion or Vat Photopolymerization, for example, require an open path from which unused support material can be emptied. Companies using additive manufacturing should incorporate these constraints as part of Design for Additive Manufacturing training for designers.

Work is underway to classify the material properties of 3D Printed parts, but the infinite array of materials, technologies, and printing parameters make this a daunting process [45]. Several characteristics of 3D Printing further complicate this task. First, many of the photo-cured polymers used by Vat Polymerization or Binder Jetting techniques quickly degrade under UV exposure, changing their mechanical properties over time [45]. Next, 3D Printed parts tend to have non-isotropic qualities caused by sequential fusing of layers—parts can have significantly different mechanical properties in the X-Y axis versus the Z-axis. Research is underway in each of these areas to both improve the existing technologies and to best inform users of the properties of printed parts [27]. Fully understanding material properties is critical for the medical devices industry—products need to be dimensionally stable, be able to stand up to sterilization, and be highly reliable to ensure the best patient care [46].

Another drawback to 3D Printing is slow build speed. Despite new technologies that have drastically improved speeds [47], most are still too slow for mass manufacturing. For example, the fastest polymer systems can produce small parts in about fifteen minutes, which is several orders of magnitude faster than previous technologies [48]. In comparison, though, injection-molding operations can produce similar parts in just seconds [49]. Despite avoiding development time for capital tooling, it is clear to see given these figures that 3D Printing is not yet competitive in high-volume applications.

The final drawback to 3D Printing identified in this project is somewhat limited material availability. While subtractive manufacturing or injection molding techniques can produce parts in almost any material, each current 3D Printing technology is limited to a comparatively narrow material selection. Many of the products J&J produces are made from proprietary bio-absorbable polymers that are not available for use in any 3D Printer. 3D Printers require finely tuned parameters and well-understood material properties to accurately deposit material in the right location—this requires months of experimentation, and prohibits many materials from ever seeing use in certain technologies. Despite these challenges, manufacturers are diligently expanding the available portfolio of materials for 3D Printing. With the recent availability of elastomeric polymers, silicone, tool steel, and carbon fiber, material selection is becoming less of a barrier to 3D Printing.

3.1.5 Emerging Technologies

Several developments are worth highlighting that may increase the penetration of 3D Printing in product development at J&J. The first of these is a relatively new class of technologies called Continuous Liquid Interface Production (CLIP). CLIP technology is similar to Vat Photopolymerization, but utilizes an oxygen-permeable membrane to retard curing and generate a gradient of semi-cured polymer called a “Dead Zone”. This gradient eliminates layer stratification, resulting in parts that rival the quality and

appearance of injection molding. In addition to higher quality, CLIP technology can print at speeds approaching 1 cm/min because it is not limited by a stepwise process. The architecture of this process is shown in Figure 16 below.

Because of its speed and print quality, CLIP technology can potentially change the economics of 3D Printing polymers. Because they do not require expensive molds, past 3D Printing technologies are less costly than injection molding for volumes of up to approximately 100 units [44]. Discussions with experts in the field suggest that CLIP technology could increase this figure by up to two orders of magnitude depending on part specifications. Because of its ability to print high quality parts at higher volumes than previous technologies, CLIP may have medium-volume applications (<10,000 parts per year), such as clinical trials. Therefore, clinical trials that require injection-molded devices may benefit from the responsiveness of 3D Printing and the cost savings from avoiding capital tooling.

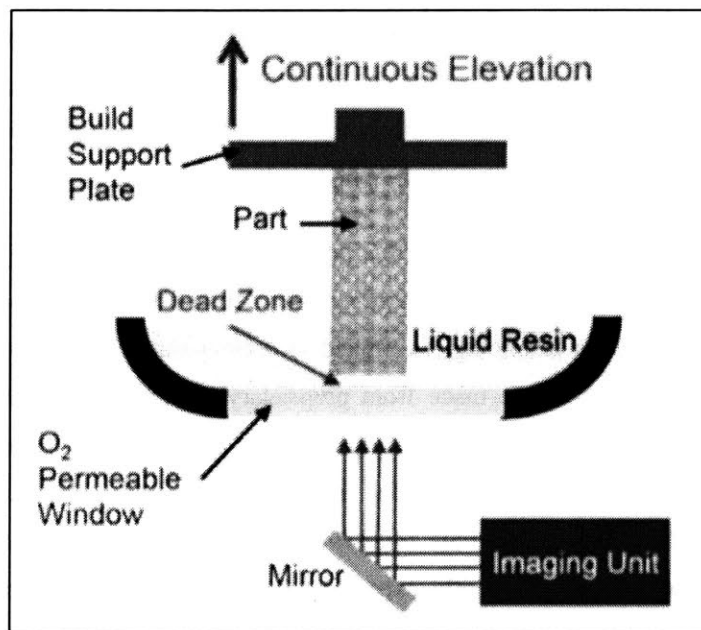


Figure 16: Basic process of Continuous Liquid Interface Production (CLIP) [48]

One of the pioneers in CLIP technology, Carbon Inc. (Carbon), has introduced several new materials that increase the breadth of applications for its products. Of particular interest for the healthcare industry are the company's Elastomeric Polyurethane (EP) and Cyanate Ester (CE). EP allows high-resolution printing in an elastic, resilient material, where CE prints in similar quality but with high strength, stiffness, and temperature resistance [50]. In fact, CE parts can be steam-sterilized, which opens their use into surgical applications [51].

Another technology that has the potential to disrupt the economics of injection molding is HP's Multi Jet Fusion, which is reportedly up to ten times faster than any existing 3D Printing technology [47]. This layer-based process uses existing high-speed HP technology to deposit layers of resin and powder to build a semi-cured part, which is then sintered to achieve its final properties. The novelty of this technology comes from the ability to print in both "Fusing" and "Detailing" resins; these allow for both fast and high-quality part production. Additionally, the process allows for additional "Transforming Agents", which modify properties such as strength, opacity, color, or electrical conductivity. As with CLIP, the speed and quality of HP's technology may enable 3D Printing for low to medium-volume applications. While details of Multi Jet Fusion's full capabilities have yet to be released, this technology may also be capable of producing advanced parts, such as those with integrated circuits, which may have greater value to J&J Medical Devices [52].

The main challenge addressed by both of these technologies is economics. Each uses a different method to increase 3D Printing's cost competitiveness. As manufacturers continue to invest in new techniques and materials, and all technologies benefit from improved economies of scale, 3D Printing will continue its path to becoming a desirable alternative to traditional manufacturing. Maintaining awareness of these trends is critical to capturing value from this rapidly evolving space.

3.2 Use of Additive Manufacturing in Medical Devices

3D Printing has become an important tool in the Medical Devices industry, and its role continues to change. The following sections discuss overall trends in the industry regarding this technology, along with several key developments and focus areas that signal continued growth.

3.2.1 Industry trends

The use of 3D Printing in the medical devices industry has steadily increased since 2010. While its use for prototyping and testing continues to expand, companies have also begun experimenting with the technology for end-use part production. Figure 17 shows the number of FDA approved medical devices launched in each year that are manufactured using 3D Printing [53].

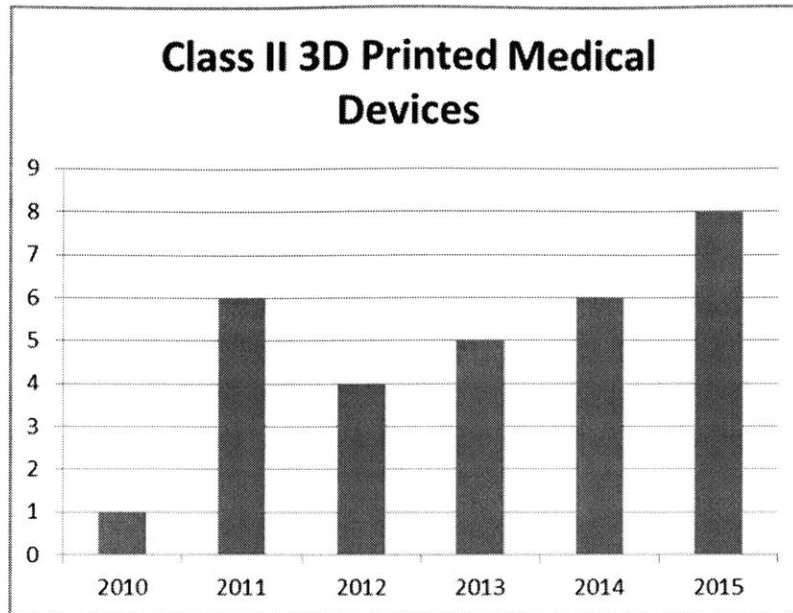


Figure 17: *Quantity of 3D Printed medical devices with FDA approval [53]*

Research performed at Stanford helped to gauge the worldwide use of 3D Printing in medical devices through systematic literature review [54]. In total, 352 papers written between 2010 and 2014 were identified that describe devices in various stages of development, but which were ultimately to be produced using additive manufacturing. This data was then broken down by country of origin; the United States lead development with 67 publications, followed by China (51), Germany (19), and the United Kingdom (19). The data was further broken down by technology, with 15.9% of projects utilizing FDM technology, followed by SLS (13.4%), SLA (10.2%), and Powder Bed Fusion (10.2%). Interestingly, DMLS was used in only 2.8% of the research. The vast majority of all publications focused on devices falling under FDA Class II requirements. Despite over 1700 different FDA classifications, the 352 different devices identified in this research fell into just 30 categories, illustrating that 3D Printing has not yet become pervasive across the industry [54].

3.2.2 Key competitor behavior

One of J&J's competitors in the Medical Devices space showed strong commitment to 3D Printing in 2016. Stryker announced an investment upwards of \$400M in an advanced 3D Printing facility in Cork, Ireland, to use the technology to develop new and innovative devices [55]. The company has already launched a 3D Printed tibial baseplate, which uses porous titanium to enable bone fixation, and recently received FDA clearance for a 3D Printed lumbar cage, which uses proprietary titanium developed specifically for additive manufacturing [56] [57].

3.2.3 Key industry focus area: scan-to-print

Apart from accelerating product development and reducing cost, healthcare companies such as Stryker and J&J are looking to 3D Printing for customization. Many applications in the industry benefit from patient-specific geometry, such as orthopedic implants. Producing these products first involves imaging the patient using Computed Tomography (CT), Magnetic Resonance Imaging (MRI), or Cone-Beam Computed Tomography (CBCT). The patient geometry from the scan is then used to create a digital model of the device, which is then printed [58]. This process is shown in Figure 18 below.

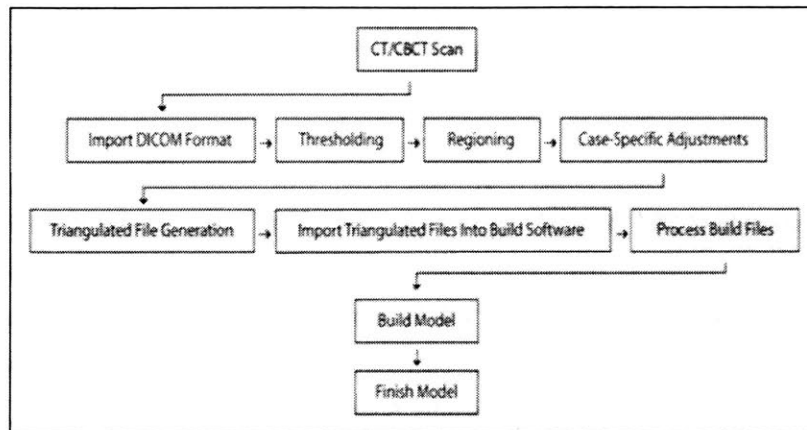


Figure 18: Process of producing physical models from medical imaging [58]

The ability to create patient-specific devices has many benefits. First, there is opportunity for improved patient outcomes; instead of using a standard size and geometry, a surgeon can use a device that is tailored to the specific application. This application creates increased value for the patient, and can potentially drive business growth. The next benefit is cost reduction; typically a surgeon takes several sizes of implants into the operating room, in case they experience fit issues. A customized implant eliminates this issue and saves on excess inventory, sterilization, and logistics expenses in addition to time in the operating room. The FDA has released technical guidance on patient-matched devices, and specifies that these devices can begin with a standard template, which is then altered as necessary by the clinical staff or by a third party [2]. These types of devices, while patient-specific, are not considered “customized” devices under the Custom Device Exemptions guidance [59].

Use of 3D Printing in medical devices will continue to grow, for the reasons outlined in Table 1. Whether it is used for device customization by advanced manufacturers, or for low-cost prototypes at academic institutions, 3D Printing will continue to change the medical devices industry [3].

3.2.4 FDA Guidance

The increased activity surrounding 3D Printing in the medical devices industry motivated the FDA to release guidance on its use in 2016. The document, titled “Technical Considerations for Additive Manufactured Devices”, provides recommendation on device design, software workflow, material control, post processing, validation, and quality consideration for new devices. Additionally, it discusses materials, sterilization, and biocompatibility concerns that need to be addressed prior to device approval. Official guidance on additive manufacturing helps device makers on future development projects by highlighting FDA focus areas concerning the new class of technology. It is an important step towards wider implementation of 3D Printing for end-use applications that will enable future guidance on point-of-care manufacturing or other significant developments [60].

3.3 Use of Additive Manufacturing at J&J

3D Printing has been used at J&J in some capacity for over fifteen years. In this time, the organization has developed significant expertise and procured advanced additive manufacturing equipment. Despite this, in most cases the use of 3D Printing at J&J is limited to early prototyping during the concept generation phase of development. The following chapter describes the current state of each of the focus areas in J&J, which are further detailed in Appendix Section 6.1: 3D Printing expertise, organizational learning, external and internal capabilities, processes, and business commitment. Additionally, this section concludes with a brief discussion of where J&J is currently generating value from the technology.

3.3.1 3D Printing Expertise

Separately from the Medical Devices franchise and the NPD organizational structure detailed in Section 2.2.1.1, J&J supports a 3D Printing Center of Excellence called the “3D Printing & Netshape Technology Center” (3DP & NSTC). This group serves as an enterprise-wide body of knowledge on additive manufacturing, with a stated purpose to mature and implement 3D Printing technology, develop a pilot roadmap, and grow strategic partnerships to maximize value. This group has had success proving several additive manufacturing techniques, including the use of DMLS for production tooling and prototype injection molding through PolyJet. This group has significantly increased the body of 3D Printing knowledge within the business, despite having relatively low headcount and a core team of just seven members.

In addition to coordinating internal research and application, the 3DP & NSTC has also established over 50 strategic partnerships with equipment manufacturers, academic institutions, and government entities [61]. These partnerships help to keep the company either on or close to the cutting edge of the technology.

Where the 3DP & NSTC acts as a centralized body of knowledge, various labs across J&J are also available for consultation. Because 3D Printing has been in use for well over a decade in certain parts of the company, these labs have developed additive manufacturing expertise; as it has been developed over time and through experimentation, this practical knowledge is somewhat confined to the J&J locations that have the advantage of 3D Printing capabilities.

3.3.2 Organizational learning around 3D Printing at J&J

The 3DP & NSTC is also tasked with procuring and coordinating use of new technologies, such as CLIP. It keeps good working relationships with the various labs across J&J and maintains a comprehensive list of internal capabilities as described in Section 3.3.3.

Figure 19 illustrates the relationships between groups influential in the adoption of 3D Printing technologies at the start of this project. Because there is high-level governance on activities to pursue, the 3DP & NSTC has no official obligation to individual project teams; piloting of new technologies is coordinated on an ad-hoc basis, and consulting services are arranged per request. The same is true between the project teams and the 3D Printing Service Providers; furthermore, observations and interviews have shown an inconsistent link between these groups, especially if they are not collocated.

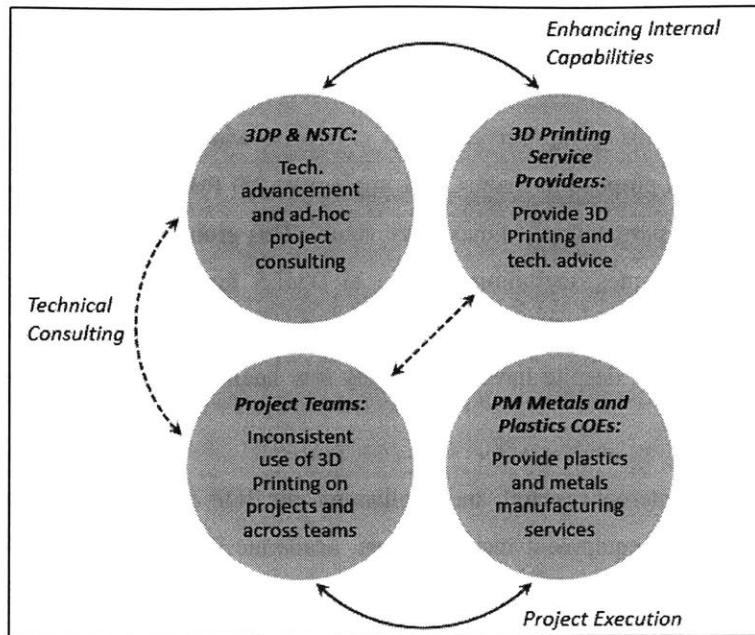


Figure 19: Relationships of groups influential in use of 3D Printing at the start of this project

The result of this organizational structure is a strong core body of knowledge and significant internal 3D Printing capabilities, but inconsistent utilization at a project level. Some project teams, which are often under the direction of an enthusiastic engineering fellow or Product Manager, have significantly higher levels of experience with—and value captured from—3D Printing than others. In some cases, even if project teams pursue the use of additive manufacturing, they are unaware of internal capabilities and instead turn to outside vendors, who can be slower and are significantly costlier.

3.3.3 Internal Capabilities

J&J maintains a portfolio of 3D Printing technologies. The most pervasive technologies across its business are extrusion, specifically FDM, and binder jetting, such as Stratasys’s PolyJet. These machines are excellent for early prototyping, which fits with the overall pattern of use across the business. In addition, J&J also has metals 3D Printing capability for building prototype parts. It regularly updates a list of available equipment, along with the responsible owner, and shares it on the company’s intranet. Despite publishing this list of internal resources, interviews with project teams and analysis of lab order history revealed limited use of equipment between sites; Figure 20 shows an example of the lack of diversity of incoming orders for a specific lab. In the example, all operating companies are collocated with the exception of the “other” and the “Trauma” categories, despite advanced and unique capabilities at this particular site. This shows that even if a lab has advanced resources, collocation—and awareness of capabilities—is still important for project teams.

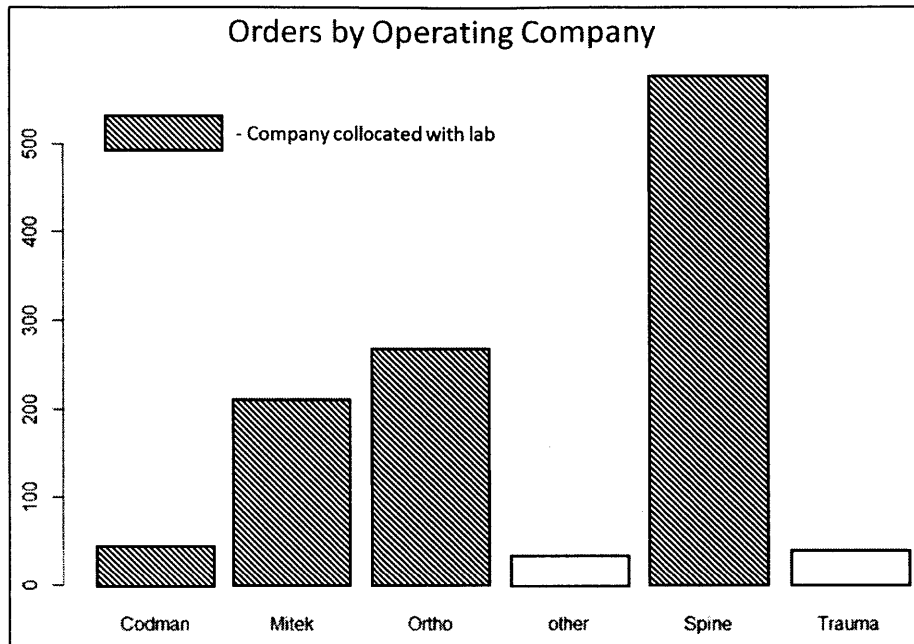


Figure 20: Orders by operating company for one J&J lab

The 3D Printers at J&J are operated in one of two different ways, either in a lab or by a functional group. If the machine is in a lab setting, it becomes part of a portfolio of technologies, and is shared across functional groups. An experienced operator, who can consult on projects to determine the best technology for the application, runs a 3D Printing lab. While the labs typically use a first-in-first-out system, the lab operator can choose to move parts up in the queue if they are considered business critical. This structure has the advantage of high machine utilization, but often results in significant queue times due to high volumes. Queue times at one lab typically run 2-3 days for polymer parts, and 1-2 weeks for metal parts.

If owned by a functional group, the opposite is true; fewer parts produced leads to greater responsiveness, but also more idle time. Functional group ownership also presents the challenge of true responsibility—one designer interviewed stated that in his group, three members were forced to become “gatekeepers” of the machine to control material costs and coordinate efficient use of the equipment. This presented a burden of roughly an hour a day on three senior level design engineers, which he stated was clearly an inefficient use of their time [5].

In addition to the portfolio of machines available for daily use, J&J also collaborates with equipment manufacturers to pilot new technologies through the 3DP & NSTC. This allows the company to stay on

the leading edge of industry trends, and it exposes engineers to potentially new applications. Use of these machines is performed on an ad-hoc basis through a 3DP & NSTC contact.

3.3.4 External Capabilities

When project teams choose to have 3D Printed parts, fixtures, or tooling made externally they typically use national prototyping shops, such as Proto Labs, Inc. These shops have relatively fast turnaround time for parts; in most cases polymer parts are delivered within one week, and metal parts are delivered within two weeks. One advantage of using a prototype shop is that they typically have advanced capabilities and expertise. These capabilities include a variety of available technologies and advanced simulation software, coupled with many post-processing techniques. Advanced capabilities come at a cost—these shops charge a premium for their services, with estimates at roughly four times the cost of producing parts internally. Despite the cost of parts, working with external vendors remains a good option when J&J is missing either the equipment or expertise needed to perform a job internally.

3.3.5 Current Process for producing 3D Printed parts

The process of ordering 3D Printed parts at J&J differs significantly depending on both individual location and whether a lab, a functional group, or the 3DP & NSTC own the machine. Because there is no standard process, project teams have difficulty in several areas: they have no way of identifying the most efficient resource and they are unfamiliar with process for ordering parts. For this reason, teams tend to favor familiar collocated resources, even if there may be a better technology for their application at a different site.

Another option teams have is to get assistance from the 3DP & NSTC. In this case, an engineering fellow consults with the project team to identify the most efficient resource, who then works with a coordinator to produce the parts. Figure 21 shows this process, and is based on experience working with one of the three pilot project teams.

At least one lab at J&J maintains a digital ordering system for relatively simple part production. It describes useful information such as suggested technology, expected cost, current queue time, and past order history. As shown in Figure 20, the current use of this system is largely limited to collocated operating companies.

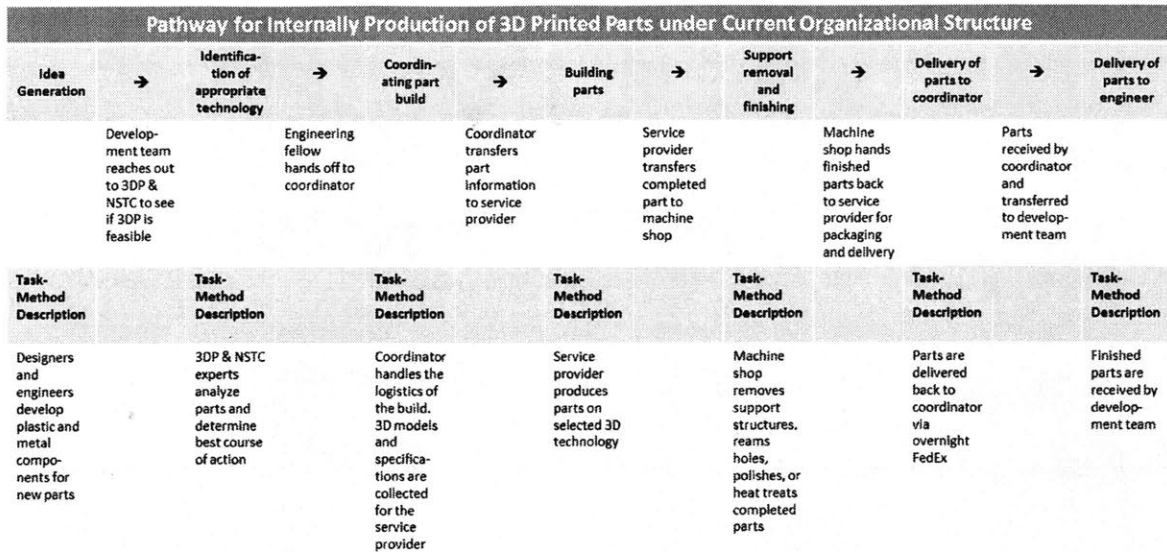


Figure 21: Pathway for internally producing parts at J&J

3.3.6 Business Commitment to 3D Printing

J&J's leadership has shown strong commitment to 3D Printing through advocacy and investment. The company has formed a 3D Printing Center of Excellence through the 3DP & NSTC, and continuously invests in new technologies. In the summer of 2016, J&J hosted a 3D Printing summit with leaders in the industry from the top manufacturers and academic institutions. This summit drew several hundred attendees from all segments of J&J. In addition, much of the leadership interviewed during this project has 3D Printing related annual goals. Company leadership recognizes that the technology will have a significant benefit to both design and supply chain, and it has done an excellent job fostering a culture of curiosity among all segments.

On the project level, commitment to 3D Printing is more variable and depends on the project and the project manager. If use of a new technology poses significant risk to either the project schedule or quality, then it is likely that it will not be investigated. Additionally, experience with the technology was an indicator of future support; those who had used 3D Printing successfully were much more likely to advocate for it. Overall, interviews with project-level engineers found that project leadership is generally supportive of using 3D Printing, and adequately balances the risk of using a new technology with the potential reward of project acceleration or design improvement [5], [62].

3.3.7 Value Generation from AM

Currently, value driven from 3D Printing at J&J is largely limited to time and cost savings in the R&D stage. Several recent applications of the technology have begun to expand its value proposition; J&J now

uses it for development tooling, fixtures, and production tooling on a relatively small scale. The 3DP & NSTC coordinates these niche applications on an ad-hoc basis, and their use is not yet regular among project teams. Thus far, 3D Printing is not used for end production on a large scale due to quality concerns and high costs. One product that is produced using additive manufacturing is the TruMatch cutting guide, which leverages 3D Printing's infinite customizability to improve patient outcomes in knee replacement surgeries.

4 Developing an Improved Strategy for using 3D Printing in NPD

4.1 Introduction

The first line of J&J's Credo, which is the document that has defined the company's principles for over a century, states, "We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services." The company uses this idea to guide its product development, with the goal of each project to best serve the patient. Therefore, it sees value in any innovation that can bring improved products to the patient in less time; 3D Printing is being explored for just this reason.

While 3D Printing is currently used for prototyping in the early stages of development, it has not been widely used over the remainder of the New Product Development (NPD) process at J&J. To test the technology's value proposition in New Product Development, this project involved a cross-functional approach that coordinated the efforts of three NPD project teams, internal technology experts, company-wide equipment owners, and external vendors, with a goal of reducing cycle time by 5-10%. The research focus was not limited to technological improvements. I learned that organizational structure plays a critical role for enabling successful implementation of any new technology.

This project focused on product development only in the Medical Devices segment. Ultimately, the improvements recommended by this work are intended for the Consumer Products and Pharmaceutical segments of J&J as well, where applicable. The following sections first describe the process taken to identify improvement opportunities. Next, organizational recommendations are proposed that will enable an efficient and learning-focused structure that maximizes benefit from both resources and expertise. To complement these organizational enhancements, possible new technologies or techniques that can speed development are discussed. Finally, several company-specific considerations are discussed that may affect the successful implementation of the improved strategy.

4.2 Opportunity Identification and Analysis

Several project schedules were analyzed to begin to understand where there might be opportunity to shorten development time for new products. Within the Medical Device franchise's schedules, projects contain two types of events: those with fixed duration and those with variable duration. Fixed duration events, such as accelerated aging tests, biocompatibility tests, or regulatory submissions, are dictated by predetermined factors and are not affected by project team performance. Variable duration events are those such as Engineering Builds, validations, and tooling orders that are under a project team's control. This work focuses on influencing the variable duration events, as these present the best opportunities to accelerate product launches.

Product Managers at J&J generally provide both “most optimistic” and “most probable” schedules—the former allowing essentially no room for error and the latter based largely off past NPD performance. Comparing the two versions gives insight into expected pain points where teams have struggled in the past and there exists a significant amount of uncertainty. The pain points identified through this analysis are described below:

Total number of Engineering Builds: The number of Engineering Builds, which are meant to test the reliability and tune the overall design of a product, is uncertain at the start of a project. In most “optimal” cases there are two planned builds, where in most “probable” cases there are three or more. A worst-case scenario is when the project team cannot meet business requirements after several Engineering Builds, and the project is cancelled. An additional Engineering Build represents approximately three months of development work, and a significant opportunity for 3D Printing. Increasing the total number of iterations prior to Engineering Builds will increase the likelihood of landing on a successful design earlier in the process, and may lead to fewer Engineering Builds overall.

Production tooling lead-time and modification: Production tooling is on or near the critical path for a typical Medical Devices project. A typical lead-time estimate ranges from eleven to fourteen months, depending on any design changes to the tooling during development and the vendor’s overall speed. Additionally, the “most probable” scenarios allow time for tooling modification; this is a period where the tool is modified, or “groomed”, to meet design specifications. The uncertainty posed by both lead-time and modification account for a potential timesaving opportunity of roughly six months of development. A solution that captures some of this opportunity could significantly affect the success of a new product launch.

Duration of Engineering Builds: Though somewhat less impactful than the number of Engineering Builds, their individual duration also brings uncertainty to a project schedule. The durations of these builds are heavily influenced by the type and lead-time of prototype tooling utilized—“soft” tooling, which is a prototype precursor to production tooling, can have a lead-time of up to eight weeks. Increasing the options available to engineers and designers in this phase is important—especially because the iterative nature of these builds multiplies the impact any improvement effort. Furthermore, advanced 3D Printing capabilities can help a project team be more responsive overall, adapting to design changes, test failures, or scope creep with ease, as opposed to major time and expense spent on traditional prototype tooling.

Duration of R&D work: Schedules in this phase of development are not tracked as rigorously as later stages, but may carry greater importance. This early work, referred to as the “Fuzzy Front End”, often involves years of background investigation, proving new technology, and early concept development [22]. This work is also highly iterative as engineers experiment with different designs and materials on a daily basis. While managers may put less emphasis on schedule in a project’s early stages, time saved in this portion of development is equally important to time saved later on. Providing R&D teams with the best tools could have significant benefit to the overall duration of NPD projects and the frequency of their launches across the business.

An important factor to consider in the project schedule analysis is that as a project approaches launch, the number of parallel path activities increase. For example, during the early R&D phases, speeding up a design iteration will almost certainly impact the critical path, because there is very little support activity occurring in parallel. Conversely, reducing the lead-time for capital tooling has a lower chance of affecting the launch time, because it occurs in parallel with reliability testing, survival studies, and regulatory submission. In either case, feedback from J&J management stated that shortening any activity is beneficial to the project because it allows reallocation of resources to the most impactful tasks and reduces risk by shortening the duration of activities near the critical path—therefore even if an activity does not directly impact a project’s critical path, allowing dedication of resources to other activities may still impact the overall project schedule. With this in mind, this project did not have a bias against opportunities at the end of the NPD cycle; it sought to identify areas where 3D Printing could save time or cost across all development, even if the targeted activity did not fall directly on a project’s critical path.

In addition to analyzing project schedules to identify where 3D Printing may provide opportunity, interaction with NPD project teams further clarified the current state of the NPD process at J&J. It is highly iterative, and most project teams already use either 3D Printing or a speed-focused prototyping shop, such as Proto Labs, in some capacity. For the teams that use 3D Printing, commonly used polymer technologies include FDM and PolyJet, while somewhat less commonly used are metals technologies such as DMLS. Currently 3D Printing is largely confined to the very early development stages, before engineers turn to higher volume production-oriented technologies. Additionally, 3D Printing is often bypassed for perceived shortcomings in quality, convenience, or material availability. Figure 22 shows a composite of quotes from various J&J employees gathered over the course of this project—each represents an observation that can be used to improve upon J&J’s current 3D Printing strategy.

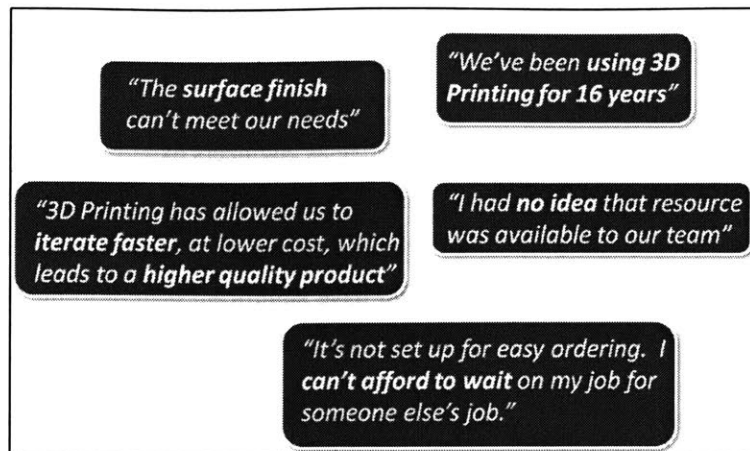


Figure 22: Quotes from various employees at J&J

“The surface finish can’t meet our needs”: This quote identifies a common theme expressed by several project teams at various sites. The engineers brought up valid concerns—each 3D Printing technology has its limitations, whether it is layer stratification, roughness, or inability to produce glossy finishes. Further research in this area identified many different methods to improve these drawbacks, including proper technology selection and various post-processing techniques.

“We’ve been using 3D Printing for 16 years”: This quote was meant to question the value of further research into the area, and showed that parts of the organization had an outdated view of the capabilities of modern 3D Printing technology. 3D Printing is in fact experiencing exponential growth with the proliferation of technology options, and J&J needs to develop a system that keeps its project teams on the cutting edge to capture the most value from new technologies [27]. Several new technologies have shifted economic production volumes of 3D Printing, as described in Section 3.1.5, and maintaining awareness of these trends through continued research is critical to the successful implementation of 3D Printing.

“I had no idea that resource was available to our team”: Despite maintaining a cutting-edge 3D Printing Center of Excellence, teams at the project level often did not have good visibility into available resources or technologies. There were several instances where a slower, more expensive external vendor was utilized instead of an internal resource. This phenomenon was especially apparent between sites; several key labs at J&J were underutilized by other sites due to a lack of awareness. For J&J to maximize benefit from its vast internal resources, it needs to design a process that increases the chance of using the best available resource on every development project.

“It’s not set up for easy ordering. I can’t afford to wait on my job for someone else’s job”:

Even when all the right conditions were in place for a project team to use a 3D Printing resource, there still remained reasons for them to choose either a different technology or a sub-optimal resource. A concern that was raised several times was the issue of lead-time; when design time, queue time, post-processing time, and inefficiencies were added to print time, it became advantageous to turn elsewhere for prototyping. This signaled that there may be potential the capture more value from 3D Printing through operational or organizational improvements.

“3D Printing has allowed us to iterate faster, at lower cost, which leads to a higher quality product”: This quote showed that above all, the organization saw the potential of 3D Printing and was willing to explore new technologies. Capturing these success stories and making them known to different parts of the organization will be critical to the continued expansion of 3D Printing at J&J.

It was clear from the quotes cited above that no single change could vastly shorten NPD cycles at J&J—the topic needed to be approached from both a technological and organizational perspective. The following sections take these observations as inputs to help develop an improved strategy through identification of promising new technologies, new techniques, or organizational changes. This strategy will ultimately help to drive value from 3D Printing through improved development speed, among other benefits.

4.3 Improving Organizational 3D Printing Knowledge to Speed New Product Development

This section discusses adjustments to J&J’s organizational structure that will facilitate a greater learning rate around 3D Printing and begin to address the concerns identified in Section 4.2. It first details the high-level design of the proposed structure, then discusses its practical implementation at J&J MD, and concludes with discussion of a model that was built to refine it. The recommendations in this section are meant to capture significant value with little up-front cost to the business.

4.3.1 Designing an organization to facilitate 3D Printing learning

As described in “The High Velocity Edge”, an organization’s ability to capture value depends on understanding where knowledge is needed, generating new knowledge, and sharing that knowledge such that an individual’s expertise is combined with the expertise of the whole [63]. In an industry which uses technology such as 3D Printing, where new gains are made every year and the proliferation of technology options is exponential, it is important to structure a development organization to not only learn new information, but also to maximize the potential value of the technology. Take for example two

extremes—constant learning and no learning. The first extreme, where an organization devotes every working hour to understanding the benefits of a new and evolving technology, it has an enormous opportunity cost from the lost time that could have been focused on product development. In the second extreme, if an organization affords no time to learning cutting-edge technology, it is impossible to capture value from it. Between these two extremes lies an optimal strategy of time and resources dedicated to technological understanding and practical implementation.

Building on the current organizational structure of groups involved in New Product Development at J&J, as outlined in Section 2.2.1.1, a realigned structure is proposed which changes roles and responsibilities. This structure, shown in Figure 23, establishes the roles of “Pioneer”, which advances the new technology, “Service Provider”, which makes it available and provides project-level expertise, and “Developer”, which implements it on projects. In the case of J&J Medical Devices, these roles would largely be filled by the 3DP & NSTC, the PM Metals and Plastics COEs, and the project teams, respectively.

Experience at Toyota during its period of globalization provides evidence to support this structure—despite involvement in very different industries, significant parallels are visible. During the 1980’s when Toyota surmised it could no longer rely on exports for growth, the company began to open factories in its major markets. During this period of expansion, it realized that exporting managers to run factories in the United States was not a sustainable practice. Instead, it successfully developed a system to train American managers and export its management philosophy instead of its cars [63]. Similarly, this model can be applied to J&J—the 3DP & NSTC can move from a model of project-level involvement to a more sustainable model of training members of the existing NPD organizations to be experts in 3D Printing technologies, thereby multiplying its efforts.

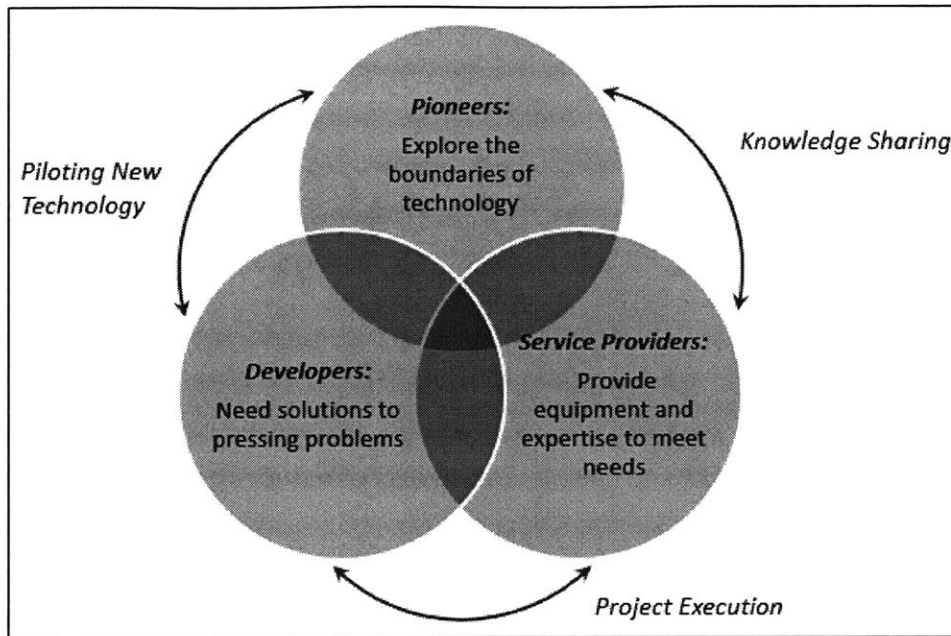


Figure 23: Proposed organizational structure to maximize value from 3D Printing technologies

It is important to note that there is an ascending number for resources from the Pioneers to the Developers, as depicted in Figure 24. The Pioneers, which in J&J's case will be the 3DP & NSTC, will be a tight core group of n_p experts, which the segments share. It will not only collect and share information between franchises, but it will also work with outside vendors, send representation to industry conferences, and produce practical training.

Moving out from the Pioneers, the Service Providers, under the Product Management groups at J&J MD, will be specific to their franchise but will maintain awareness of and need-based communication with the other segments. Another reason for segmenting the Service Providers is incentives; their primary goal should be generating successful outcomes for their segment. While the Pioneers may advocate for a technology that is risky because it has wide-ranging benefits, the Service Providers will act as a check to ensure that any technology used is in the best interest of the project. This structure will enable each franchise's Service Providers to focus largely on its specific segments projects, while providing access to company-wide resources as needed. The number of Service Providers, n_s , will be larger than the core group of the Pioneers ($n_s > n_p$).

Finally, the Developers, which are largely made up of individual project teams, are both more numerous and more segmented than the previous two groups. The vast majority time spent by an engineer or

designer in this group will be focused on project-specific development. The quantity of Developers, n_d , is larger than both the Service Providers and the Pioneers ($n_d > n_s > n_p$).

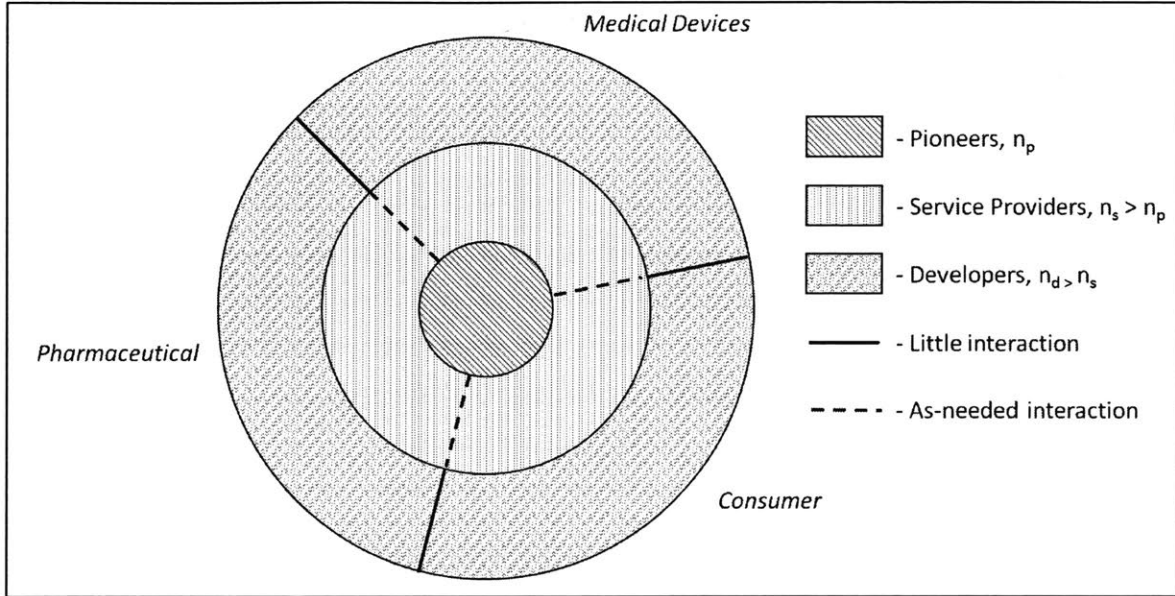


Figure 24: Ascending volume of resources from Pioneers to Developers

The result of this new structure should be more efficient dissemination of knowledge through the organization. Instead of experienced engineering fellows from the 3DP & NSTC coordinating builds for multiple projects using well understood processes, they are free to research and push boundaries through select pilot projects and vendor interaction. Furthermore, the project teams would no longer be tasked with reaching out to the appropriate vendor based on a limited knowledge of additive manufacturing—they would instead communicate their needs to a knowledgeable intermediary with whom there is an existing relationship, who directs them to the most effective resource. At the core of this model is a balance between training efficiency and advancement of technology understanding.

Figure 25 illustrates the dissemination of 3D Printing knowledge over the three key groups under the proposed organizational structure. It shows near continuous learning for the Pioneers, regular learning for the Service Providers, and as-necessary learning for the Developers. This structure is meant to reduce the organizational effort dedicated to learning a new technology, while maximizing value from it. This model is further explored in Section 4.3.3 using Monte-Carlo simulation to optimize the cost-benefit of these relationships.

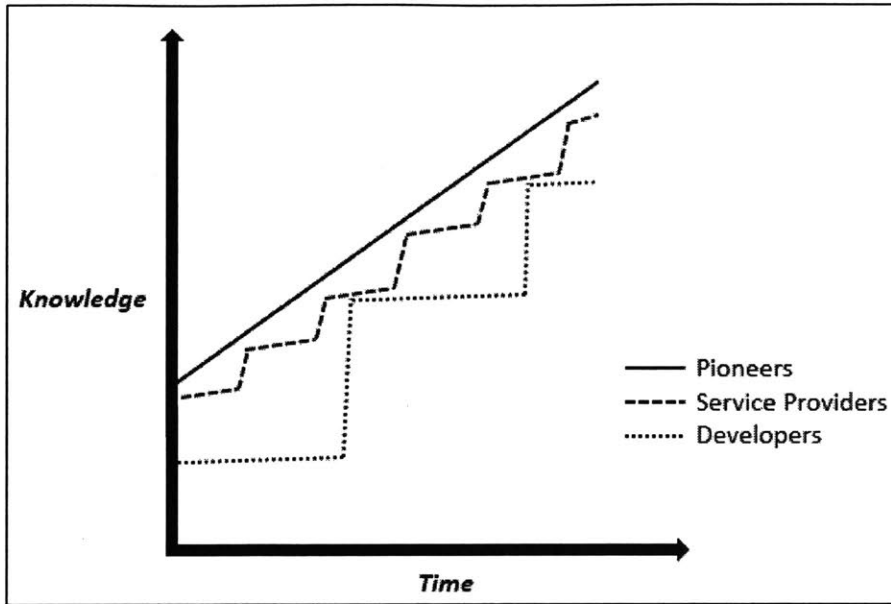


Figure 25: Cascade of industry knowledge between 3D Printing functional groups

An important step to facilitate organizational learning is to incorporate built-in-tests [63]. This structure will allow for this, with a minor adjustment—each interaction between the groups should include time dedicated to learning and capturing knowledge developed since the previous interaction; for example, if a Pioneer recommends a new technology to a Service Provider, there should be an update on its implementation at the next meeting. This way, knowledge can grow continuously and be shared across the business. In addition to knowledge flowing down from the Pioneers to the Developers, there will also be a flow of knowledge up resulting from application experience. The Developers will feed back success stories, failures, and business needs, which can then be researched or piloted at the Pioneer level and shared across the enterprise.

4.3.2 Practical implementation of the new organizational structure at J&J

At the core of the structure proposed in Section 4.3.1 is the idea that there is a balance between the effort spent on training a workforce in a new technology, and the value captured from the use of the technology. While effort is spent at the Pioneer, Service Provider, and Developer levels, value is only captured if implemented on projects at the Developer level. Keeping this in mind, the following recommendations provide a platform that is tunable to optimize the value captured from using 3D Printing at J&J.

4.3.2.1 Integrate 3D Printing service providers with PM COEs

The first organizational change needed to facilitate the proposed structure is for the PM Metals and Plastics COEs to assume the responsibilities of the 3D Printing Service Providers. The reasoning for this

change is that there is already an established and regular relationship between the COEs and the project teams, enabling 3D Printing to become another tool in an already successful portfolio. 3D Printing, with few exceptions, can naturally be broken down into the existing COE groups by technology; either metal, such as DMLS, or plastic, such as FDM, SLA, etc. This change will allow 3D Printing technologies to be used where appropriate, as soon as a need is identified, and compared fairly against traditional technologies.

The COE's will also evaluate the risk of using a new technology and communicate it to the project team; many teams cannot tolerate risk, so relying on 3D Printing would not be an option. If this is the case, additional resources would be required to increase the Technology Readiness Level (TRL) prior to use on a project. This process, developed by NASA, is currently used at J&J to measure the technical maturity of a new technology on a one through nine scale [64]. For example, an unproved benchtop idea is considered TRL 1, where successfully implemented and field-proven techniques are considered TRL 9 [64]. One way in which this is currently handled at J&J is for the 3DP & NSTC to study and perfect the process independent of a specific project. Another method is to "Parallel Path" 3D Printing with traditional manufacturing if risk is a concern. For example, a critical path Engineering Build could produce 3D Printed parts, but still order a traditional injection mold. If the 3D Printed parts are unacceptable, the cost to the project is small compared to increased schedule duration—this method significantly reduces the risk of using an unproven technology. Both of these methods improve the organization's body of knowledge, with the hope that project teams will eventually be able to use 3D Printing without additional risk to the project schedule.

In addition to providing greater 3D Printing expertise at the project level, integration of the PM Metals and Plastics groups with the current 3D Printing service providers will streamline the process of producing 3D Printed parts, depicted in Figure 26. In the proposed scenario, the PM groups assume ownership and responsibility for the development-focused 3D Printing labs across J&J—reducing the number of handoffs needed to take parts from idea to delivery. Compared to the current process shown in Figure 21, the proposed process is simplified and should reduce order-to-delivery times. It should be noted that research-focused labs across J&J, which are those used to study new technologies and increase their TRL levels, would remain under the direction on the 3DP & NSTC. Additionally, future production-focused 3D Printing facilities will remain under J&J's "Make" organization, which is responsible for post-launch production.

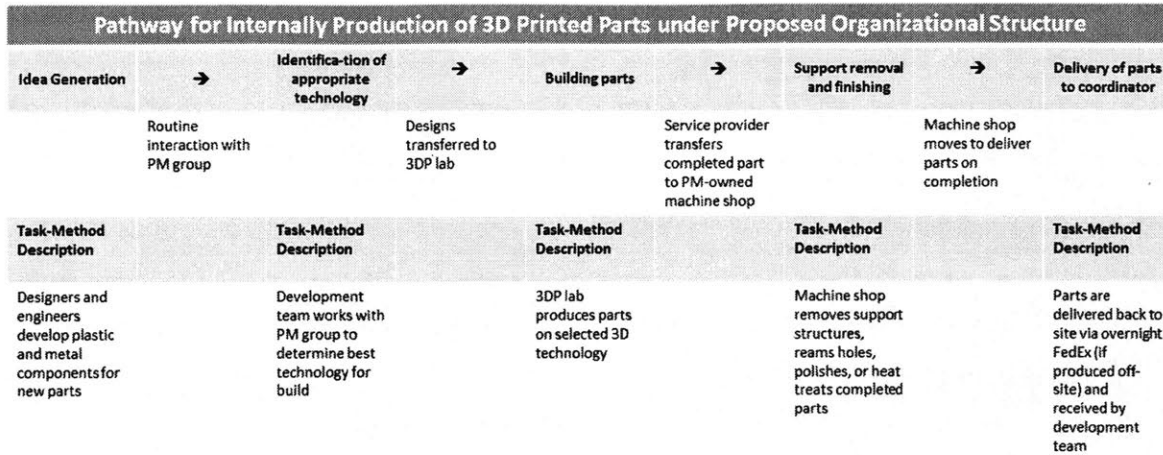


Figure 26: Pathway for internal production of 3D Printed parts under proposed structure

Work with project teams suggests that increasing the speed of 3D Printing services would both increase the number of design iterations, resulting in higher quality final products, and decrease the use of external vendors, resulting in cost savings [5]. Ultimately, J&J should work to reduce its time from idea generation to delivery from the current state, described in Section 3.3.3, to as close as possible to “entitlement,” or the physical print time for each technology. This is especially true for applications where responsiveness is a key driver of value from 3D Printing, such as prototyping. Figure 27 shows that there is significant room for improvement as 3D Printing becomes more important in New Product Development, especially with DMLS and CLIP technologies. Closing this gap through continuous process improvement will help J&J drive significantly more value from 3D Printing in New Product Development.

Typical 3D Printing Entitlement vs. Actual Time-to-Delivery		
3D Printing Technology	Approximate Entitlement	Actual Time-to-delivery
Direct Metal Laser Sintering	24-72 hours	14-21 days (Includes post-processing and heat treating)
Fuse Deposition Modeling	6-24 hours	2-4 days
Selective Laser Sintering	3-12 hours	2-3 days
Continuous Liquid Interface Production	1-2 hours	>2 weeks
Polyjet Printing	1-3 hours	Same day

Figure 27: Entitlement vs. actual Time-to-Delivery for various 3D Printing technologies in MD

4.3.2.2 Provide initial training to Service Providers

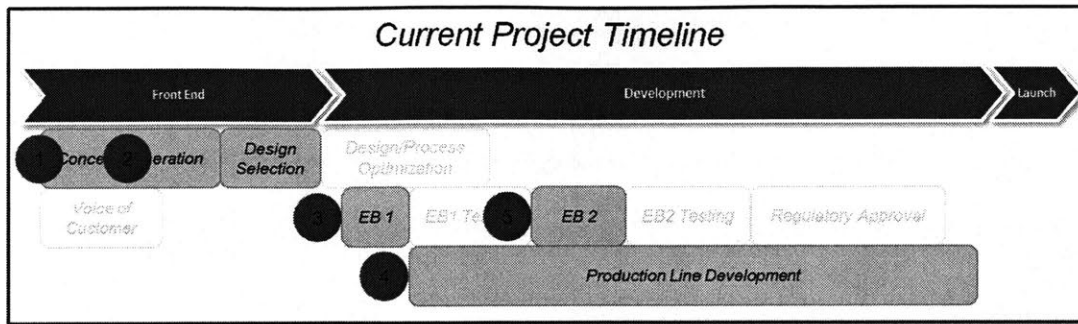
If the PM Metals and Plastics COEs take on the role of “Service Provider”, as outlined above, providing this group initial training will be critical to the success of the proposed strategy. The value from the training program will be adversely affected by “overtraining”, which arises when the individual project teams have a deeper knowledge of 3D Printing than the Service Providers, who are supposed to be bringing expertise. When this situation occurs, cost is spent on the training sessions, with little to no value added. To avoid this phenomenon, initial in-depth training for the Service Providers is important to avoid investing in low-value training—it ensures that the PM COEs are indeed “experts” compared to the project teams. This recommendation is further examined through simulation in Section 4.3.4.

4.3.2.3 Set a regular training cadence between 3DP & NSTC and the PM COEs

In order to equip the PM COEs with sufficient knowledge to act as project-level consultants, they will require an appropriate level of training and exposure to 3D Printing. To accomplish this, the proposed organizational changes must include regular training sessions facilitated by the 3DP & NSTC, which update the Service providers on the current body of knowledge. While the Service Providers need not have the cutting-edge expertise of the Pioneers, they should have a practical working knowledge of the technology, such as surface finish capabilities, available materials, and drawbacks of each type of 3D Printing. One variable that was explored in this project is balancing the cost of this training with the value gained from it. The optimal cadence for these training sessions is further explored through simulation in Section 4.3.3.

4.3.2.4 Provide as-needed training to project teams through “Blitzes” and design reviews

Lastly, the proposed organizational structure requires coordinated interaction between the three groups at the project level. Experience working as part of project teams repeatedly showed that the most effective training method to capture value from 3D Printing was project-specific application—instead of providing generic training with little context, such as information about various printers and materials, training should be applied at the project level by analyzing parts of the specific product. This is accomplished by performing a part-by-part analysis of a representative portion of the product, as shown through the process in Appendix Section 6.3. Facilitated by the Service Providers, these training sessions tailor the training materials to focus on driving real value from 3D Printing by determining which technologies to use and connecting project teams with specific Service Providers that can execute the plan. Figure 28 shows the critical stages during a typical J&J Medical Devices NPD cycle where 3D Printing is expected to create value, and where the technical opportunities described in Section 4.4 can be applied.



- - Continued education through 3DP&NSTC
- - 3DP "Blitz" to identify early opportunities
- - 3DP review prior to first Engineering Build
- - 3DP design review for production tooling
- - 3DP review prior to second Engineering Build

Figure 28: Key proposed interactions between Service Providers and Developers during NPD cycle
(Contrast to Figure 8 on page 28)

This format again focuses on the value-centric idea that 3D Printing training should be relevant to the project, and should be delivered only when necessary. **Point 1** in Figure 28 refers to base-level training delivered prior to the start of a project; this could involve introductory 3D Printing training, or it may be as simple as distribution of an updated Service Provider capabilities document. The Service Provider should optimize this training based on the current knowledge level of the team and the type of product being developed. The main purpose of the initial training should be to bring the developer to a level at which they have a general understanding of available technologies and also are aware of Service Providers with whom they can seek guidance.

Point 2 in Figure 28 is the approximate location of the "3D Printing Blitz", outlined in more detail through the SIPOC Diagram in Appendix Section 6.3. This training session should occur once the project team has an understanding what the final product launch will entail, but before making major design decisions or equipment purchases. This session will require a short amount of time—roughly four hours for each project was effective in practice—where the majority of the project team and a sector Service Provider are fully dedicated to training on 3D Printing.

Over the course of this project, a 3D Printing Blitz was completed with each of the three pilot project teams. These sessions saw varying degrees of success—anywhere from almost no timesaving potential to eight weeks of timesaving potential were identified through the use of 3D Printing. The degree of success seen from the Blitzes was largely the result of two factors: timing and leadership support.

These three sessions showed that it is critically important to approach project teams very early in the development phase. The first reason for this is that during this stage of the development process, the new product is undergoing rapid, low-volume iterations, which is fertile ground for 3D Printing. Second, major design decisions have yet to be made at this point—characteristics such as material choice, fundamental design, or manufacturing process are still being experimented with. These decisions, made early on in the development process, have a huge impact on overall cost and development time. For example, making a decision to machine a gear versus using an injection-molded version of a similar design would later add significant cost. If the designers can experiment with a variety of polymer materials through 3D Printing to determine if a plastic version is strong enough, then they can quickly make a decision and drive value for the organization without impacting schedule.

The above example also illustrates the value of project-specific training. For the project teams to capture value from a Blitz, the product would need at least an initial idea for the end product—the fact that the hypothetical team above knew that they were going to need, for example, a gear is important to drive valuable discussion with 3D Printing experts. With a wide variety of available vendors, resources, materials, and technologies available, high-level training may not be adequate to seize opportunities enabled by 3D Printing. An important component of the Blitz process should be to deliver *actionable* recommendations; that is, the Service Provider recommendations coming out of a Blitz should be in the form of a *specific* material for a *specific* part to be produced by a *specific* resource on a *specific* machine. This allows Developers to not only have a clear pathway to prototype parts, but also develop relationships with vendors and gain highly practical experience to supplement any technology training.

As previously mentioned, leadership support of 3D Printing is an important factor for success coming out of a Blitz. The three pilot projects showed varying degrees of leadership support, which ranged from general aversion to new technologies to embracing them as a valuable tool. Without a doubt, project leadership set the tone for the Blitz sessions, and it was reflected by either support or hesitation from the project teams. One method of ensuring supportive leadership is to provide both detailed explanation of the benefits, as detailed further in Section 4.4.1.3, and case studies of success stories prior to the Blitz session. This two-pronged approach addresses both risk and reward; it mitigates the perceived risk of a new technology by showing proven past examples, and it increases awareness of the potential benefits of

speed enabled through 3D Printing. Decisions coming out of a Blitz should have support of both the Developers and the Service Providers; they should strive to strike a balance between minimizing risk to the project and capturing benefit from the new technology. If value is identified but risk is a concern, one of the methods described in Section 4.3.2.1 may be used.

While the Blitz, shown in Point 2 of Figure 28, is likely the most important interaction between the Developers and the Service Providers, it is important that the remaining major decisions are evaluated individually prior to proceeding. **Points 3-5** show that each activity on the critical path presents a significant time or cost savings opportunity. A similar format to the Blitz is recommended for these reviews, but with increased focus on the upcoming activity. Because a typical NPD cycle is over approximately three years, these sessions will also serve to update the project teams on any new advances in the 3D Printing industry that may have applications to other parts of the project.

Finally, Point 6 in Figure 28 outlines a post-launch review of how successful 3D Printing was for each application. This information is critical to advancing the organization's body of knowledge on the subject, and will help other teams in future technology selection.

4.3.3 Refining Organization Structure through Optimization Model

A model was developed to better understand the impact of the proposed organizational structure on the dispersion of technical knowledge and determine an optimal structure that will best capture value from 3D Printing. The model builds off previous research showing that 3D Printing will positively impact development speed, and thus result in cost savings for the business. It is structured to reflect the theory recommended in section 4.3.1, with the three groups including "Pioneers", who work to advance technology, "Service Providers", who have practical expertise, and "Developers", who are project-focused.

4.3.3.1 Structure of the model

The model seeks to find a balance between training cost and savings opportunity, and assumes that the savings gained from 3D Printing is proportional to the level of knowledge applied to projects at the Developer level. "Knowledge" in this model is the cumulative experience and understanding of materials, capabilities, resources, applications, techniques, costs, and lead times; essentially, it can be seen as the ability to practically implement 3D Printing in a way that provides opportunity for the business. Observations and analysis show a positive correlation between the level of knowledge among the developers and their value captured from the technology; therefore, it is appropriate to model it as a linear relationship to savings. Key model inputs include cadence and duration of 3D Printing focused training sessions. The key model output is the estimated aggregate savings resulting from the training program

over the one-year duration of the simulation. Model inputs and outputs are detailed in Appendix Section 6.4. These inputs should be revised as the training program evolves to ensure an accurate estimate of program value. Figure 29 shows the output of one iteration of the model over the 365-day simulation. The full results from four 1000-iteration simulations are shown in Appendix Section 6.4.4

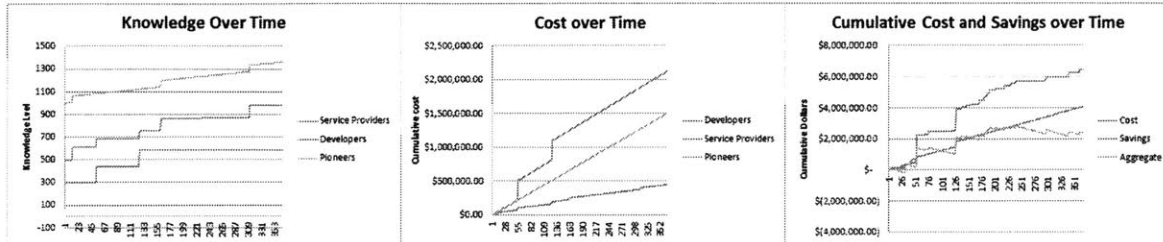


Figure 29: Example plots of model outputs from one iteration

The model tracks three outputs, as shown in Figure 29: Knowledge Level, Cost, and Aggregate Savings. Knowledge Level is a function of the amount of time a group dedicates to training, coupled with the availability of training resources. Cost is simply a function of the man-hours spent on training and the opportunity cost of the corresponding group. Finally, Savings is a function of both the Knowledge Level and the available opportunity for savings. These outputs are discussed in greater detail in the following sections.

This simulation was performed in Excel, using the @Risk simulation package [65]. This package was selected for its ability to incorporate Monte-Carlo capability and produce detailed sensitivity analyses. For each variable input, a uniform distribution was used over a range specified in Section 6.4.1. Each individual trial consisted of 1000 simulations. The sensitivity analyses presented in Section 4.3.4 consisted of 42 trials of 1000 simulations; one trial for each of the six @Risk inputs held constant at 1%, 5%, 25%, 50%, 75%, 95%, and 99% of its specified range. Each simulation is iterative over 365 days, with the Knowledge Levels, Costs, and Savings modeled as cumulative functions.

Each group is assigned an Initial Knowledge Level, $k_{d,0}$, $k_{s,0}$, and $k_{p,0}$, for the Developers, Service Providers, and Pioneers, respectively. $k_{p,0}$ is set to a reference value of 1000, which can be considered the highest level of practical industry knowledge at the start of the simulation; this was done so based on the observation that J&J has cutting-edge industry experts in-house, regularly sends representatives to industry conventions, and partners with a wide variety of both vendors and academic institutions. The initial values for $k_{d,0}$, and $k_{s,0}$, which are some fraction of $k_{p,0}$, are varied through experimentation as

shown in Appendix Section 6.4.2.2 to simulate project teams or segment COEs with varying levels of 3D Printing experience.

4.3.3.2 Modeling organizational learning under the proposed structure

An important feature of the model developed is that there are two different learning rates for each group. The first learning rate, called the “Normal Learning Rate”, is determined by the fraction of time dedicated to independent research on 3D Printing and a group-dependent constant. For example, the Pioneers, who spend the majority of their time dedicated to advancing 3D technologies and learn through time-consuming experimentation, have a significantly different Normal Learning Rate than the Developers, who are generally focused on product development but have access to useful training materials developed by the Pioneers. The Normal Learning Rate for the Pioneers, Service Providers, and Developers, are shown through the following equations:

$$k'_{d,N} = m_d N * D_d \quad (2)$$

$$k'_{s,N} = m_s N * D_s \quad (3)$$

$$k'_{p,N} = m_p N * D_p \quad (4)$$

where $k'_{d,N}$, $k'_{s,N}$, and $k'_{p,N}$ are the Normal Learning Rates of the Developers, Service Providers, and Pioneers, respectively as functions of the Normal Learning Abilities, $m_d N$, $m_s N$, and $m_p N$, and the Fraction of Dedicated Time, D_d , D_s , and D_p . In the model, the Fraction of Dedicated Time for the Pioneers is set to one, given this group is the set of dedicated experts. D_d and D_s become the first decision variables, which are analyzed based on their effects on the Aggregate Savings, which is detailed in Appendix Section 6.4.

To determine an appropriate range for $m_p N$, the assumption was made that the 3D Printing Pioneers would add roughly 10-20% new knowledge over the course of the year. This was seen to be a good estimate, given the growth of the industry and the enthusiasm for 3D Printing within J&J. With $k_{p,0}$ set to 1000, $m_p N$ then falls within the range of 0.27-0.55; that is, the Knowledge Level of the Pioneers at the end of the 365-day simulation falls in the range of 1100-1200 without additional learning from interaction with the Service Providers. For the purposes of the simulation, $m_p N$ follows a uniform distribution as described in Appendix Section 6.4.1.2.

Because the Normal Learning Rates of the Service Providers and the Developers are rendered less important by D_s and D_d , respectively, m_sN and m_dN are not varied for analysis as with m_pN . Instead, these values are fixed as shown in Appendix Section 6.4.2.1.

Equations (2)-(4) describe the speed at which each of these groups learn during normal daily activity—the alternate of which is the rate at which each accumulates 3D Printing knowledge during dedicated learning sessions.

Under the new organizational structure shown in Figure 23, there will be two interactions which will diffuse knowledge across the organization and encourage learning to flow both down to and up from the Developers. The first of these interactions is between the top-level Pioneers and the second level Service Providers called a “Knowledge Transfer Session.” These training sessions are meant to inform Service Providers from across the company of not just new industry advances, but also internal enhancements to capabilities and external partnerships. For example, a Service Provider from the Consumer Products franchise would rely on these regular training sessions for information about new capabilities within the Medical Devices franchise that are available for use. Interviews have shown that there is minimal knowledge and subsequent utilization of internal 3D Printing capabilities outside of one’s own segment [25], and the Knowledge Transfer Sessions would serve to use the central 3DP & NSTC to mitigate this issue.

As opposed to Equations (3) and (4), which are proportional to time dedicated to the effort, the Learning Rates during the Knowledge Transfer Sessions do not include such a term, because full effort is expected. In other words, D_d and D_s are equal to one. During a Knowledge Transfer Session, the Learning Rate of the Developers remains unchanged, and the Learning Rate of the Pioneers and the Service Providers is as follows:

$$k'_{s,K} = m_sK \quad (5)$$

$$k'_{p,K} = m_pK \quad (6)$$

where m_sK and m_pK are the Knowledge Accumulation Rates of the Service Providers and the Pioneers, respectively. The model has been designed with the assumption that during these sessions, learning will occur in both directions; the Service Providers will learn at a faster rate, but the Pioneers will also gain from the experiences and project-level interaction that the Service Providers offer. Values for each of

these inputs are outlined in Appendix Section 6.4.2.1. The total amount of knowledge acquired during a Knowledge Transfer Session on Day (i) is as follows:

$$k_s(i) = k'_{s,K} * tK \quad (7)$$

$$k_p(i) = k'_{p,K} * tK \quad (8)$$

where tK is the amount of time, in days, dedicated to the session. tK becomes the next decision variable in the model, where the cost spent on extending the training session is optimized against the benefit gained from additional training. Feedback from the COEs at J&J and input from the 3DP & NSTC specified that practically, these sessions would be no shorter than half a day and no longer than one and a half days. For this reason, these are the boundaries of the input distribution as detailed in Appendix Section 6.4.1.1.

Given they are not tied to project-level milestones, it is assumed that a regular cadence will be developed for Knowledge Transfer Sessions. This cadence, CAD , is the third decision variable for which the model tests. Practically, these sessions would not occur more frequently than once a month or less than once a year, so this is the distribution which was tested for its effect on the Aggregate Savings. This distribution is further outlined in Appendix Section 6.4.1.

The second interaction facilitated by the structure outlined in Figure 23 is a “Project Blitz” between the Service Providers and the Developers, which is similar to the Knowledge Transfer Session described above. These intense project-specific sessions bring knowledge down to the Developers through application. This process is further detailed in Appendix Section 6.3, and was proven effective among the pilot projects. The Project Blitzes are meant to prepare the project teams for major decisions that both drive the direction of the project and present major savings opportunities through application of 3D Printing. These sessions would correspond to the points detailed in Figure 28, and represent events such as the purchase of injection molding equipment or the product’s final material selection. As opposed to Equations (2) and (3), which are proportional to time dedicated to the effort, the Learning Rates during the Blitz do not include such a term, because full effort is expected. In other words, D_d and D_s are equal to one. Thus, the Blitz Learning rates are described as follows:

$$k'_{d,B} = m_d B \quad (9)$$

$$k'_{s,B} = m_s B \quad (10)$$

where $m_d B$ and $m_s B$ are the Blitz Knowledge Accumulations Rates for the Developers and the Service Providers, respectively. As with the Knowledge Transfer Sessions, the Blitzes are modeled such that learning occurs for both parties involved. The total knowledge gained for each party on a Blitz day is calculated using the following equations:

$$k_d(i) = k'_{d,B} * tB \quad (11)$$

$$k_s(i) = k'_{s,B} * tB \quad (12)$$

where tB is the amount of time, in days, spent during a Blitz. As with the value for tK , input from various groups helped to develop bounds for the range of this decision variable, which are detailed in Appendix Section 6.4.1.1.

Because the Blitzes are directly tied to project milestones, as shown in Figure 28, their timing was not modeled as an even cadence, as with the Knowledge Transfer Sessions. Instead, the Blitzes were timed randomly, with an average occurrence of two per year. This was seen as reasonable, because there are five key milestones outlined over a project length of approximately three years.

An important feature of the model developed is that Equations (2)-(12) only hold true if a knowledge gap exists and there is “room to learn”. For example, a constraint is built into the model such that the Service Providers cannot have a greater level of expertise than the Pioneers, which in practice will be true if the Pioneers are on the cutting edge and the Service providers rely on training materials developed by them. Similarly, because in this model the Developers rely on the Service Providers for expertise, the Developers are constrained to a maximum level of knowledge equal to that of the Service Providers. This constraint raises the possibility of “overtraining”—a situation where time and cost are spent on learning about 3D Printing, but no new knowledge is absorbed because the information was learned previously.

Appendix 6.4.3.2 provides detailed explanations of the formulas developed in this section.

4.3.3.3 *Modeling cost under the proposed organizational structure*

Cost is modeled as a function of the total man-hours each group dedicates to the advancement of 3D Printing, and its corresponding opportunity cost. The estimated opportunity cost for each group, L , is based on their value when not spent focusing on 3D Printing. For example, the Developers have dedicated projects that are generally high-priority, so this group has a high opportunity cost. On the other hand, the Pioneers sole responsibility is to develop 3D Printing expertise, so this group’s opportunity cost

is essentially the cumulative salaries of those involved. Official opportunity costs for each group were difficult to determine, and warrant further investigation to increase the model's accuracy. The detailed estimates are outlined in Appendix Section 6.4.2.1. Given the estimates for opportunity costs, L , the Fraction of Dedicated Time, D , and the headcount of each group, n , the rate of cost accumulated through the strategy on a normal day is calculated by the following:

$$c'_{d,N} = L_d * D_d * n_d \quad (13)$$

$$c'_{s,N} = L_s * D_s * n_s \quad (14)$$

$$c'_{p,N} = L_p * D_p * n_p \quad (15)$$

As described in Figure 24, $n_d > n_s > n_p$. The values input to the model are based on interviews with leaders in J&J, estimates of the average project team size, and the number of active projects in the Medical Devices franchise.

Equations (13)-(15) are modified slightly during either Blitz Sessions or Knowledge Transfer Sessions, as D for each group reaches unity under the expectation of full time commitment. For the Blitz Sessions involving the Service Providers and the Developers, the following equations are used:

$$c'_{d,B} = L_d * tB * n_d \quad (16)$$

$$c'_{s,B} = L_s * tB * n_s \quad (17)$$

Similarly for the Knowledge Transfer Sessions between the Pioneers and the Service Providers, rate of cost accrual is calculated using the following:

$$c'_{s,K} = L_s * tK * n_s \quad (18)$$

$$c'_{p,K} = L_p * tK * n_p \quad (19)$$

The cumulative cost at the conclusion of the 365-day simulation is tracked as an @Risk output for analysis, which is discussed further in Section 4.3.3.5. Detailed explanation of the cost calculations can be found in Appendix Section 6.4.3.2.

4.3.3.4 *Modeling savings under the proposed organizational structure*

Under the proposed structure, value is captured at the Developer level through application. It is important to note that, despite effort and cost spent training the Service Providers and Pioneers, those groups do not contribute to overall savings. There are two prerequisites to capture savings through this strategy: the opportunity to save, and the knowledge to act on that opportunity.

The magnitude of any savings opportunity is modeled as a function of the potential number of days saved, and the value of each day of acceleration. Data collected from current MD projects suggests that a reasonable value for project acceleration is on the order of \$1M/month, or roughly \$30,000/day. The model couples this estimate with a function that randomizes both the date and the weight of events that can present savings opportunities.

Savings opportunities are broken down into two main categories: Major Decisions, and Minor Decisions. Relating back to the events outlined in Figure 28, Major Decisions are those which are planned for, and are large enough to warrant a special Blitz; for example, ordering capital tooling or preparation for an Engineering Build. Minor Decisions, on the other hand, are unplanned or are not large enough to necessitate a Blitz; these might include an extra iteration to refine a design, or a last minute fixture that will be used to test a prototype. While both of these decisions carry weight, Major Decisions have a much larger effect per event. On the other hand, Minor Decisions occur much more frequently. This structure is based off interaction with project teams, and represents the flow of decision making on a typical Medical Devices Project. Appendix Section 6.4.3.2 further details the methods used to develop both the weight and the frequency of Major and Minor Decisions.

The total opportunity for savings for the 365-day simulation was tuned to approximately two months, which is the estimated savings potential based on interaction with the project teams, given input from 3D Printing experts. There are, on average, two Major Decisions, and five Minor Decisions modeled per calendar year. For the purposes of the simulation, Major Decisions present either 15-day or 25-day opportunities, and Minor Decisions carry a weight between one and 10 days. These values represent an order-of-magnitude estimate for time-saving opportunities enabled by 3D Printing, based on experience with pilot teams in Medical Devices. They present an estimate which can later be adjusted to better fit the other franchises.

With the Potential Savings, *PS*, established, the Savings on each day is calculated using the following equation:

$$s(i) = PS(i) * [(k_d(i)/k_{p,0}) - (k_{d,0}/k_{p,0})] * n_d \quad (20)$$

Equation (20) is structured to capture just the savings resulting from the enhanced 3D Printing Strategy; it is referenced against the base value of $k_{d,0}$ to account for previous knowledge that the Developers already have. This equation also assumes that given full industry knowledge, which the Pioneers are modeled to have at the start of the simulation, the Developers could capture the entire savings potential presented on any given day.

To develop an estimate for the total value proposition of the new 3D Printing strategy, the “Cost” column is subtracted from the “Savings” column to develop the “Aggregate Benefit” column, as shown in Table 8. The cumulative Aggregate Benefit is tracked as an @Risk output, and is referenced against the @Risk input variables to develop sensitivities.

4.3.3.5 Modification of critical variables in training optimization

The value of additional training and focus on 3D Printing is strongly dependent on the initial knowledge levels of both the instructor and the instructed. For example, a fresh engineer has much to learn from a seasoned expert, especially on a niche topic like additive manufacturing. On the other hand, knowledge flow is limited between two peers that have nearly the same understanding of capabilities. With this in mind, an experiment was run using the model described in this section. Table 3, also shown in Appendix Section 6.4.2.2, details the experimental values assigned to $k_{d,0}$ and $k_{s,0}$, keeping in mind that the reference value is set at 1000, which equals the maximum available practical 3D Printing industry knowledge on the first day of the simulation.

Exp. #	Initial Knowledge Level			
	Developer		Service Provider	
	Hi/Lo	Value	Hi/Lo	Value
1	High	650	Low	650
2	Low	300	High	850
3	High	650	High	850
4	Low	300	Low	650

Table 3: Experimental values for Initial Knowledge Levels

This experiment was designed to better understand the effect of initial knowledge on the overall value of the program. Research with project teams showed widely varying levels of understanding between sites, and even between co-located project teams. Additionally, the groups that have been identified to take on the Service Provider role also have varying levels of expertise; some with no more knowledge of 3D Printing than the Developers with whom they will be working with.

The value of each input is based off experience with the three pilot project teams—in this initial estimate, Developers have approximately one-third to two-thirds the Knowledge Level of the Pioneers. The engineers on whom this estimate is based had a good understanding of the fundamentals and knew of some service bureaus, but lacked knowledge of internal capabilities and some very applicable techniques. The Service Providers, on the other hand, had a more detailed understanding of available techniques and resources, but lacked much of the cutting-edge expertise of the Pioneers in the 3DP & NSTC. The values in Table 3 provide a reasonable estimated range based on interaction with project teams, and allow for a directionally accurate analysis of the program's value. These inputs can be specifically tailored to different segments should this model be used to develop strategy in the future at J&J.

Section 4.3.4 discusses the results of this simulation, as well as some of the recommendations that can be made based off the generated data.

4.3.4 Discussion of Results and Recommendations from Simulation Data

The following discussion is based largely on the data generated by the simulation, which are shown in Appendix Section 6.4.4. The simulation and the accompanying sensitivity analyses show that the proposed strategy needs to be carefully designed in order to be successful. The Decision Variables, which J&J can control, are D_d , D_s , t_B , t_K , and CAD ; the results show that several of the variables clearly dominate the effectiveness of the training program, which is a useful insight for its design.

The insights below were developed from analysis of the simulation results, and provide direction for the optimal strategy:

The value proposition of a training program is highly dependent on the Initial Knowledge Levels: Figure 30, which is shown again in Appendix Section 6.4.4, compares the Aggregate Benefit from each simulation. It illustrates the impact that the Initial Knowledge Level of each group involved has on the value that can be effectively captured through an improved strategy. This figure shows that a combination of high Developer Initial Knowledge and low Service Provider Initial Knowledge will severely dampen the value proposition. Furthermore, as shown in Simulation 3 below, it shows that even a small gap in the Initial Knowledge Levels will allow for significant value generation.

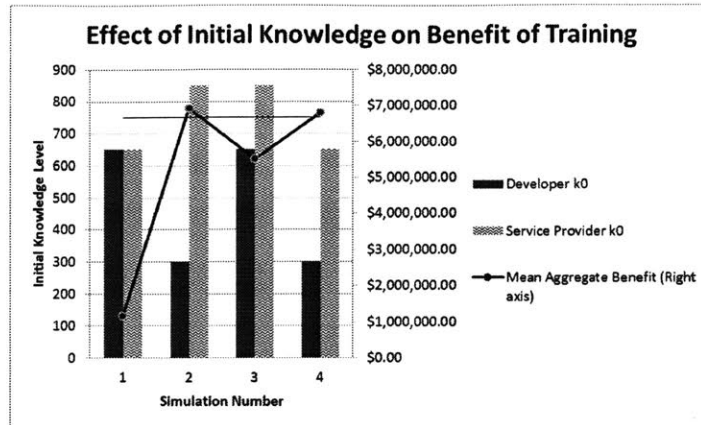


Figure 30: Impact of Initial Knowledge on Aggregate Benefit of proposed strategy

Two main recommendations can be made from this information: First, if a development team has a very high proficiency in 3D Printing, then it may not immediately benefit from this strategy. Second, it is critical for the Service Providers to have a high knowledge level at the onset of the training program. For example, despite a modest difference between $k_{s,0}$ in Simulations 1 and 3, there is roughly a fourfold increase in program value.

Time Dedicated to Blitzes is the most important decision variable, and should be maximized: As shown in Figure 55, Figure 58, Figure 61, and Figure 64, the simulation results are dominated by t_B . This is logical, because much more knowledge transfer to the Developers occurs during a Blitz than during a non-Blitz. The ramification of this result is that J&J needs to schedule ample time for the Blitzes, and avoid the temptation to “get back to work” too soon. These sessions are the cornerstone of the entire strategy; they are critical in capturing value from the ongoing work of the Pioneers. As shown in Figure 54, Figure 57, Figure 60, and Figure 63, the optimal range for t_B was beyond the maximum input range of three days—this result shows conclusively that the Blitzes should not be compressed into just a few hours. Despite being the dominant variable in each of the four simulations, the impact of t_B only increases with the gap in $k_{d,0}$ and $k_{s,0}$, as shown in Figure 31.

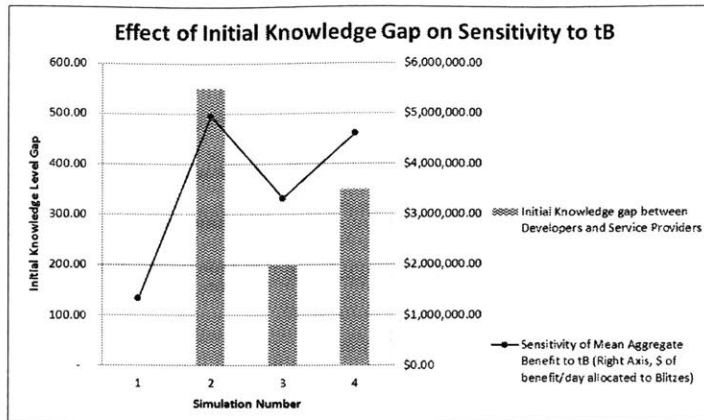


Figure 31: Importance of tB with respect to initial knowledge gap

Apart from ensuring enough time for knowledge transfer through the Blitizes, this information can also potentially be used to reduce cost over time. After the first year, when the gap between the three groups closes substantially, J&J may benefit from reevaluating the time spent on Blitizes. While Blitizes will remain an important part of the overall strategy as the program reaches steady-state, effort may be better spent on one of the other levers such as increasing the frequency of the Knowledge Transfer Sessions.

Developers and Service Providers should leverage interaction with other groups for knowledge when possible: As shown by Figure 55, Figure 58, Figure 61, and Figure 64, increasing the value of either D_d or D_s , which are the fraction of time dedicated to independent study of 3D Printing for the Developers and Service Providers, respectively, has an adverse effect on the overall program value. This is a result of both interaction between the groups and project-specific recommendations leading to significantly higher learning rates during Blitizes and Knowledge Transfer Sessions than during normal periods. The 3D Printing strategy can benefit from this information; it should leverage the high-value interaction between groups instead of encouraging excessive independent study. For example, if individual Developer teams identify a need, it benefits the organization if they involve either the Pioneers or the Service Providers—doing so increases both the speed at which they can solve their problem and the overall learning of the organization. This type of interaction needs to be encouraged by company leadership and ultimately become part of the company culture. Blitizes and Knowledge Transfer Sessions are an effective way to identify issues, solve them, and share the results across the segments.

The importance of training Service Providers increases over time: As time goes on in the simulation, the levels of knowledge between the three groups tend to converge. Additionally, as stated earlier, the overall program value increases dramatically with the knowledge gap between the Developers and the Service Providers. Given these two characteristics of the results, it can be shown that as time goes on,

J&J will need give more focus to training Service Providers. Doing so will help to prevent “over training” of the Developers—a situation that occurs when the Service Providers cannot offer new knowledge to the Developers during a Blitz. This situation destroys value by increasing cost while providing minimal benefit. Practically speaking, it may be useful for the 3DP & NSTC to develop a metric for knowledge of each project team and Service Provider group, which can be used to determine if there is the potential for an over training scenario. While this project did not attempt to develop a detailed metric, a potential framework for doing so is outlined in Appendix Section 6.1. While this situation is unlikely to happen initially—especially if initial training of Service Providers is effective—it is increasingly likely to happen over time as the Developers get more experienced.

The importance of the Pioneer Learning Rate also increases over time: Building on the previous observation, it can be shown that the importance of the Normal Learning Rate for the Pioneers also increases over time because of the convergence trend. The Pioneers determine the ultimate “Ceiling” of knowledge, and thus dictate the maximum level of knowledge in the system at all times. Initially the Pioneer Normal Learning Rate has little effect on overall value, as demonstrated by the tornado chart in Figure 64, which is based on a plausible scenario for the early stages of a training initiative. Eventually, though, its importance rises as shown in Figure 61, which is based on elevated Initial Knowledge Levels for both the Service Providers and the Developers. An extreme situation is shown in Figure 32 below. This scenario models total convergence of knowledge, with the Initial Knowledge Level of all three groups set to 1000. In this case, the Pioneer Learning Rate becomes the most important decision variable, and the mean program value drops below zero.

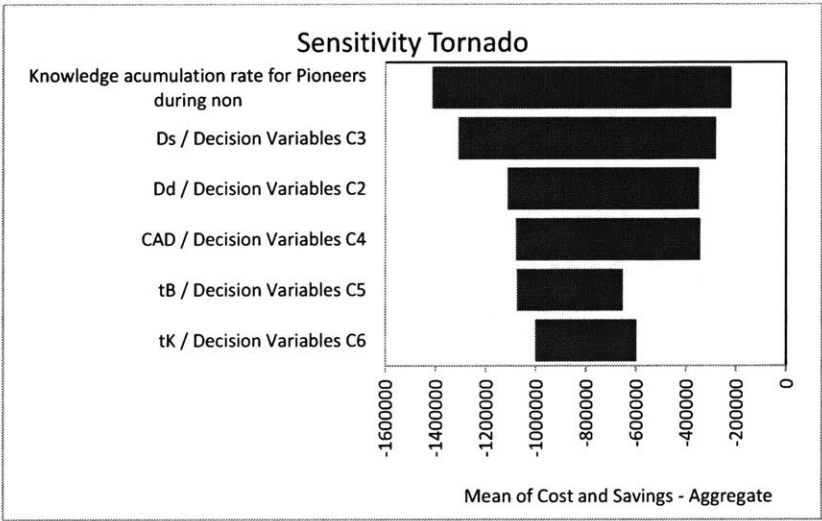


Figure 32: Extreme case illustrating the importance of the Pioneer Learning Rate over time

To compound this observation, the Pioneers' Learning Rate will likely plateau as the technology matures, which will further negatively affect the overall value of the strategy. This example shows that as the technology plateaus and the Service Providers and Developers close the knowledge gap on the Pioneers, J&J's 3D Printing strategy will require significant changes. Fortunately, for the near future, 3D Printing is experiencing exponential growth and this problem should not arise.

4.4 Improving Organizational 3D Printing Capabilities to Speed New Product Development

While Section 4.3 focused on improving organizational knowledge, this section focuses on improvements that can be made to J&J's 3D Printing Capabilities, as outlined in Appendix Section 6.1. These recommendations generally involve improving the tools with which engineers can use during a development project. This section discusses new technologies, new techniques, and process improvements that J&J can use to capture significant value from 3D Printing technologies. These improved capabilities will multiply the value captured from increased organizational knowledge alone.

4.4.1 3D Printing Technologies, Techniques, or Process Improvements to Enable NPD Acceleration

The following sections detail specific improvement areas that will help J&J reduce NPD cycle time. Some of these recommendations would require significant up-front investment, while others are process improvements with little capital cost. Each of these recommendations addresses one or more of the concerns identified in Section 4.2.

4.4.1.1 Increase use of conformal cooling for production tooling

A very promising technique for accelerating New Product Development at J&J is using DMLS to build production injection molds. Using heat-treatable maraging steel, production molds can be made quickly, cost-competitively, and with very advantageous design enabled by 3D Printing. 3D Printing not only allows for potentially shorter lead times, but it also enables the use of conformal cooling lines. The process involves embedding a production mold with cooling lines that are contoured to the mold cavity. Advanced analysis can be coupled with the technique to tune the final geometry of parts and decrease production cycle time.

This process, originally developed at MIT in the early 2000's, has been significantly improved through the application of computer modeling and automated design [41] [66]. Several companies, including Linear AMS in Livonia, MI, are very capable vendors for conformal cooling and have been employed by J&J on a limited number of applications. Despite in-house DMLS capability, J&J has not yet experimented with manufacturing its own conformally cooled injection molds.

The process for designing conformally cooled molds is somewhat different from designing a traditional mold, and requires knowledge of the potential post-processing techniques required. All the limitations involved with DMLS printing apply, so characteristics such as potential shrinkage and surface finish need to be accounted for. For example, depending on the surface finish required, between 0.008” and 0.03” extra material should be designed into the mold cavity to allow for finishing operations [67].

The benefits of manufacturing injection molds with this process are numerous, and go beyond the potential for improving speed-to-market. Production part cycle-time reduction estimates range from 15-60%, depending on the part geometry. Additionally, one case study reported a scrap rate reduction of 97%, due to improved cooling characteristics and more predictable shrinkage [68]. With respect to this analysis though, conformal cooling presents a significant opportunity over traditionally machined molds; the enhanced dimensional stability resulting from predictable cooling can significantly reduce the total time of order-to-delivery.

The process of manufacturing a traditional mold begins with selecting a vendor and transferring the part design. A typical lead time from this point is 14 weeks until test parts are produced—these parts are often out of specification, and require several iterations of “grooming”, where the mold is modified to meet specification. In the best case, grooming involves removing material from the existing cavity. In the worst case, it involves an additional step of welding in inserts, which add back material before finishing. Conservative estimates for the grooming process range from six to eight weeks, with thousands of scrapped parts produced along the way. An additional problem posed if grooming is necessary is that there becomes a “Nominal” mold design, and an “As-Built” mold design. Without careful document control, this can lead to issues later in the product lifecycle when it comes to tool replacement [69].

Utilizing 3D Printing to make production tooling circumvents these issues. By taking advantage of conformal cooling’s greatly enhanced dimensional stability and advanced modeling, the grooming process can be eliminated. Several company trials at J&J have shown similar order-to-test part times for conformally cooled molds, but with an overall reduction in development time of eight weeks. Additionally, these trials have shown 34-50% cycle time reduction and reduced warpage [70].

To better understand the process of designing a conformally cooled mold, part of this project involved working with Linear AMS to analyze a specific part as a candidate for this process. The specific purpose of the analysis was to determine the benefits of a 3D Printed injection mold over a traditionally machined one. To do so, Moldex 3D industrial finite-element simulation software was used to simulate two different scenarios: one employing a traditional cooling channel design, and another using a conformally

cooled design. The results of which were then analyzed to estimate the resultant cycle time and warpage under each scenario. Figure 33 shows the product geometry, along with the associated sprue, gate, and runner. As shown, the part modeled is thin-walled and relatively simple. The mold is designed as having two cavities for larger throughput.

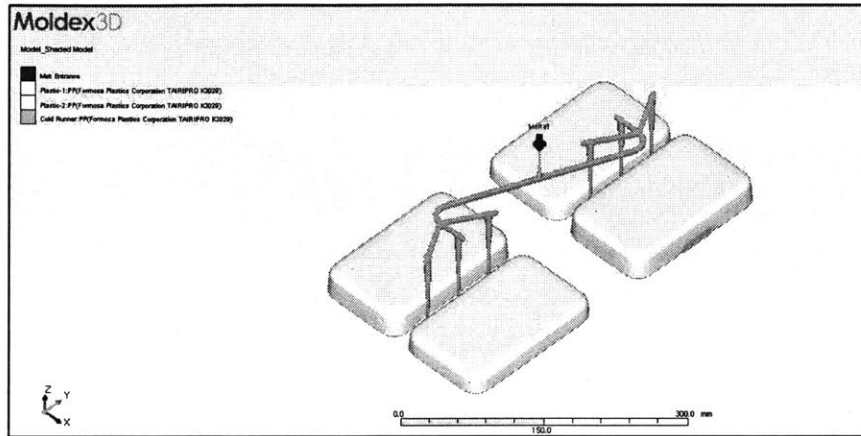


Figure 33: Cavity, sprue, gate, and runner design for sample part

The next step was to model the traditional cooling channel design. Linear AMS performed this work under contract of J&J. As shown in Figure 34, there are 15 cooling channels designed into the injection mold insert. These cooling lines, constrained by traditional drilling and machining, run in a planar pattern that approximates the contour of the part.

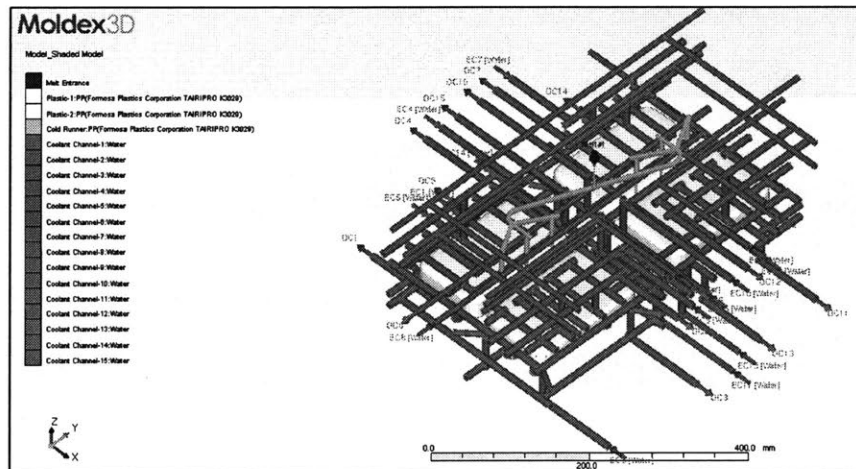


Figure 34: Sample part shown with traditionally machined cooling channels

Separately, another simulation was built incorporating conformal cooling lines. Linear AMS is also credited for this design. Instead of being constrained to traditional machining, 3D Printing allowed for near total freedom of cooling channel design, which enabled them to follow the true contour of the part. Figure 35 shows the redesigned mold, with 13 conformal cooling channels.

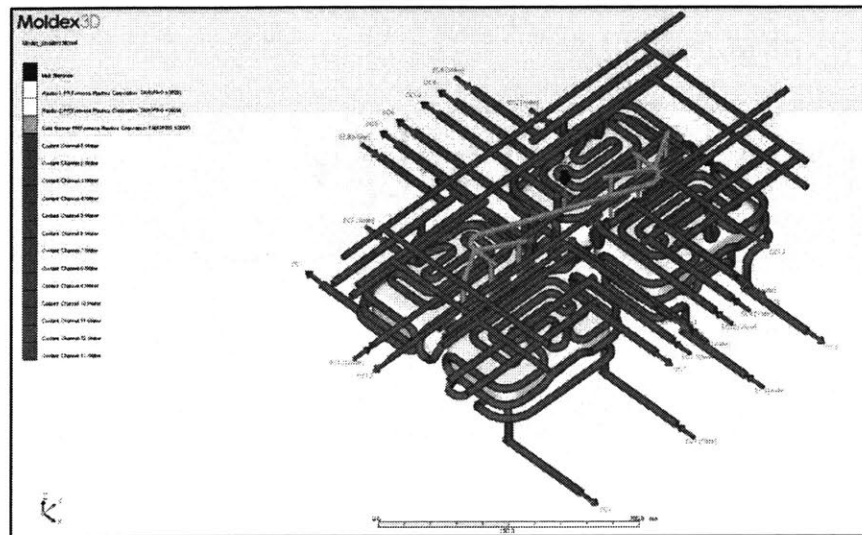


Figure 35: Sample part shown with conformal cooling channels

With the sample part modeled with both traditional and conformal cooling lines, two analyses were completed for each: a cooling analysis, and a warpage analysis. The purpose of the cooling analysis was to compare the expected production cycle times of each mold, and the purpose of the warpage analysis was to identify potential issues where grooming may be needed to bring a mold into specification—the former affects profitability after product launch, where the latter affects time-to-launch.

Figure 36 and Figure 37 show the results of the cooling analysis for the conventional and conformal molds, respectively. As shown, the functional part component in each case freezes in less than a second, due to its thin wall. In each scenario, the gate is the last region to freeze.

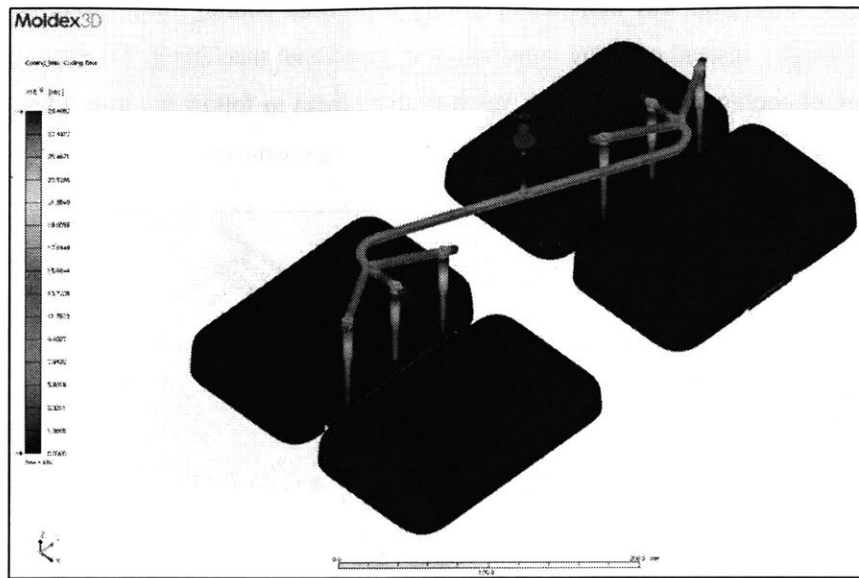


Figure 36: Cooling analysis for conventionally cooled mold (total cooling time 29.4 seconds)

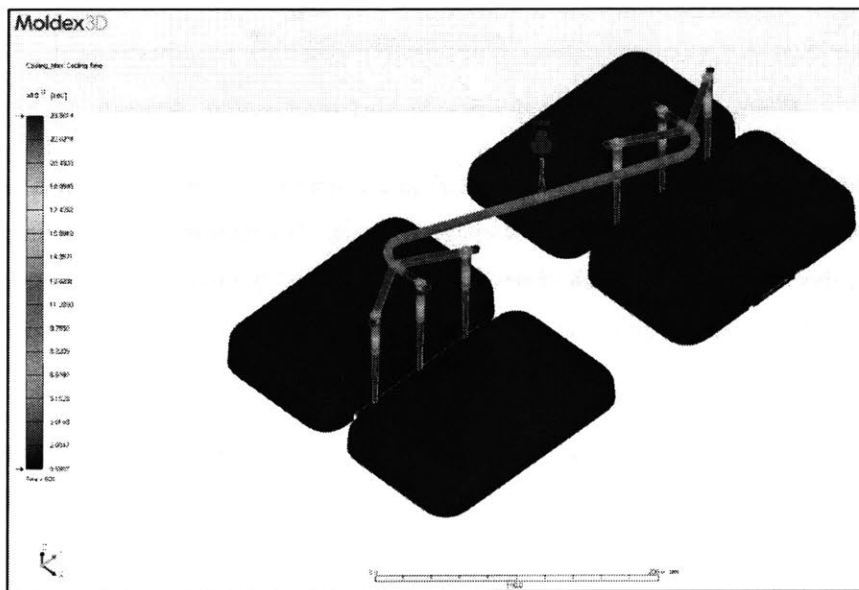


Figure 37: Cooling analysis for conformally cooled mold (total cooling time 23.6 seconds)

The cooling analyses for this component demonstrates a 19.7% reduction in cycle time—within the estimates provided in literature review. The thin-wall nature of this design seems to be the reason that this particular part is near the lower bound of the estimate range, but nonetheless the improvement is

significant. Assuming this part is produced at a volume of one million per year, the modified mold design saves roughly 800 machine-hours per year compared to the conventional design.

The warpage analyses were performed to predict the necessity of grooming the mold after the first iteration. The more deflection present, the more difficult it becomes for the mold manufacturer to predict and design the mold such that it produces in-specification parts without modification. Even if the manufacturer designs the mold to counteract predicted deflection, this practice generally introduces unwanted internal stresses into the production parts. Minimizing predicted deflection is thus a valuable mold characteristic, as it reduces the likelihood of grooming and produces higher quality final parts.

Figure 38 and Figure 39 show the results of the warpage analyses, and are presented in terms of absolute deflection from nominal. These results show a 22.5% reduction in peak deflection using conformal cooling versus traditional cooling lines. As with the cooling analysis, conformal cooling enables significantly improved mold performance, which may be enough to eliminate the grooming process.

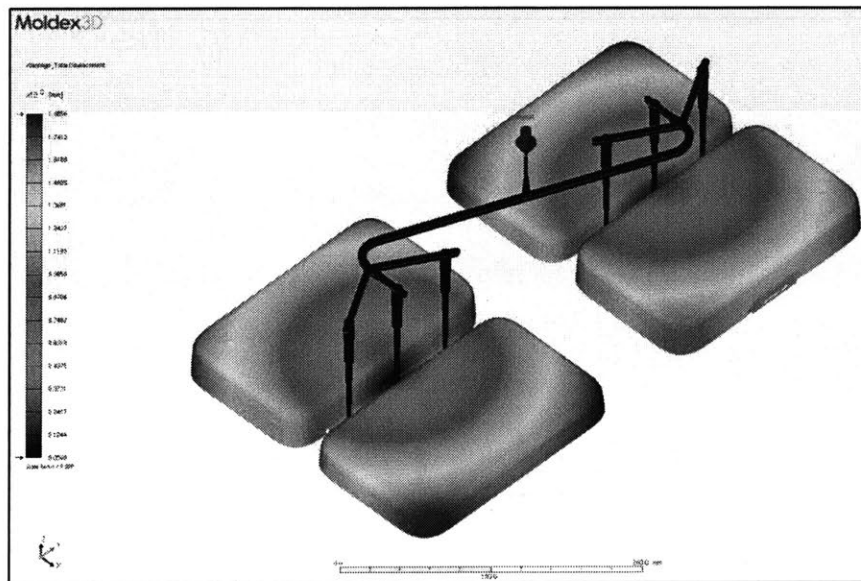


Figure 38: Warpage analysis for conventionally cooled mold (max deflection 1.87mm)

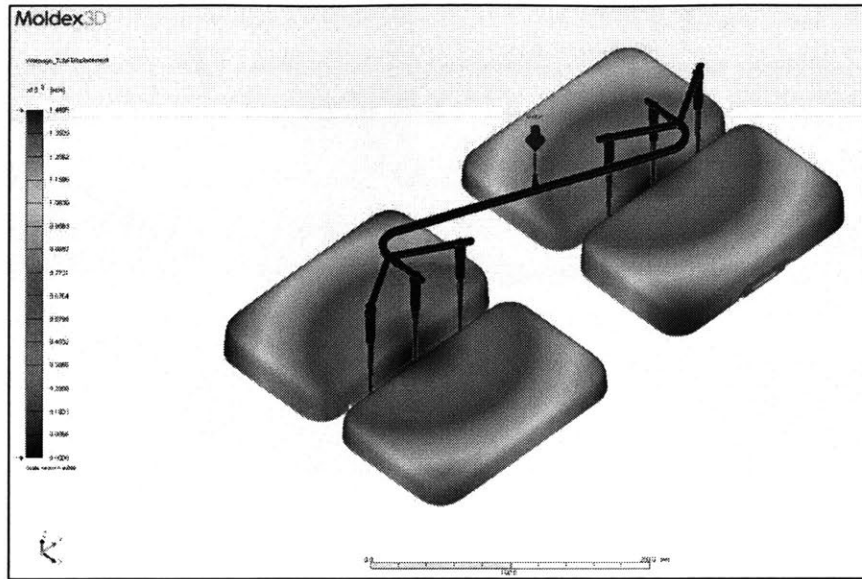


Figure 39: Warpage analysis for conformally cooled mold (max deflection 1.45mm)

Conformal cooling has been successfully experimented with at J&J and elsewhere, and its use is expected to continue growing. The molds can be produced with roughly the same cost and lead-time of traditional molds, while producing superior parts that are much more likely to meet quality requirements without mold modification. Additionally, these molds have shown near comparable durability to traditionally machined steel injection molds using a variety of materials including glass-filled polycarbonate and glass-filled nylon [71]. These qualities have the ability to significantly reduce New Product Development time by shortening the effective lead-time for capital tooling.

Conformal cooling may have applications beyond plastic injection molding; another promising application is Metal Injection Molding (MIM), which is a manufacturing process frequently used by J&J to produce complex metal parts. The MIM process involves injecting a mixture of metal powder and binder into a mold, and sintering the resultant “green” part to produce a net-shape metal part [72]. Several experiments have shown that utilizing conformal cooling can significantly reduce both cycle time and part defects. In these experiments, the manufacturer saw 60% cycle time reduction, defect and void reduction, improved runout control, and acceptable tool life when using DMLS to produce a conformally cooled MIM mold [73].

Together these applications show that conformal cooling is a highly valuable technique enabled by 3D Printing. J&J Medical Devices, along with the other two segments of J&J, produces many injection-

molded and MIM parts that could benefit from this technology, making it a potentially impactful tool that should be available to all project teams.

Several barriers exist that have prevented wider use of conformally cooled molds. The first is that few tooling vendors have both the expertise and equipment required to produce them—developing these skills across the industry will take time, collaboration, and experimentation. Another barrier is the development process itself—at J&J, engineers typically use the later Engineering Builds to fine-tune their designs for production tooling. This presents a challenge because to support a conformally cooled production mold, prototype injection molds would ideally also use this technology. This process may add significant cost and complexity to the current development cycle, and would need to be weighed against the benefits of using the technology. Time and wider use of conformal cooling will decrease both of these barriers, but for the time being implementation of this technology remains limited to a few projects across the company.

4.4.1.2 Increase access to local 3D Printing technology

When asked what were some of the barriers to increased use of 3D Printing, feedback from project teams often centered around limited local access to a variety of technologies. Many sites at J&J have 3D Printing capabilities—in fact the 3DP & NSTC maintains a list of each with the contact information of the owner—but few sites have access beyond FDM and PolyJet. During fast-paced design iterations, this presents a problem for the project teams, who want to leverage the speed of 3D Printing and have parts made in same-day or next-day timeframes.

Solving this problem without purchasing additional capital tooling can take two forms: by improving internal speed or by creating partnerships with external vendors. Leveraging external partners is an excellent short-term solution for several reasons; no capital appropriation is necessary, new technologies can be tested prior to purchase, and services come with a service bureau's expertise [74]. Gartner suggests considering a range of variables prior to choosing a service bureau: price, finished part quality, delivery time, material range, available services, and post-processing options. Furthermore, Gartner recommends choosing between a local provider and a national company; in 55% of companies surveyed, working with a local provider was preferred over working with either a national or global organization [75].

If the business chooses to use an outside vendor instead of producing parts internally, there are excellent resources available to help choose which one will be the most effective. When choosing a vendor based on specific technical abilities, it is useful to consult Wohlers Associates' Annual Report, which provides a

detailed and comprehensive comparison of various 3D Printing technologies and their working materials, tolerances, printable features, surface finishes, and limitations [27]. Additionally, Gartner publishes a list of reputable 3D Printing service bureaus along with a brief description of each one's capabilities [74]. Because of deep experience and strong competition for customers, these companies offer fast turnaround and excellent customer service that may be difficult to achieve at an internal site. Ensuring that project teams have access to—and are aware of—a variety of accessible 3D Printing options will help to speed product development.

Of course, adding capital tooling and developing on-site 3D Printing capability is also an option; but this route is capital-intensive and not likely to get approval at every site. However, J&J has successfully developed significant 3D Printing capabilities at several of its sites. Data was not available to perform an in-depth value analysis of these labs, but estimates from leadership are that the marginal cost of producing stainless steel DMLS parts internally is roughly 25% that of using an external vendor. Producing parts in-house has the potential improve both speed and cost, but should be carefully considered given the high capital costs of new tooling and the pace of advances in the industry. Several tools used to justify potential capital tooling orders are discussed in Section 4.4.1.3.

4.4.1.3 Develop process for establishing “Decision Rules” for investment

A useful process to justify investment in a design or process improvement during product development, such as adding 3D Printing capabilities, is creating “decision rules” for investment. The goal of creating decision rules is to enable management to make educated decisions regarding investment in better tooling, design changes, additional resources, etc. These rules are based on the logic that the additional benefit of investment must outweigh the additional cost [22].

The hypothesis on which much of this thesis is based is that speed to market is often more valuable than most project teams estimate. For example, input from one team was that a recent project was delayed by more than six months to add a minor feature to the final design—the additional feature turned out to be nearly worthless from a marketing perspective, but cost the project team in both development effort and lost revenue. While trying to tweak the final design to perfection, this project team failed to understand the value of speed to the business. The same idea holds when considering investment in process improvement—the sticker shock of an additional 3D Printer may quickly fade with a clear understanding of the value of saving just a few weeks of development time.

To begin the process of creating decision rules, it is important to break down the underlying reasons for why speed is important for new products. Each product is different, so a new rule will need to be

developed at the start of each project. The factors that affect the top-line value of speed include longer sales life, customer loyalty, and pricing power. From a cost perspective, reducing development time saves on labor, equipment, and overhead. Advanced scenarios also involve product cannibalization, changes in the shape of market uptake curves, and shifts in competitor decision-making [22]. Developing an accurate model is a complex challenge involving input from strategy, marketing, and finance teams; ultimately this is beyond the level of complexity that NPD teams should be expected to take on.

While working with one project team, a collaborative approach was used to develop a decision rule; J&J supports a business intelligence group called Global Business Insights (GBI), which was leveraged for the analysis. Because this group is already responsible for developing similar models, the request of creating a valuation for time involved minimal additional effort; given this result, future development teams should utilize the GBI group for developing decision rules for investment.

Given the specific product, the market conditions, the expected sales curve, and the presence of existing products on the market, GBI was able to develop a simple Net Present Value for speed: accelerating that particular product's launch date by one quarter would result in an NPV of roughly \$3 million to the business. This dollar amount opened the possibility of valuing time along with any other project expense—valuing process or design changes that would accelerate development could be easily analyzed against their expected cost.

One critical area where J&J can use this information is in the decision of whether or not to expand a 3D Printing lab. There are several labs with significant capabilities across J&J, which are available to produce parts for any segment. Despite a cheaper marginal cost than external vendors, these labs have a high utilization and often have significant queue times; the administrator of J&J's largest 3D Printing lab cited a queue time of one to two weeks for DMLS printed parts [76]. To determine the value of investing in additional capacity, J&J can use the cumulative value of speed determined by GBI across projects using the lab with the G/G/N Queuing Model, outlined below [77]:

$$L = \frac{\rho^{\sqrt{2(N+1)}}}{1 - \rho} \times \frac{C_A^2 + C_B^2}{2} \quad (21)$$

where L is the average queue length in number of projects, ρ is the capacity utilization of the printers, C_A is the coefficient of variation for the timing of new orders, C_B is the coefficient of variation for print times, and N is the number of printers. Furthermore ρ can be calculated using the following:

$$\rho = \frac{\lambda}{N \times \mu} \quad (22)$$

where λ is the average rate of new orders and μ is the maximum service rate of one printer. Once L is determined, Little's Law can be used to calculate the average wait time in the queue, W_q :

$$W_q = \frac{L}{\lambda} \quad (23)$$

Equations (21)-(23) can be combined with average project value of speed developed by GBI, V_s , into the average cost per project of not expanding the 3D Printing labs. The average queue cost per project, c_q , in dollars, is calculated using the following equation:

$$c_q = V_s \times W_q \quad (24)$$

Finally, the organization's total cost of the queue, which is expressed in dollars per day, can be calculated through Equation (25):

$$C_q = L \times V_s \quad (25)$$

Equations (21)-(25) only hold true if the time spent in the queue impacts project critical path. But because prototyping, and subsequent use of internal 3D Printing labs, typically occurs early in the development process, there is a strong probability of this being the case. Insufficient data prevented a full analysis from being performed at J&J, but using this method to justify expansion of labs is a valuable opportunity that is worthy of additional research. For example, assuming an average queue length of five projects, an average value of speed at \$3 Million/quarter, and roughly half the prints falling on critical path, the queue cost at just one of J&J's 3D Printing labs approaches *\$85,000 per day*. It is easy to see in this case that an additional investment of several million dollars in new capacity would be a wise decision.

4.4.1.4 *Establish formal process for developing 3D Printing value streams*

An important step in improving J&J's body of 3D Printing knowledge is the process it has for cultivating value streams from new technology. In practice, there are two ways of identifying opportunities through 3D Printing: "Technology Driven" or "Top-Down" improvements, which arise from industry advancements, and "Application Driven" or "Bottom-Up" improvements, which are developed for specific project needs. Figure 40 describes a proposed process for assigning development responsibility for each of these two cases. This process assumes that Pioneers drive the Technology Driven improvements, where Developers identify the Application Driven needs.

Two development portfolios arise from this process. The first contains those opportunities that are managed by the Service Providers; these developments will be specific to the J&J segment, and will have a relatively small scope. An example would be to determine if DMLS gears will have the required

tolerances for a new product. In this case, the scope is manageable and very application-specific. The second portfolio is that which is managed by the Pioneers and contains both widely valuable developments and “overflow” developments when the Service Providers have insufficient resources. An example of a development project in this portfolio would be the introduction of CLIP technology as an alternative to injection molding—this requires significant resources and has broad implications on value.

Another potential scenario is when the development idea is managed by both the Service Providers and the Pioneers. This case would arise when both the project and the business see value in developing a technology. In this scenario, resources from both parties would contribute to the project-level application and the results would be quickly shared across the other segments.

This decision making process allows for efficient prioritization of development projects. Valuable developments will reach the appropriate level of the organization; either the Service Providers or the Pioneers will manage the research depending on the scope and potential organizational value. Additionally, keeping manageable technology development under the Service Providers allows for immediate benefit to the project team and fosters continuous idea generation from the Developers.

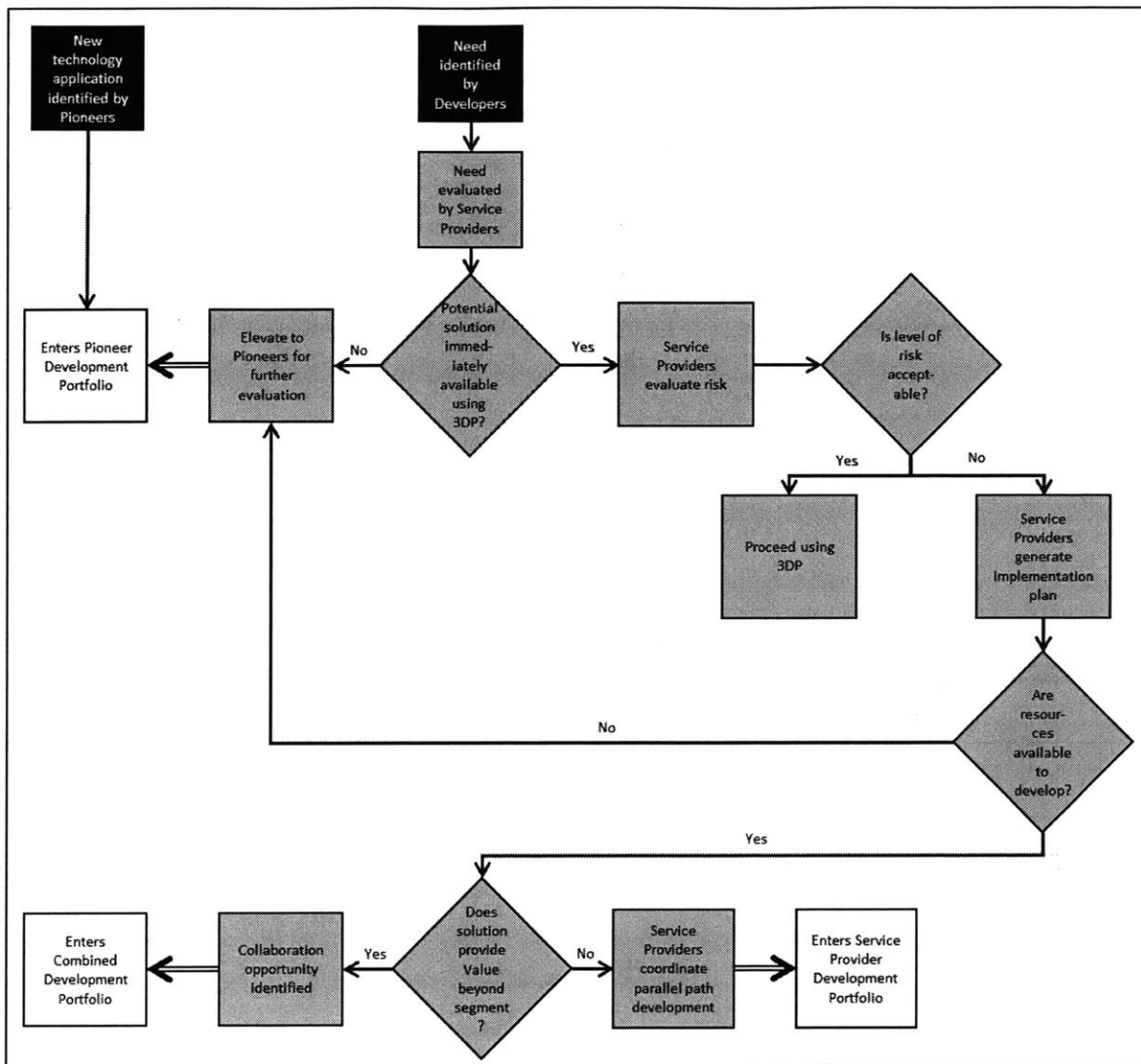


Figure 40: Decision process for cultivating value streams

4.4.1.5 Use 3D Printed Polymer Injection Molds for low-volume material-specific parts

One of the challenges 3D Printing has faced in the past, which has somewhat limited its growth for late-stage prototyping, is that there is a finite number of materials with which to print. Despite an expanding number of options, there remain important engineering materials that either cannot be directly printed using available technologies, or have different mechanical properties resulting from the process—examples include patented bio-absorbable or glass-filled polymers that are often found in medical devices [78]. For this reason, designers and engineers have often chosen machining as the preferred prototyping method, because it offers the ability to produce parts quickly and in the final material.

An issue that arises with machining is cost—because it is resource-intensive, machining a simple part out of polycarbonate can be between \$400 and \$1000 if produced by an outside vendor, as reported by one of the three pilot project teams. On the other hand, maintaining an internal machine shop for prototyping would involve purchasing millions of dollars of equipment, and staffing it with highly trained machinists.

This presents an opportunity for 3D Printing—instead of directly printing plastic parts, 3D Printing can be used to produce a prototype injection mold, called Rapid Tooling (RT). This process enables low volumes of prototype parts to be produced with very fine detail, often at a fraction of the cost of machining. Additionally, the parts are produced using a similar process to production, with the exact same material. Using 3D Printing for molds fills a gap that traditionally existed between machining and injection molding with “soft” tooling. “Soft” tooling is steel or aluminum tooling that is not built to production specifications, but is lower cost and has a reduced lead time of roughly \$6000 and six weeks, respectively, according to estimates from several project teams.

Several studies, including two by J&J, have confirmed both the viability of RT molds and their resultant reductions in cost and lead-time of 50-90% versus other methods of prototyping [31]. Plastic parts have been successfully printed on both PolyJet technology and SLA technology with similar results. Figure 41 illustrates the types of materials for which this process is a good candidate, and the number of good-quality parts that can be expected from the life of each mold.

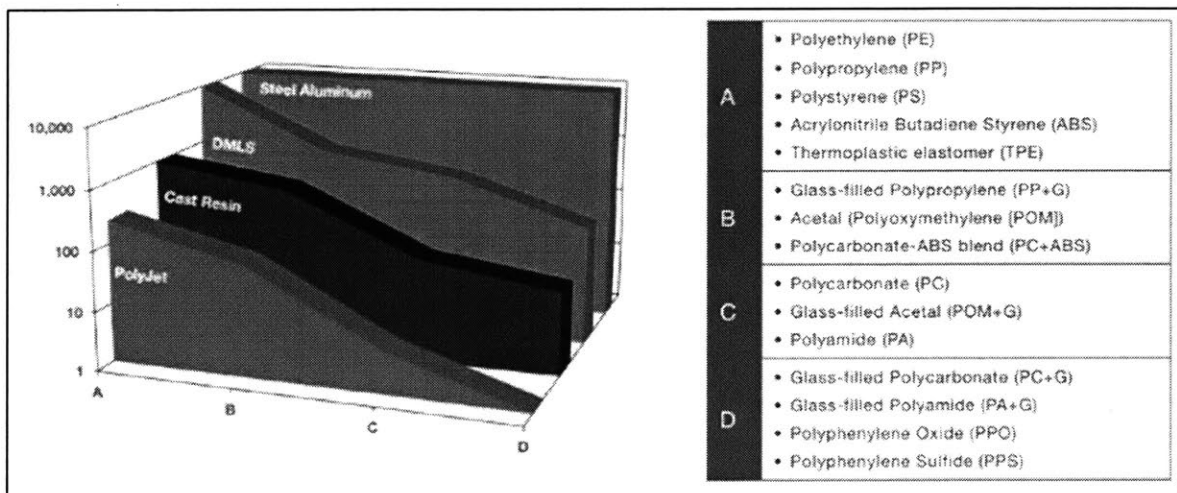


Figure 41: Useful life (in units produced) of PolyJet-printed injection molds vs. other molds for various materials [31]

There are several notable limitations to injection molding with RT. The first of which is that the cycle time for producing parts is significantly longer than traditional molds. For example, because the mold temperature needs to be carefully controlled, the individual part cycle time can be as high as five minutes to allow the mold to completely cool [79]. Additionally, some heat-concentrating geometry, such as sharp points, can be difficult or impossible to produce because the low thermal conductivity of the mold material results in melting. These drawbacks can generally be overcome by cooling fans or metal inserts, but with additional cost and complexity as well. Stratasys, the vendor for PolyJet printing equipment, has published several guides to help engineers and designers overcome some of these limitations to produce high quality prototype parts.

Despite the potential drawbacks, injection molding with RT molds fills a gap that can potentially save multiple weeks of development time per design iteration. At roughly \$500 per mold, it also represents significant cost savings over both machining and steel injection molding in the 5-100 part volume range. Additionally, some research aims to improve the technique and expand its useful range beyond 100 parts. An area of investigation is using different materials to print the molds; two experiments completed during this project at J&J took this approach. Carbon's Cyanate Ester material, which is a temperature resistant thermoset, and a metal polymer blend were experimented with [50].

In the first experiment using Carbon's Cyanate Ester material, the results showed conclusively that this was not an acceptable process. Despite this material's high heat deflection temperature of 426°F, the experiment did not reach the point of producing viable prototypes [50]. The thick sections of the mold inserts cracked during the post-print heat-treating process, rendering them unusable. Feedback from several vendors has stated that wall thicknesses of over 10mm can lead to heat-related distortion and cracking, as was observed [80]. Given this design constraint, future attempts to make mold inserts with this material are unlikely. Figure 42 shows several failed trials from this experiment.

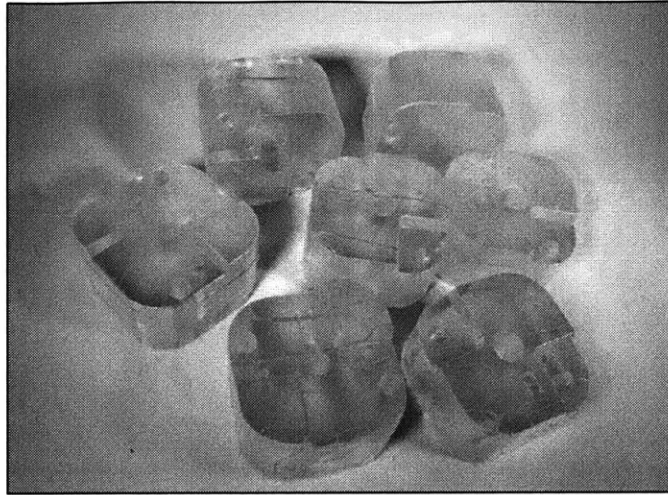


Figure 42: Attempt to create 3D Printed injection mold inserts using Carbon's cyanate ester

The second experiment used SLS technology with a metal-polymer blend to test for its feasibility as a mold material, and compare its performance to a previously tested PolyJet material. Despite the relatively low melting point of the polymer used, the hypothesis of this experiment was that the increased thermal conductivity of the metal powder would improve the mold's durability compared to PolyJet molds. Figure 43 shows the experimental setup, with the experimental mold insert in the top half of the Master Unit Die (MUD) fixture. Figure 44 shows the control setup mounted in the injection-molding machine, prior to any trials. Between each trial, the molds were cooled for approximately five minutes, until they reached room temperature.



Figure 43: Experimental setup with metal-polymer blend injection-mold inserts

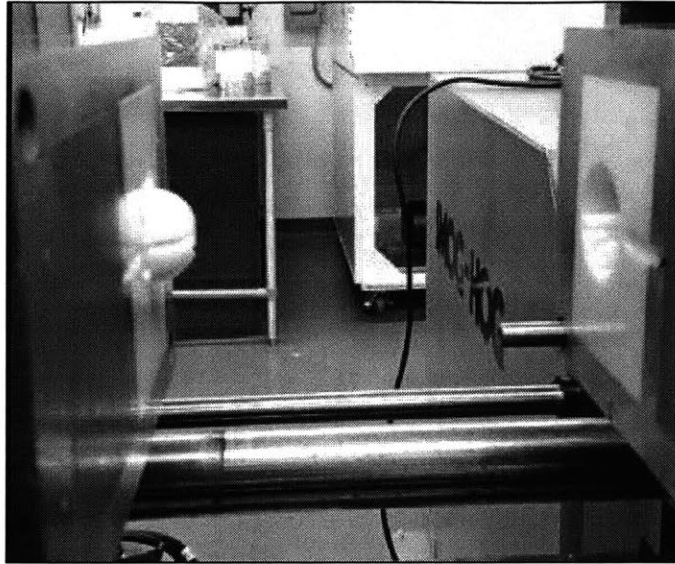


Figure 44: Control setup with PolyJet injection-mold inserts

The experiment aimed to qualitatively analyze the potential of the metal-polymer blend as a prototyping tool; this is reflected by the largely observational nature of the following results. The characteristics of each mold that were recorded over the trials included the following: presence of flash, surface finish, and mold deformation or damage. As shown in the previous figures, the molded part is roughly 2"x 2" and has a largely hemispherical shape, with a narrow cavity through its center. For each trial, the melt temperature was set to the lowest end of polycarbonate's working range. The injection volume was adjusted over the course of each trial to compensate for either excessive flash or short shots.

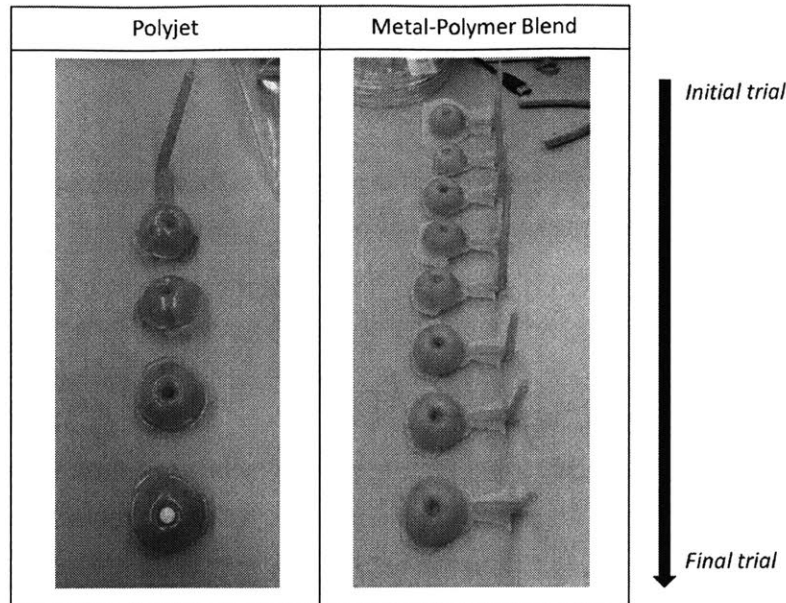


Figure 45: Experimental prototype parts for both setups

Figure 45 shows the parts produced using each mold setup. The qualitative observations and future potential research areas are as follows:

Presence of flash: The PolyJet mold produced significantly less flash than the experimental mold. The metal-polymer blend produced a rough surface finish and most likely did not create a good sealing surface between the mold halves under clamping, resulting in flash. Figure 45 shows significantly more flash present in the first trial, which was most likely caused by overfilling. Despite adjusting the injection volume to correct this, this mold continued to produce flash, especially around the gate as shown in Figure 46. The PolyJet mold produced parts with almost no flash. In future trials, the mating surface of metal-polymer blend molds should be milled to a smooth surface finish after printing. This would involve additional steps by adding material to the mold design and machining off after printing, but may add significant value through higher-quality prototype parts.

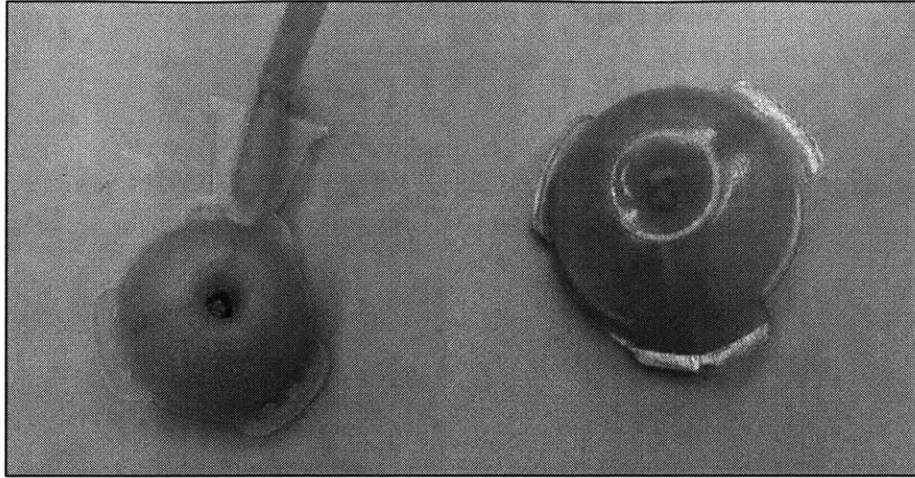


Figure 46: Example part produced using the experimental mold (left) and PolyJet (right)

Surface finish: The PolyJet mold consistently produced a high quality, glossy finish on the prototype parts. The experimental mold showed a relatively consistent, but rough surface finish over the trials. Certain areas of these parts, however, contained mold material that had melted and flaked off during the injection operation. For this particular part, which did not have strict specifications on surface finish for prototypes, the project engineer judged the surface finish of all prototypes acceptable over the range of the trials.

Mold deformation or damage: Each mold tested had a different failure mode; the experimental mold gradually degraded, while the PolyJet mold remained consistent up to its catastrophic failure, as shown in Figure 47. Even after just the first shot, there was visible degradation of the experimental mold in the form of melting at points of concentrated heat. It was evident that despite minimizing the injection temperature of the polycarbonate, the polymer present in the experimental mold was also experiencing melting. Figure 46 also shows that portions of the experimental insert feature remained with the prototype parts; this resulted in the experimental mold failing to accurately mold this feature in any of the trials. The PolyJet mold was more predictable up to the point where the feature shown in Figure 47 broke off completely as a result of both thermal and mechanical stresses.

Despite both materials showing significant potential for producing low-cost, fast lead-time prototype parts, the challenging geometry limited the PolyJet mold's life to four acceptable parts, while the experimental mold did not produce any acceptable parts. Given a part geometry without heat-concentrating features, this experiment suggests both molds would have been substantially more successful given the remaining mold features were in excellent condition at the end of the trials.

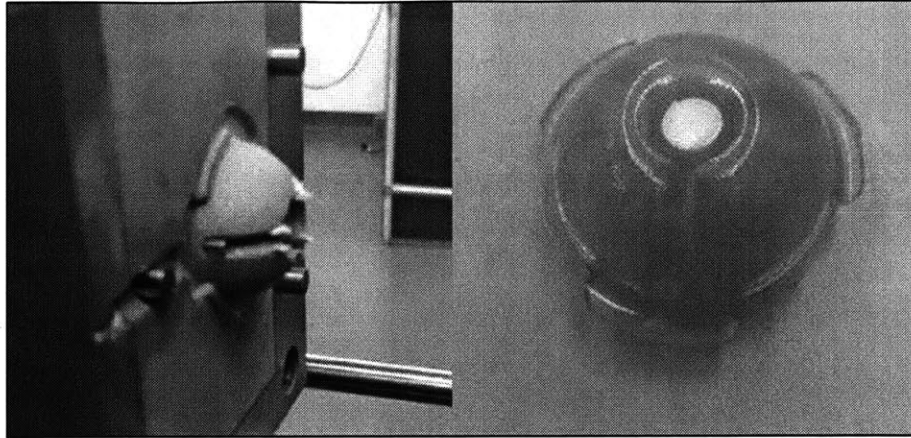


Figure 47: Failure modes of metal-polymer blend mold (left) and PolyJet mold (right)

Despite the possibility of producing acceptable parts with some modification, this study showed little reason to believe that the experimental mold material has advantages over PolyJet for RT molds; superior surface finish, reduced flash, and better consistency are all reasons that PolyJet appears to be the better material. An area of future research would be to replace heat-concentrating geometry with machined metal inserts; this could allow for significantly more parts to be produced on a prototype mold. Additionally, one study successfully used RT to produce 1250 prototype parts through the integration of conformal cooling lines [81].

Even with its disadvantages, the use of 3D Printed Rapid Tooling provides an important solution for the concept generation phase of development. Despite internal case studies proving its value, many of the engineers and designers interviewed at J&J were unaware of this technique. For New Product Development projects in the early design phase, this technique has the ability to provide both significant time and cost savings over traditional manufacturing methods. Stratasys has published a variety of useful guides that should be consulted if Rapid Tooling is considered for an application, which can significantly decrease its learning curve. Figure 50 in Appendix Section 6.2 provides high-level parameters that can help to determine if a part under consideration is a good candidate for production via RT.

4.4.1.6 Improve prototyping ability to reduce engineering builds

A significant way that 3D Printing could accelerate New Product Development is through reducing the total number of engineering builds. These builds represent several months of development time and account for a significant portion of a project's development budget. Each engineering build represents a major iteration in the product's design—typically two such builds are planned into an “optimal” schedule, where often three or more are eventually needed. Many aspects of the design potentially change for each

iteration, including material selection, design, and product features. Refining the product design through engineering builds is critically important to producing a quality product, and this process usually lies on a project's critical path.

3D Printing may help to reduce the total number of engineering builds through smaller, more frequent design iterations between builds. In the past, design revisions have warranted the procurement of “soft tooling”, or prototype injection molds to produce functional parts out of the production material. Using multi-material technologies, such as SLS or CLIP, or using 3D Printed polymer injection molds, as described in Section 4.4.1.5, shorter iterations can be achieved with similar results. For example, one project team at J&J used a polymer injection mold to test a minor design change, which led to a higher quality product; this process was completed in a matter of days, compared to an expected cycle time of six weeks with a traditional mold. Replicated several times, similar successes may cumulatively reduce the need for major iterations, and significantly shorten total development time.

3D Printing will not replace prototype molds completely—while these technologies are excellent for testing design changes, they provide no insight for the final production process. Engineers typically use the late-stage engineering builds to test their designs for manufacturability and tune in various parameters to ensure a high quality product. Therefore, it is important to use a prototype manufacturing process that is similar to the production manufacturing process. Until 3D Printing becomes economical at much higher volumes, project teams will rely on traditional tooling for late-stage engineering builds.

4.4.1.7 Increase availability of CLIP or MultiJet Fusion Technologies

To capture the most value from 3D Printing, J&J needs to continuously monitor the industry for emerging technologies. Two such technologies that have shown promise are Carbon's CLIP and HP's Multi Jet Fusion, which can both quickly print high quality, low cost parts that can be used for design iterations as discussed in Section 4.4.1.6. Because these technologies are so new, access is somewhat limited and needs to be coordinated through the 3DP & NSTC—J&J should continue to evaluate each technology's value and expand access to them where applicable.

4.4.1.8 Develop Design for Additive Manufacturing guidelines

J&J has developed traditional manufacturing expertise over decades of trial and error, research, and consultation. As a result, its engineers and designers are well aware of best practices for subtractive manufacturing. The same cannot be said, however, for additive manufacturing—this fundamentally different process has unique design challenges, limitations, and capabilities as outlined in Section 3.1, which must be learned to fully exploit its benefits.

J&J does not currently have Design for Additive Manufacturing (DFAM) guidelines or training. Without adequate training resources, engineers and designers are at risk of either not capturing 3D Printing's benefits, or succumbing to some of its pitfalls. Areas that should be covered in DFAM training should include the following: Avoidance of enclosed hollow volumes, selection of proper clearances, minimum feature sizes, consideration of surface finishes, proper selection of materials, consideration of the maximum working volume, and build cost and time [82].

DFAM can enable manufacturing of parts with more desirable properties. For example, lightweight parts can be produced using a process called topology optimization, which removes all unnecessary material from an existing design, and can only be manufactured using 3D Printing. Another example of improved properties enabled by DFAM is fluid flow—designs that optimize fluid dynamics, but cannot be produced using subtractive manufacturing, may be easily produced through 3D Printing [27].

Several methods of DFAM have been proposed, the most recent of which is the Axiomatic Design Method. This method discusses a framework that supports optimal design from the concept development phase. This method first maps customer needs, which are then translated to functional requirements. From these functional requirements, design parameters are developed, finally followed by process variables. Throughout this process, two domains are identified: the “Functional Domain”, which contains all of the desired product properties, and the “Physical Domain”, which identifies the methods used to achieve them. This process takes advantage of the geometric freedoms enabled by 3D Printing, and attempts to separate design from the traditional limitations of manufacturing. Instead of simply educating engineers on use of the various available technologies, this method changes the entire design process to support 3D Printing [82].

A practical approach to implementing DFAM would be to make guidelines that are technology-specific. Several companies, such as EOS, have developed a series of tutorials that walk users through real-world examples using a specific machine. These tutorials describe capabilities and limitations in terms of features such as lettering, round pins, wall thicknesses, gaps, and holes. Other companies that have published useful design guidelines include Stratasys, Materialise, and NIST. To complement these materials, outside vendors, such as Wohlers Associates, offer DFAM courses to corporations, which are tailored to specific customer needs [27].

There are some limitations to the benefits of developing DFAM guidelines. Because J&J typically produces parts in volumes that exceed the current economic feasibility range of 3D Printing, these parts will still need to be designed with traditional manufacturing in mind. For example, even if a designer

could prototype a geometrically complex part on a 3D Printer, he will still need to consider its manufacturability for launch. Despite this reality, the volume of parts that can be economically 3D Printed continues to increase. Given this trend, developing a set of DFAM guidelines will prepare J&J for when the technology sees wider use for end production.

4.4.2 Discussion of Results

The improvement opportunities outlined in Section 4.4.1 can be used to significantly increase development speed at J&J. While each of these improvements may not be applicable to every NPD project, empowering engineers with a suite of capabilities is very likely to have a positive effect. The following sections discuss the general applicability of each capability improvement, and its potential benefit at the project level. The discussion is broken down into two parts: near-term improvements, which can be implemented given current technologies, and future improvements, which are enabled only by advancements in the 3D Printing industry.

4.4.2.1 Near-term improvement possibilities

Use of conformally cooled production molds is one of the most promising techniques enabled by 3D Printing. This practice is technically proven, economical, and poses little schedule risk. As more vendors learn how to build these molds, these advantageous characteristics will only improve. Conformal cooling is applicable to a wide range of projects at J&J—any product with either injection molded or MIM parts, which is the vast majority of those at J&J MD, can benefit from this technique. As discussed in Section 4.4.1.1, one of the key benefits of this technology is the ability to shorten the total time from order placement to the production of parts. In some cases, use of conformal cooling can save up to two months on production tooling alone when compared to the process of procuring traditional molds. This time is on or near the critical path for most projects—thus this is a highly valuable technique that should be used whenever possible.

Increased access to local 3D Printing also has the ability to shorten a project's critical path, but typically in the early phases. Because this stage of development typically involves many iteration cycles and has flexibility for both quality and material selection, 3D Printing is a natural choice for almost every NPD project. The main benefit of increased access to local vendors in this phase is speed; shaving even one day per iteration can accelerate a product launch by two weeks or more, depending on how many design revisions are needed. An important quality of early development is that despite much less schedule pressure from leadership, this phase almost always lies on a project's critical path. With this in mind, J&J could see significant benefit from expanding access to local 3D Printing resources, whether internal or external.

If it is determined internal resources are potentially valuable, using the decision rules discussed in Section 4.4.1.3 would allow J&J to justify capital purchases to upper management. Given that J&J's largest 3D Printing lab has queue times for certain machines of roughly two weeks, it is likely that additional capacity would benefit the organization. Again, the majorities of parts built on these machines are for early development, and thus have a high probability of lying on a project's critical path. For those projects affected by an internal lab's queue time, adding capacity would provide significant value—approximately one to two weeks savings per iteration for metal parts, and one to three days for plastic parts.

Quantifying the value of establishing a formal process for developing 3D Printing value streams depends largely on how innovative the business is. The main benefit of this process is to ensure that any innovation developed by one part of the organization is shared with all other parts of the organization, where applicable. For example, if a project team at DePuy Synthes successfully uses a new scan-to-print technique, they will share their findings with the 3DP & NSTC, which can then provide training on the subject to engineers at Ethicon. This process will improve organizational learning and uneven distribution of knowledge across the segments—it has applicability to a wide range of projects, and even other technologies.

Using 3D Printed polymer injection molds can accelerate a project through the early phases of development. This technique is especially valuable when special materials are required, such as proprietary bio-absorbable plastics. In these applications, use of rapid prototype molds can save several weeks per iteration, in addition to reducing costs. As shown through research and experimentation, this technique is not applicable to high-volume production, but it can produce acceptable parts for early development. These parts may not meet design specifications for tight tolerances, but they can provide valuable direction to project teams, which would have previously required expensive and time-consuming soft tooling. This technique is applicable to any project that is rapidly iterating injection-molded parts.

The advantage of both CLIP and MultiJet Fusion are that they produce higher quality parts than previous technologies, while at a faster pace. Because they have shifted out the number of parts that can be economically produced, these technologies open the possibility of using 3D Printing deeper into the development cycle. These machines have applicability on projects where several hundred units of a product are needed for early voice-of-customer research. One challenge they face is that they are both currently limited to a small number of materials. Additionally, because they are not yet suitable for end-production, using these technologies does not help manufacturing engineers come down the product-learning curve. Because of these challenges, CLIP and MultiJet Fusion currently provide only

incremental value to project teams in MD—but as each technology improves it could potentially be used for engineering builds or low-volume end production.

Finally, developing DFAM guidelines would provide immediate value for project teams. For example, an experiment performed by one of the pilot projects resulted in failure due to material thickness; the secondary curing process caused cracking due to thermal stresses. In this case, the engineer did not properly design his part to be printed, because he was unaware of the technology's constraint. In the future, DFAM guidelines could prevent this type of error, saving both time and cost. These guidelines are especially important as the role of 3D Printing grows and engineers are learning how to use each new type. Guidelines will not provide direct time savings, but they will enable the improvements described above and facilitate efficient technology adoption.

4.4.2.2 Future improvement possibilities

Technology improvement will enable even greater benefit from 3D Printing in product development. One scenario where this may be the case is for a limited launch; in this case, a product is marketed at low production volumes well before the full launch. 3D Printing could enable this by eliminating capital tooling requirements associated with a full launch.

Figure 48 shows a typical product launch scenario in medical devices. In general, adoption of new products takes time. For at least the first year, new products typically sell at only a fraction of their peak volume. This is not unique to medical devices; in fact, most industries experience a very similar uptake for new products [22]. The shape of this curve presents an opportunity for 3D Printing; because volumes are initially low and 3D Printing does not require customized production tooling, it may enable significantly shorter times to launch. In the example below, if Q^* represents the volume of parts that can be economically produced using 3D Printing, T^* represents potential acceleration to market. The shaded area is the total quantity of products that are produced using 3D Printing—beyond T^* , J&J would then switch over to traditional manufacturing techniques as sales volumes increase.

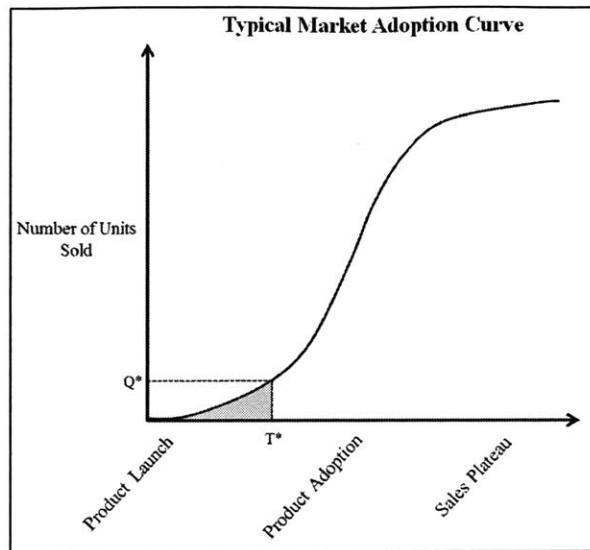


Figure 48: Typical market adoption curve showing potential for 3D Printed limited launch

There are several concerns to this approach that are preventing its adoption. The first is that this model assumes that capital-tooling procurement is on a project's critical path. In many cases it is, but other activities are also occurring in parallel for portions of its duration. Given this information, J&J would be able to capture some, but not all, of the potential time savings from the process. Second, 3D Printing does not yet offer the material selection or the quality necessary for final part production. Despite advances such as CLIP technology, no type of 3D Printing yet offers the surface finish of injection-molded parts. Because quality is a key differentiator for J&J, the company cannot yet offer mass-produced 3D Printed products for most applications. Third, the regulatory environment surrounding medical devices makes this process challenging. The FDA requires that products used for device validation are produced on equipment that is similar to production—therefore performing a limited launch using 3D Printed products would require nearly twice the regulatory effort of a traditional development. Finally, and most importantly, this model introduces risk into the supply chain. If forecasts underestimate initial demand, then this model will likely present a capacity constraint soon after launch. Additionally, the period of transition from 3D Printing to traditional methods could take longer than expected, leaving capacity well short during the Product Adoption phase shown in Figure 48.

Despite the challenges with a 3D Printed limited launch, it still presents a compelling opportunity. In a less regulated environment, the idea may still have merit and become feasible as 3D Printing technology continues to improve.

4.5 Cultural Impacts

Capturing value from the proposed organizational and capabilities improvements requires cultural change. Because 3D Printing is evolving quickly, it is essential that J&J foster a learning culture to avoid uneven distribution of knowledge. Two key elements needed to successfully implement the structure proposed in Section 4.3 are communication between functional groups and identification of learning experiences.

Communication should consist of both a “push” and a “pull” of information from the Developers, Service Providers, and Pioneers. If one group identifies an area where 3D Printing can benefit the organization, it is their responsibility to push the findings to the other groups such that knowledge is shared. On the other hand, if a need comes up during development, they need to feel comfortable engaging the other groups for help. As identified in Section 4.3.4, the proposed structure functions much more efficiently if groups leverage interaction over independent research. Formalizing much of this communication will help, through Blitzes and design reviews, but building day-to-day relationships will be even more valuable. The more frequent interactions become, the better knowledge will be shared, and the faster products will be developed.

Additionally, individual projects should be seen as learning opportunities. Currently project managers are risk-averse towards new technologies, because they have little incentive to do otherwise. While this generally benefits the project team, it does little to improve organizational knowledge. For example, if a project could potentially benefit from using a new 3D Printed technology, but doing so might require additional resources to perform in parallel with more proven methods, then the learning opportunity should be elevated to the 3D Printing Service Providers. This may not only benefit the team, but also others in a different segment of J&J. Instead of shutting down ideas because they involve some risk, the organization should foster experimentation and have a process in place to do so.

4.6 Applications of Research to Other Areas of J&J

This section is broken down into two parts. The first discusses application of the 3D Printing opportunities identified to J&J’s Pharmaceutical and Consumer Products franchises. The discussion then moves to potential application of these findings to technologies other than 3D Printing.

4.6.1 Applications of 3D Printing research

Both the Pharmaceutical and Consumer Products segments of J&J can benefit from the 3D Printing opportunities identified in this project. Despite operating on different timescales than Medical Devices, speed is still critical to the success of any product launch. To capture the most value from these techniques, it is important to create a similar organizational structure to that which is proposed in Section 4.3. Medical Devices is conveniently organized, such that the Service Provider role can be assumed by

the Metals and Plastics COEs. The other segments, however, currently do not contain these functions. With that in mind, it will be necessary to form teams and carefully assign responsibilities in these segments.

For the Pharmaceutical franchise, there is opportunity in the Devices group. Many new drugs require drug-specific injectors, which are somewhat similar to those in the Medical Devices segment. In this case, almost all of the opportunities identified can carry over seamlessly. In addition, particular interest has been shown for clinical research—these low-volume trials may be well served by 3D Printed Devices. The pharmaceutical industry is subject to even more stringent regulatory requirements than the medical devices industry, so further research is required to investigate its effects.

While the Consumer Products segment is subject to less stringent regulatory requirements, it produces in volumes that are generally prohibitive to 3D Printing products. The largest benefit seen by this segment will most likely come from the tooling, gauges, and fixtures that facilitate the manufacturing process. Conformal cooling, for example, can be applied to a mold for packaging to speed launch. Additionally, 3D Printed polymer molds can be used to test new bottle designs. The best way for management to discover new applications for 3D Printing is to equip engineers in each segment with the appropriate knowledge and resources—through this exposure and the learnings shared from the other segments, these engineers will undoubtedly find new ways to speed development.

4.6.2 Applications of organizational structure research

Aside from the 3D Printing-specific opportunities identified in this project, another important application could be to other quickly evolving technologies. Section 4.3 outlines a framework that can increase the learning capability of an organization, regardless of technology studied. Modeling this structure shows that an organization can benefit from giving careful attention to its technology transfer process. Creating a centralized body of knowledge, which is connected to the project level by knowledgeable intermediaries, serves as an efficient structure that can collect and disperse knowledge across a wide organization. This structure allows for both a “push” and a “pull” of ideas between groups, while allowing experts to focus largely on research and project engineers to focus largely on product development.

An example where this structure could be implemented is in the field of data analytics. This field is evolving quickly, with new software packages and statistical methods continuously developed. In this case, project-level employees will not have the bandwidth to keep up with the state-of-the-art. Segment level “Service Providers”, who maintain a good knowledge of the field and have access to software licenses, can offer consulting advice to projects as necessary. If new applications are needed that are

outside the realm of the Service Providers, a corporate-level group of Operations Researchers can be brought in solve outstanding issues. Subsequently their learnings will be shared to other segments. Similarly, frequent training can be administered to Service Providers and as-needed training can be given to Developers.

This example shows that the model developed in this project has applications beyond 3D Printing, and may provide significant benefits when applied to other new technologies. It provides a solution that enables a large, segmented company like J&J to leverage its size to become a fast-learning organization.

5 Recommendations and Conclusions

Based on literature review, 3D Printing expert interviews, and work with three pilot projects in J&J's Medical Devices segment, evidence suggests that 3D Printing can significantly accelerate product development. Additionally, this project suggests that a well-implemented 3D Printing program can also increase product quality while reducing cost and supply chain risk. Because the field of 3D Printing is rapidly evolving, success of such a program relies not just on enhancing an organization's technological capabilities, but also requires an organizational design to facilitate continuous learning.

At J&J Medical Devices, the implementation of methods described in this body of work is expected to reduce New Product Development cycle time by at least two months. Some of these methods involve capital expenditures, but many do not—realigning responsibilities to promote problem identification, solution building, and knowledge sharing could be the single biggest driver of value identified. In addition to organizational recommendations, eight focus areas are highlighted that can give project teams enhanced tools to accelerate product development and improve quality. While largely unsuccessful, this project included exploration of new materials to extend the usable life of 3D Printed polymer injection molds. It also briefly explored the efficacy of 3D Printed conformal cooling through Finite Element Analysis. While many techniques identified in this work focus on using 3D Printing early in the product development cycle, several techniques and applications are identified that expand the use of 3D Printing all the way to production. While it has been successfully used for low-volume end products, future advances in the industry will enable even greater use of the technology for production parts.

In addition to facilitating the use of 3D Printing in New Product Development, the proposed organizational structure can potentially be applied to other new technologies. A Monte-Carlo simulation developed in this project can be used as a framework to determine the optimal organizational characteristics that maximize the overall benefit to the company. This model provides insight into training cadences, resource allocation, and potential strategy changes as the technology matures.

In conclusion, this work has shown that 3D Printing can significantly accelerate product development in the medical devices industry. The acceleration enabled by this technology has benefits including increased revenue, first-mover pricing advantage, and improved reputation, in addition to enhanced patient outcomes. This project has shown that the benefits of an enhanced 3D Printing strategy outweigh the costs, and will continue to do so as the technology evolves. 3D Printing's abilities to speed product development, enable custom solutions, and reduce costs create significant value for patients; for all of these reasons, it will be an important technology for years to come.

6 Appendix

6.1 3D Printing Utilization Assessment Framework

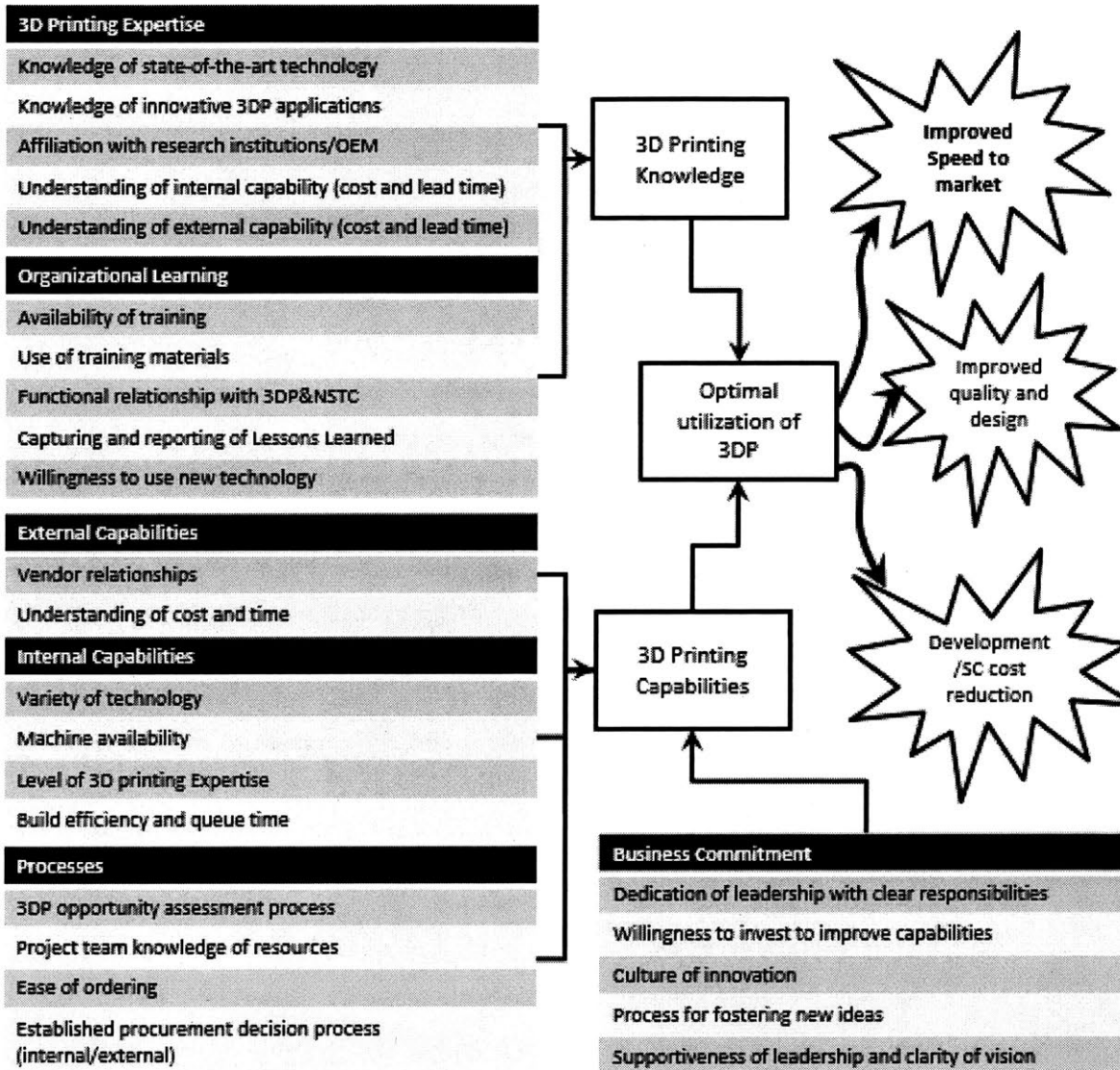


Figure 49: Framework for determining 3D Printing capabilities

6.2 Best Fit Parameters for 3D Printed Rapid Tooling

BEST FIT PARAMETERS

PolyJet molds are a best fit for the application when working with:

Thermoplastics:

- Reasonable molding temperatures < 300° C (570° F)
- Good flow behavior
- Candidates:
 - Polyethylene (PE)
 - Polypropylene (PP)
 - Polystyrene (PS)
 - Acrylonitrile Butadiene Styrene (ABS)
 - Thermoplastic elastomer (TPE)
 - Polyamide (PA)
 - Polyoxymethylene or Acetal (POM)
 - Polycarbonate - ABS blend (PC-ABS)
 - Glass-filled resins

Quantity:

- Low quantities (5 to 100)

Size:

- Mid-sized parts <165 cm³ (10 in³)
- 50 to 80-ton molding machines
- Manual hand presses can also be used.

Design:

- Multiple design iterations are required.

Testing:

- Functionality confirmation is required.
- Compliance testing (e.g., UL or CE) is required.

Figure 50: Best fit parameters for using 3D Printed (PolyJet) Rapid Tooling [83]

6.3 SIPOC Analysis for 3D Printing Blitzes

6.3.1 High-level diagram

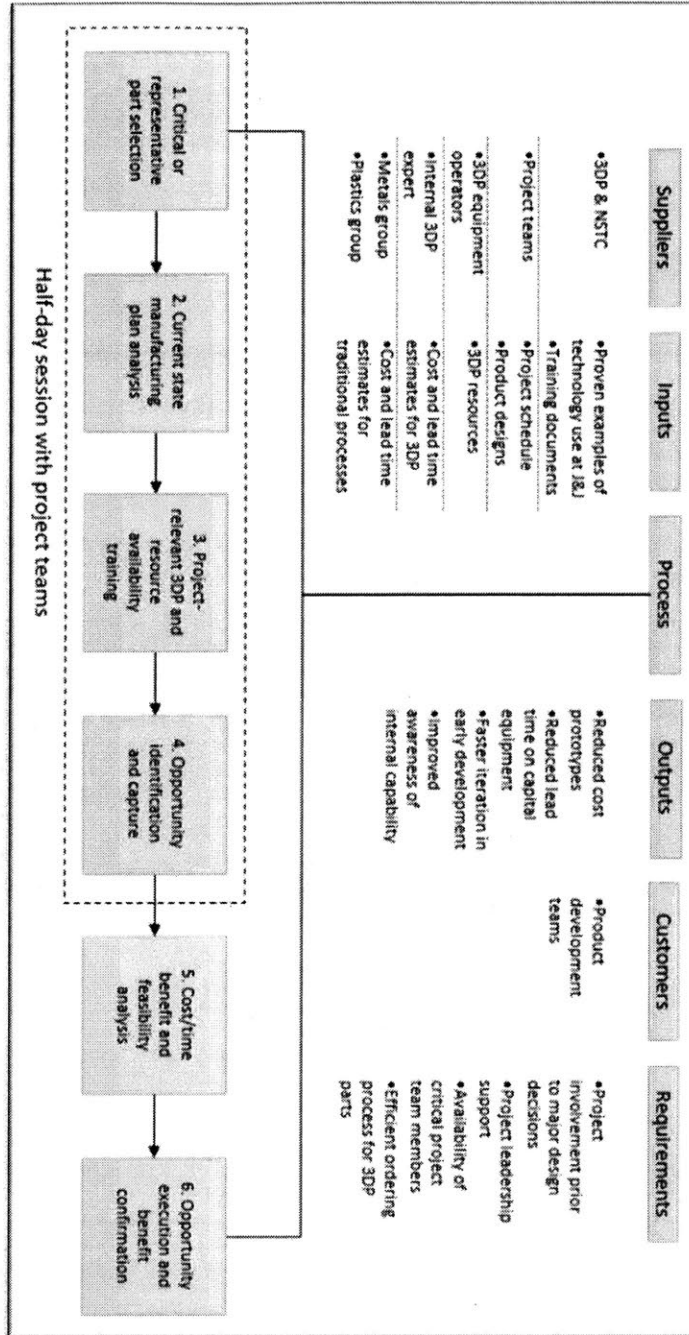


Figure 51: SIPOC diagram for 3D Printing Blitzes

6.3.2 Detailed explanation of SIPOC analysis

Suppliers

3DP & NSTC: This group brings up-to-date industry expertise, knowledge of vendors, internal and external resource connections, and case studies of successful 3DP implementation at J&J.

Project teams: This group is composed of the engineers, designers, and managers responsible for the product under investigation. They should understand the processes planned for manufacture, the critical components, and the expected materials.

Metals group: This group can add additional input on manufacturing plans for metal components.

Plastics group: This group can add additional input on manufacturing plans for plastic components.

Internal 3DP experts: These will be technology experts within J&J that have direct access to 3DP resources and experience using the technology.

Knowledgeable facilitator: This person will direct the discussion, and must have at least a moderate understanding of different 3DP technologies and how they have been used at J&J.

Inputs

Product designs: Supplied by the project teams, the product designs should be in a state where the general form of the final product is known, but questions may still remain about final materials, form, manufacturing process, etc.

3DP resources: These include both internal and external resources that can be available to the project teams. Ideally these will include a wide variety of metals and plastics capabilities.

Training documents: These documents will provide a basic understanding of available technologies, strengths, weaknesses, and materials.

Project schedule: It is important to have an understanding of the project schedule to evaluate the benefit of various opportunities to the project critical path.

Cost and lead time estimates: Understanding rough estimates of cost and lead time for comparison to new technologies.

Proven examples of technology use at J&J: General risk-aversion among teams necessitates success stories and proven trials of new technologies at J&J.

Process

(~Half-day session with project teams)

Critical or representative part selection: Facilitator, project team

- Select at least one part of each material family (plastic, metal, silicone, etc.) which will be analyzed by the group over the four-hour opportunity identification session
- Include parts that are especially unique, or have provided challenges to the team thus far
- It is important to limit the number of selections to 4-5 parts total. This will allow for enough time to analyze each part in depth

Current state manufacturing plan analysis: Facilitator, project team, metals and plastics groups

- Walk through the development process of each of the parts selected, one at a time (i.e. Development, EB1, EB2, Production).
- Understand and capture the purpose, lead time, and cost of each development step.
- Capture the expected manufacturing process, and critical qualities of the components including tolerances, surface finish, materials, etc.
- Also consider critical tooling and fixtures of each process step.

Project-relevant 3DP and resource availability training: 3DP & NSTC, internal 3DP expert

- Provide overview training on various relevant 3DP technologies. Include specific examples of strengths and weaknesses involved in each technology.
- Include case studies to show where specific technologies have been successfully used at J&J.
- Provide equipment directory, contact list, and recommendation for various 3DP resources both internally and externally.
- Highlight the cost and lead time associated with each technology.

Opportunity identification and capture: Facilitator, 3DP & NSTC, project teams, internal 3DP expert, metals and plastics groups

- Walk through each part selected, and identify potential areas for improvement in various process steps.
- Identify and capture improvements in cost, quality, or lead time.
- Also capture the reason why this improvement had not been considered in the past, to identify improvement opportunities
- Provide recommendations and contact information of potential resources for follow up after the session

(Beyond session with project teams)

Cost/time benefit and feasibility analysis: Project teams, 3DP & NSTC, 3DP equipment operators

- Select internal or external resources and work with vendor to ensure tolerances, necessary speed, surface finish, etc. will be acceptable.
- Perform schedule analysis to understand opportunity effect on project critical path.
- If necessary, work with Global Business Insight to determine the value of estimated time savings to justify any additional cost or necessary investment.

Opportunity execution and benefit confirmation: Project teams, 3DP & NSTC, 3DP equipment operators

- Carry out feasible opportunity improvements.
- Capture observations on actual vs. estimated cost and lead times, and feed back to 3DP & NSTC for future use.
- If improvement was new to business, add to training materials
- Continually update information on vendor performance.

Outputs

Reduced cost prototypes: This will typically come as a result of reduction in machining, soft tooling, and other expensive prototyping methods.

Reduced lead time on capital equipment: Additively manufactured tooling can be produced faster and can provide more accurate parts with fewer iterations.

Faster iteration in early development: 3D Printing allows for rapid, low-cost prototyping early in development. Traditional (direct part print) and non-traditional (3D Printed injection molds) have distinct advantages and will both provide benefits.

Improved awareness of internal capability: Forming a connection and fostering a lasting relationship between project teams and 3D Printing resources increases equipment utilization, provides access to expertise, and can drastically lower costs.

Customers

Product development teams: The ultimate goal is to enable project teams with better tools to develop products faster, with higher quality, and lower cost.

Requirements

Project involvement prior to major design decisions: Timing of intervention is critical. The product should be at a stage where the final form is roughly understood, but not yet detailed. This typically occurs prior to the first Engineering Build, before any capital-intensive decisions have been made.

Project leadership support: The project team leaders set the tone for the acceptance of new technology. They should encourage experimentation and be willing to take calculated risks.

Availability of critical project team members: The Lead R&D engineer, designer, and PM are important to provide insight from within the project team.

Efficient ordering process for 3DP parts: Once opportunities have been identified, there needs to be an established and efficient ordering process to ensure value is not lost. Most of the value seen from 3D Printing comes from speed, thus an efficient connection between the technology and project teams is very important.

6.4 Simulation Details

6.4.1 @Risk Model Inputs

6.4.1.1 @Risk decision variables

@RISK Model Inputs							
Date: Tuesday, December 27, 2016 4:24:15 PM							
Name	Graph	Function	Min	Mean	Max	Input Name	Explanation
Category: CAD							
CAD / Decision Variables		RiskUniform(90,364,RiskStatic(90))	90	227	364	Cadence	The cadence, in days, of Knowledge Transfer Sessions between the Service Providers and the Pioneers
Category: Dd							
Dd / Decision Variables		RiskUniform(0,0.01,RiskStatic(0.01))	0	0.005	0.01	Fraction of Dedicated Time, Developers	The fraction of the overall workweek, which is spent dedicated to independent study of 3D Printing.
Category: Ds							
Ds / Decision Variables		RiskUniform(0,0.15,RiskStatic(0.15))	0	0.075	0.15	Fraction of Dedicated Time, Service Providers	The fraction of the overall workweek, which is spent dedicated to independent study of 3D Printing.
Category: tB							
tB / Decision Variables		RiskUniform(0.5,3,RiskStatic(1))	0.5	1.75	3	Time Dedicated to Blitz	The amount of time, in days, scheduled for Blitz sessions between Service Providers and Developers.
Category: tK							
tK / Decision Variables		RiskUniform(0.5,15,RiskStatic(1))	0.5	1	15	Time Dedicated to Knowledge Transfer Sessions	The amount of time, in days, scheduled for Knowledge Transfer Sessions between Pioneers and Service Providers

Table 4: @Risk decision variables

6.4.1.2 Other @Risk inputs

For mpN, an @Risk distribution was implemented to enable in-depth analysis after simulation. mpN dictates the “Ceiling” of the organization’s Knowledge Level, so it was important to track the effect of mpN on the Aggregate Savings.

Inputs			
Symbol	Input name	Input Value	Explanation
mpN	Knowledge accumulation rate for Pioneers during non-Blitz	Uniform between 0.27-0.55	The available Learning Rate for the Pioneers during normal periods. This number is an estimate based on the growth rate of the industry, so an @Risk output is assigned to enable a 10-20% learning rate per year.

Table 5: Non-decision variables utilizing @Risk distributions

6.4.2 Non @Risk Model Inputs

6.4.2.1 Fixed non-@Risk inputs

The inputs shown in Table 9, which continues through page 116, are fixed over the course of individual simulations and are not changed for different experimental runs.

Inputs			
Symbol	Input name	Input Value	Explanation
T	Total number of days in analysis	365	Analysis over one year
nd	Number of developers	200	Approximate number of engineers and designers working on new projects
ns	number of service providers	40	Approximate number of engineers in the PM Metals and Plastics COEs
np	number of pioneers	15	Approximate headcount in the 3DP & NSTC
Dp	Fraction of pioneer time dedicated to 3D training when not on Knowledge Transfer	1	Full dedication expected from 3DP & NSTC
Ld	Opportunity cost of developer time (\$/day)	1000	Estimated daily opportunity cost of a New Product Engineer
Ls	Opportunity cost of service provider time (\$/day)	600	Estimated daily opportunity cost of a manufacturing engineer in the PM group
Lp	Opportunity cost of pioneer time (\$/day)	274.0	Estimated daily opportunity cost of an engineering fellow (\$100,000/365)
mdN	Knowledge accumulation rate for developers during non-Blitz	1	Roughly 2-4X the Learning Rate available as the Pioneers, given higher gap to state-of-the art and available training materials.
msN	Knowledge accumulation rate for service providers during non-Blitz	0.75	Roughly 1.5-3X the Learning Rate available as the Pioneers, given higher gap to state-of-the art and available training materials.
mdB	Knowledge accumulation rate for developers during Blitz	80	Assume ~8% of practical industry knowledge can be accumulated in one

Inputs			
Symbol	Input name	Input Value	Explanation
			day's time of intense and focused study.
<i>msB</i>	Knowledge accumulation rate for service providers during Blitz	20	Assume Service Provider rate of learning at 25% that of Developers during Blitz due to experience sharing.
<i>msK</i>	Knowledge accumulation rate for service providers during knowledge transfer	60	Similar learning rate to Developers during a Blitz, but adjusted to compensate for a smaller gap between the Service Providers and the Pioneers
<i>mpK</i>	Knowledge accumulation rate for Pioneers during Knowledge transfer	10	Assume half the reverse-learning flow of a Blitz section, as there is a smaller amount of knowledge to be learned
<i>kp0</i>	Initial knowledge level of pioneers	1000	Set at 1000 as a reference point. A knowledge level of 1000 is seen as the highest attainable practical 3D Printing knowledge level at the start of the simulation.
<i>#B</i>	Average number of major or mid-level decisions made during a project each year	2	These are decisions that are planned for, and thus prompt a Blitz session to occur between the Developers and the Service Providers. Examples would be capital tooling orders or initial design.
<i>#dd</i>	Average frequency of minor design decisions (days between)	70	These are decisions which are of less magnitude, but occur with significantly higher frequency than major design decisions. These decisions are not planned for. An example would be an additional design iteration or a tooling fixture.

Inputs			
Symbol	Input name	Input Value	Explanation
<i>tdt</i>	Pioneer time dedicated to training materials between service providers and pioneers (assuming 2 days spent developing materials per knowledge transfer)	0.02	This factor adjusts the Pioneer learning rate to account for 2 days work of developing training materials for each Knowledge Transfer Session. This number goes up or down depending on the CAD input.
<i>pp</i>	Fraction of effected projects	1	For this simulation, all projects are assumed effected.
<i>dT</i>	Developers per team	10	Estimated that there are roughly 10 Developers to each project
<i>TP</i>	Total number of projects.	20	Calculated by dividing nd by dT
<i>S</i>	Estimated savings per 1 quarter of project acceleration	\$ 3,000,000.00	Based on NPV value estimated for project launch acceleration of 3 months.
<i>s</i>	Estimated savings per day accelerated	\$ 32,876.71	Daily savings rate based on S.
<i>SPm</i>	Savings potential of a mid-level planned decision	15	Weight, in days of time savings potential, from mid-level decisions. These decisions are planned for a prepared for with a Blitz or review session.
<i>SPM</i>	Savings potential of a major-level planned decision	25	Weight, in days of time savings potential, from major-level decisions. These decisions are planned for a prepared for with a Blitz or review session.

Table 6: Fixed non-@Risk model inputs

6.4.2.2 Variable non-@Risk inputs

These inputs remain fixed over the course of individual simulations but are changed for different experimental runs.

Simulation #	Initial Knowledge Level			
	Developer		Service Provider	
	Hi/Lo	Value	Hi/Lo	Value
1	High	650	Low	650
2	Low	300	High	850
3	High	650	High	850
4	Low	300	Low	650

Table 7: Experimental values for Initial Knowledge Levels

6.4.3 Calculation Details

6.4.3.1 Calculation section from optimization model

Table 8 shows the Calculations section of the optimization model, with detailed explanation for each column in Table 9. The simulation in the optimization model continues through Day 365.

Day	Random vars		Potential Savings (Days per project)	Knowledge transfer ?		Knowledge level			Cost				Savings	Aggregate
	Minor design decision	Major design decision		Random var to start	yes/no	Developers	Service Providers	Pioneers	Developers	Service Providers	Pioneers	Aggregate		
0						300	850	1000	0	0	0	\$ -	\$ -	\$ -
1	104	31	0	139 no	300.010	850.007	1000.378	\$ 1,942.30	\$ 210.99	\$ 4,109.99	\$ 6,262.88	\$ -	\$ (6,262.88)	
2	38	347	0	140 no	300.019	850.013	1000.756	\$ 3,884.60	\$ 421.99	\$ 8,219.18	\$ 12,525.77	\$ -	\$ (12,525.77)	
3	700	343	0	141 no	300.029	850.020	1001.134	\$ 5,826.90	\$ 632.98	\$ 12,328.77	\$ 18,786.65	\$ -	\$ (18,786.65)	
4	655	204	0	142 no	300.039	850.026	1001.512	\$ 7,769.20	\$ 842.98	\$ 18,428.36	\$ 25,051.53	\$ -	\$ (25,051.53)	
5	401	162	0	145 no	300.049	850.033	1001.890	\$ 9,713.50	\$ 1,054.97	\$ 20,547.95	\$ 31,314.42	\$ -	\$ (31,314.42)	
6	354	42	0	148 no	300.059	850.040	1002.267	\$ 11,657.80	\$ 1,267.98	\$ 24,817.93	\$ 37,577.90	\$ -	\$ (37,577.90)	

Table 8: Abridged calculations page from optimization workbook

6.4.3.2 Detailed explanation and formulas from optimization model

Table 9, which continues through page 123, provides explanation for the columns in Table 8. The index value (i) refers to the day of the simulation, as shown in the “Day” column. For several columns, the initial row contains a different formula than the following rows, which is outlined below.

Column	Sub-Column	Formula (Day 0)	Formula (Days 1-365 if different from Day 0)	Explanation
Day		=0	=[Day(i-1)]+1	This column initializes at zero and counts the day of the simulation
Random vars	Minor design decision		=RANDBETWEEN(1,[#dd]*10)	This column inserts a random number between a range of 1 through 10X the frequency between minor design decisions as specified in the inputs. It is used to randomly assign both a weight (in days of potential savings per project of range 1 through 10) and a timing to minor design decisions. See the "Potential Savings" explanation for further detail.
	Major design decision		=RANDBETWEEN(1,365/[#B]*2)	This column inserts a random number which dictates if there is a major or mid-level design decision, based on the frequency described in the inputs. It is used to randomly assign both a weight (in days of potential savings per project) of either 15 days or 25 days and timing of the decisions. See the "Potential Savings" explanation for further detail.

Column	Sub-Column	Formula (Day 0)	Formula (Days 1-365 if different from Day 0)	Explanation
Potential Savings (Days per project)			$=IF([Random\ vars,\ Minor\ design\ decision(i)]<11,[Random\ vars,\ Minor\ design\ decision(i),0]+IF([Random\ vars,\ Major\ design\ decision(i)]=[SPm],[Random\ vars,\ Major\ design\ decision(i),0]+IF([Random\ vars,\ Major\ design\ decision(i)]=[SPm],[Random\ vars,\ Major\ design\ decision(i),0])$	<p>This column determines, based on the previously discussed random variables, if there is the potential to save time on this day. The first IF statement checks if the Minor Design Decision column is between 1 and 10; if it is, then this value is added to the total sum. The frequency of this occurrence is based on #dd. The next two IF statements check to see if the Major Design Decision equals either 15 or 25, which are the weights specified in the inputs for mid-level and major-level design decisions. The chance of this occurring is based on #B. If it is determined that a major or mid-level design decision occurs, the weight is added to the total sum. The cumulative sum of this column (which is dependent on #B and #dd), has been tuned to average approximately 60 days, which is the number of days research suggests for potential acceleration opportunity given full team knowledge of the state-of-the-art in practical 3D Printing expertise.</p>
Knowledge transfer ?	Random var to start	=RAND BETWEN(0,[CAD]-1)	$=IF([Knowledge\ transfer?,\ Random\ var\ to\ start(i-1)]=[CAD],1,[Knowledge\ transfer?,\ Random\ var\ to\ start(i-1)]+1)$	<p>The purpose of this column is to determine if a Knowledge Transfer Session occurs on this day. The first row initiates a random variable between 1 and CAD-1, which allows for the first Knowledge Transfer Session to occur any day between the first day and up to CAD days into the simulation. Beyond day 0, the simulation determines if a Knowledge Transfer Session occurred on the previous day, and if so resets to 1.</p>
	yes/no		$=IF([Knowledge\ transfer?,\ Random\ var\ to\ start(i-1)]=[CAD],"yes","no")$	<p>The purpose of this column is to indicate if a Knowledge Transfer Session has occurred by showing "yes" or "no".</p>

Column	Sub-Column	Formula (Day 0)	Formula (Days 1-365 if different from Day 0)	Explanation
Knowledge level	Developers	=[kd0]	=IF([Knowledge level, Developers(i-1)]+IF(Random vars, Major design decision(i)=[SPM],[tB]*[mdB],IF([Random vars, Major design decision(i)=[SPm],[tB]*[mdB],[Day(i)-[Day(i-1)])]*[mdN]*[Dd]))<[Knowledge level, Service Providers(i)], [Knowledge level, Developers(i-1)]+IF(Random vars, Major design decision(i)=[SPM],[tB]*[mdB],IF([Random vars, Major design decision(i)=[SPm],[tB]*[mdB],[Day(i)-[Day(i-1)])]*[mdN]*[Dd]))],[Knowledge level, Service Providers(i)])	This column calculates the Knowledge Level of the Developers for each day in the simulation. It is initialized at the Initial Knowledge Level, and then becomes cumulative; that is, knowledge is only gained over the year. The top-level IF statement determines if the calculated Knowledge Level is below that of the Service Providers: if it is not, then the Developers' Knowledge Level equals that of the Service Providers'. The second-level IF statements determine if a major or mi-level design decision occurs: in this case the added knowledge is dictated by the time spent on a Blitz and the Blitz Learning Rate. Finally, if it is determined that there is no Blitz, the additional knowledge is calculated based on the Normal Learning Rate and the Fraction of Dedicated Time.

Column	Sub-Column	Formula (Day 0)	Formula (Days 1-365 if different from Day 0)	Explanation
	Service Providers	=[ks0]	=IF([Knowledge level, Service Providers(i-1)]+IF([Knowledge transfer?, yes/no(i)]="yes",[tK]*[msK],IF([Random vars, Major design decision(i)]=[SPM],[tB]*[msB],IF([Random vars, Major design decision(i)]=[SPm],[tB]*[msB],[msN]*(1)*[Ds]))<[Knowledge level, Pioneers(i)],[Knowledge level, Service Providers(i-1)]+IF([Knowledge transfer?, yes/no(i)]="yes",[tK]*[msK],IF([Random vars, Major design decision(i)]=[SPM],[tB]*[msB],IF([Random vars, Major design decision(i)]=[SPm],[tB]*[msB],[msN]*(1)*[Ds]))),[Knowledge level, Pioneers(i)])	This column calculates the Knowledge Level of the Service Providers for each day in the simulations. The top-level IF statement ensures that this level never exceeds that of the Pioneers. The second-level IF statements determine if there is a Knowledge Transfer Session or a Blitz. In either case, the additional knowledge for that day is a function of the length of time spent during the learning session times the specified learning rate for each situation. If it is determined that no learning session occurs, then the cell defaults to the normal calculation, which is a function of fraction of dedicated time and the normal knowledge accumulation rate.
	Pioneers	=[kp0]	=([Knowledge level, Pioneers(i-1)]+IF([Knowledge transfer?, yes/no(i)]="yes",[tK]*[mpK],0)+IF([Knowledge transfer?, yes/no(i)]="no",1*[mpN]*([Dp]-[tdt]),0)	This column initializes the Pioneer Knowledge Level at 1000, and then determines if there is a Knowledge Transfer Session. If there is, then the additional knowledge accumulated is a function of the time spent on the session and the learning rate during the session. If there is no Knowledge Transfer Session with the Service Providers, then the additional knowledge accumulated remains a function of the normal knowledge accumulation rate.

Column	Sub-Column	Formula (Day 0)	Formula (Days 1-365 if different from Day 0)	Explanation
Cost	Developers	=0	=([Cost, Developers(i-1)]+IF([Random vars, Major design decision(i)]=[SPM], [tB]*[Ld]*[nd], IF([Random vars, Major design decision(i)]=[SPm], [tB]*[Ld]*[nd],[Dd]*1*[Ld]*[nd])))	This column calculates the cumulative cost of the 3D Printing strategy with respect to the Developers. The IF statements determine if there is a major or mid-level design decision made, which indicates a Blitz occurs. In this case, the Developers are fully dedicated to learning new 3D Printing knowledge for the specified time period and their costs go up accordingly. If there is no Blitz, the cost is a function of their opportunity cost, their Fraction of Dedicated Time, and the total number of Developers.
	Service Providers	=0	=([Cost, Service Providers(i-1)]+IF([Random vars, Major design decision(i)]=[SPM], [tB]*[Ls]*[ns], IF([Random vars, Major design decision(i)]=[SPm], [tB]*[Ls]*[ns],[Ds]*1*[Ls]*[ns]))+IF([Knowledge transfer?, yes/no(i)]="yes", [tK]*[ns]*[Ls],0)	This column calculates the cumulative cost of the 3D Printing strategy for the Service Providers. The first set of IF statements determine if a Blitz occurs, and if so the Fraction of Dedicated Time Ds is increased to 1 for the specified time tB. The next IF statement determines if there is a Knowledge Transfer Session, and similarly modifies the equation. If there is no special learning session, the cell defaults to cost as a function of the Fraction of Dedicated time, the Opportunity Cost, and the total number of Service Providers.
	Pioneers	=0	=([Cost, Pioneers(i-1)]+IF([Knowledge transfer?, yes/no(i)]="yes", [tK]*[np]*[Lp], [Dp]*1*[np]*[Lp]))	Because the Pioneers are fully dedicated to advancing 3D Printing knowledge, their cost is essentially linearly dependent on their opportunity cost and the number of Pioneers.
	Aggregate		=SUM([Cost, Developers(i)], [Cost, Service Providers(i)], [Cost, Pioneers(i)])	This column shows the total cumulative cost of implementing the 3D Printing strategy through the current simulation day.

Column	Sub-Column	Formula (Day 0)	Formula (Days 1-365 if different from Day 0)	Explanation
Savings	Developers	=0	=[Savings, Developers(i-1)]+[Potential Savings(i)]*([Knowledge level, Developers(i)]/[kp0]-[kd0]/[kp0])*[TP]*[s]	The Savings columns only factors in project-level acceleration opportunities: therefore only the Developers are factored in. These cells look at the opportunity for acceleration on any given day, and the ability of the Developers to act on it. Savings are measured as relative to those which would have been captured had no 3D Printing strategy been implemented: for example, there is more to gain if the Initial Knowledge Level of the Developers is low compared to if it is high. Because the estimated total opportunity is based off the current knowledge of the 3DP & NSTC, the ability to capture value is calculated as the fraction of the Pioneers' Initial Knowledge Level that the Developers have on any given day.
Aggregate			=[Cost, Aggregate(i)-[Savings, Developers(i)]	This column determines the overall benefit of the 3D Printing strategy as a function of its cost and savings generated.

Table 9: Detailed explanation of calculations from optimization model

6.4.4 Simulation results

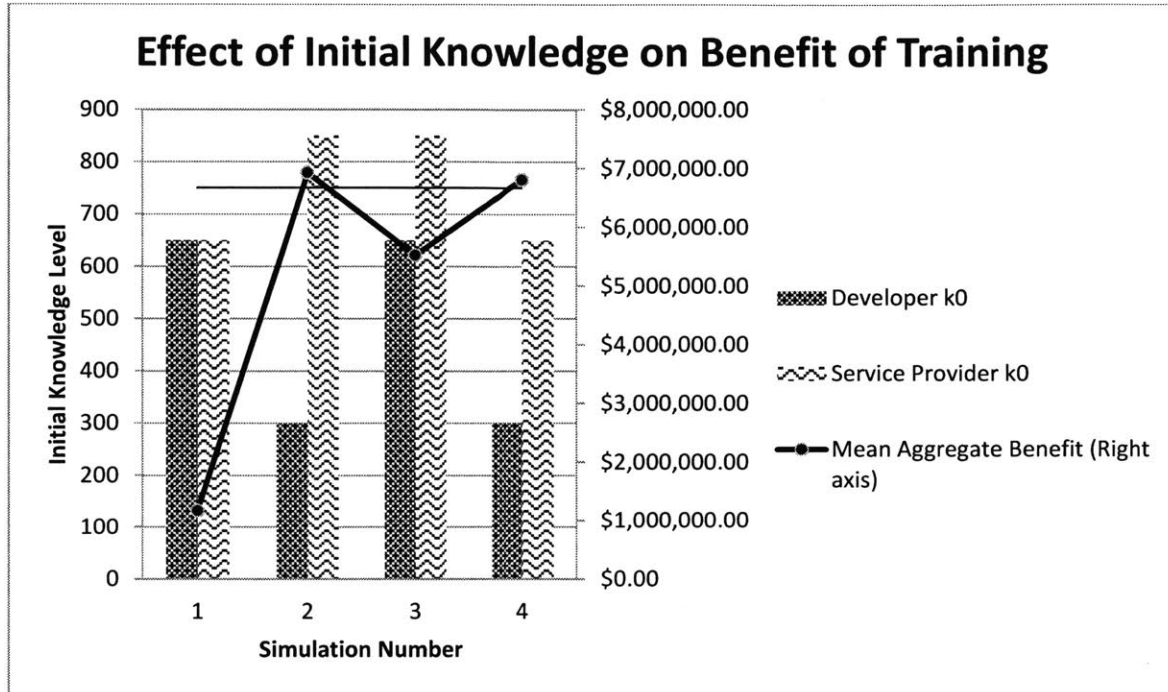


Figure 52: Impact of Initial Knowledge on Aggregate Benefit of proposed strategy

6.4.4.1 Detailed results for Simulation 1

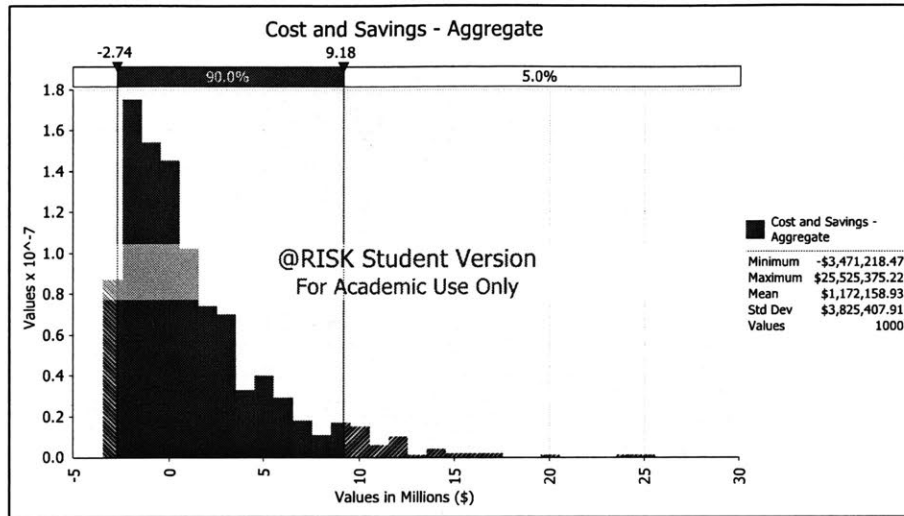


Figure 53: Probability distribution of Aggregate Benefit for Simulation 1

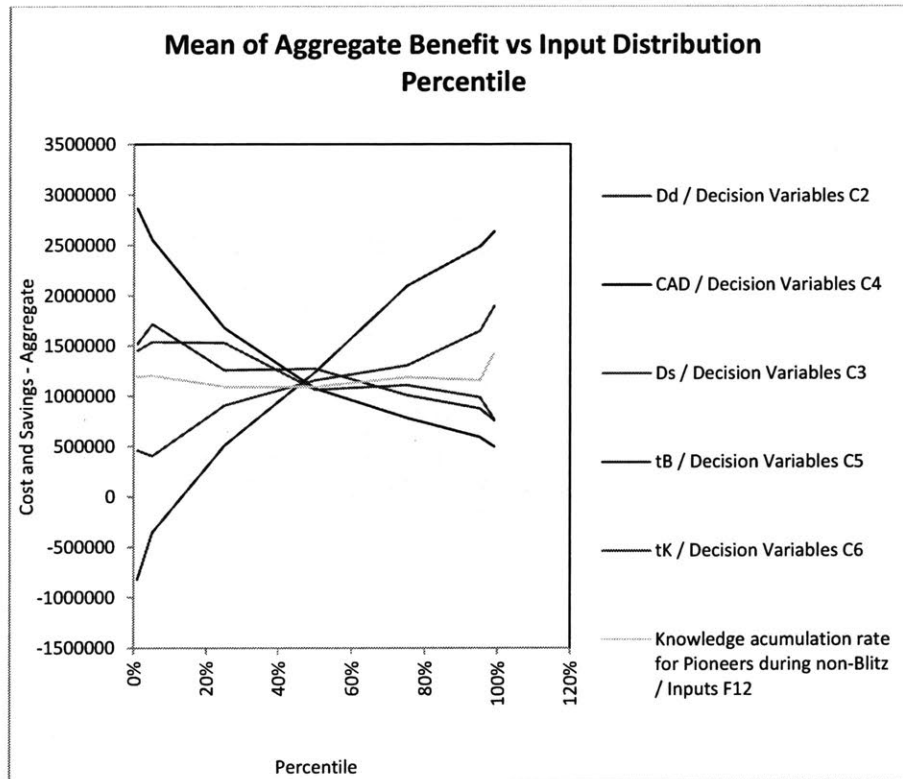


Figure 54: Sensitivity of Aggregate Benefit to various input ranges for Simulation 1

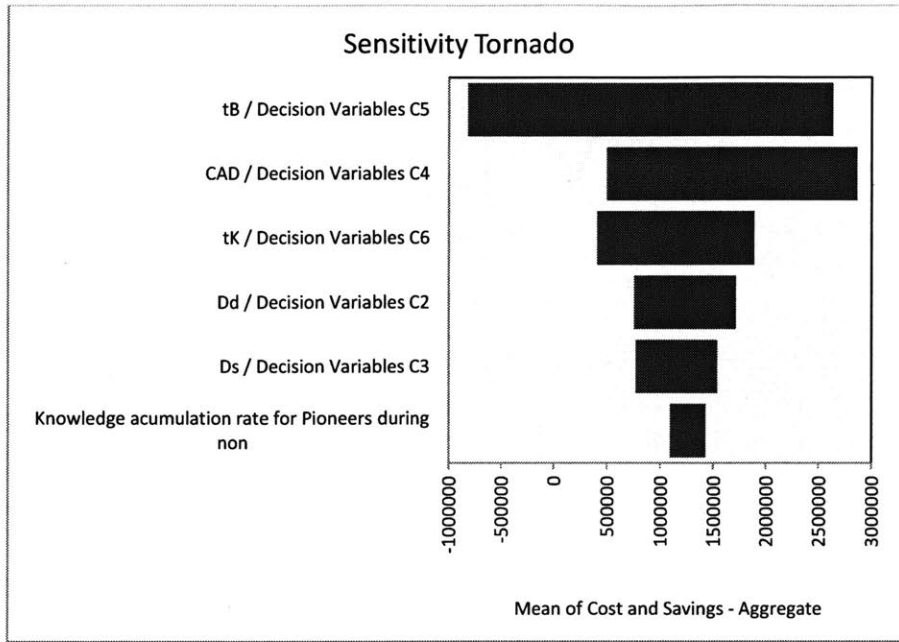


Figure 55: Ranking of input variable impact on program value over specified range for Simulation 1

6.4.4.2 Detailed results for Simulation 2

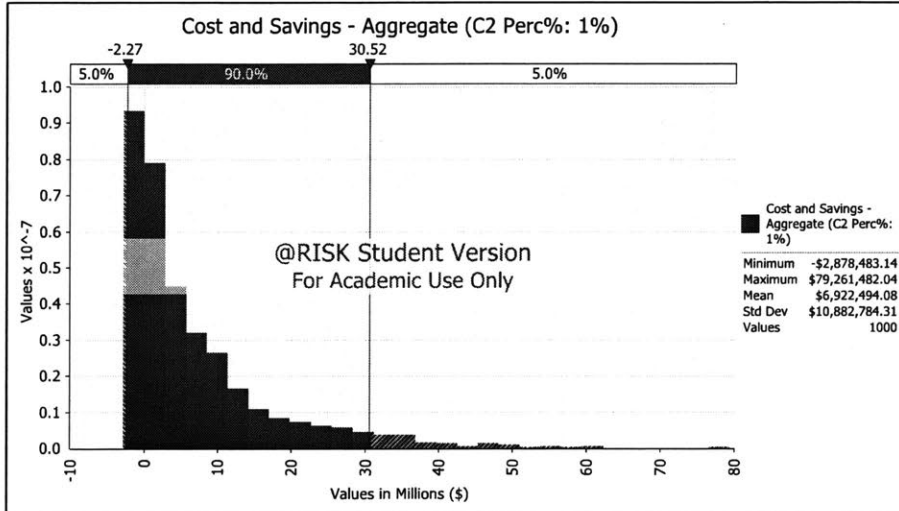


Figure 56: Probability distribution of Aggregate Benefit for Simulation 2

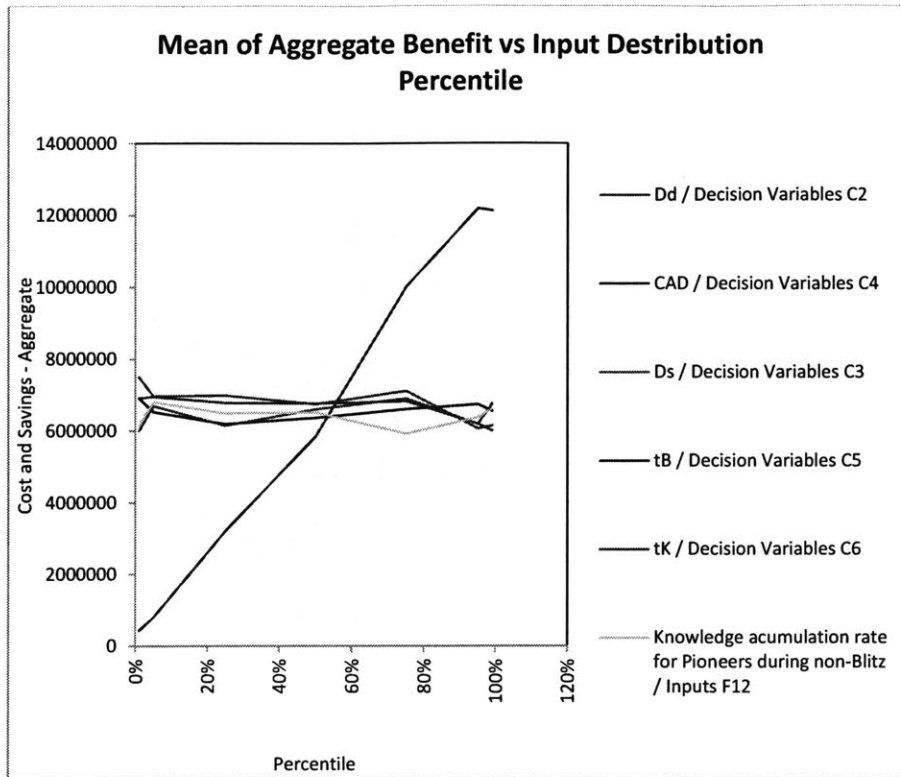


Figure 57: Sensitivity of Aggregate Benefit to various input ranges for Simulation 2

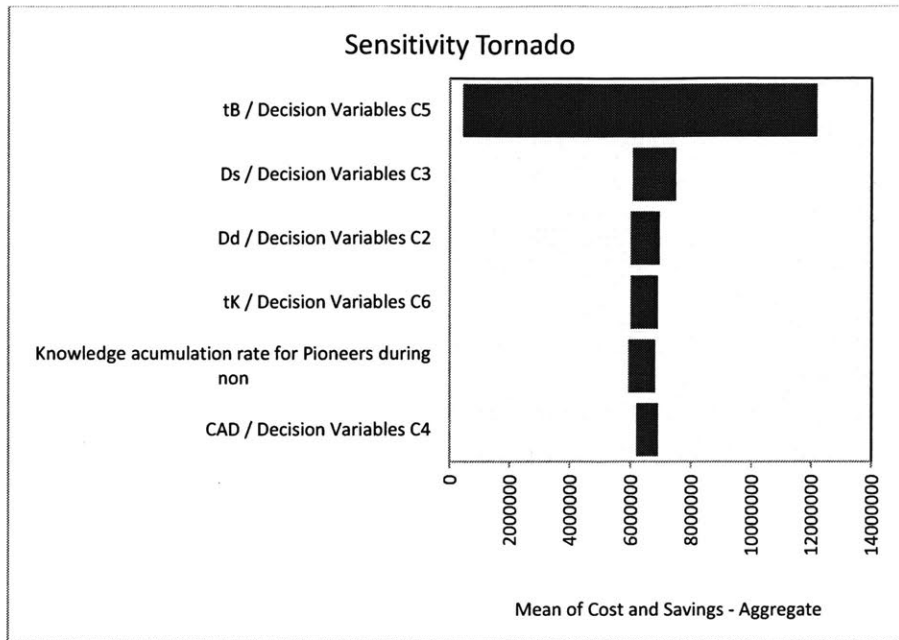


Figure 58: Ranking of input variable impact on program value over specified range for Simulation 2

6.4.4.3 Detailed results for Simulation 3

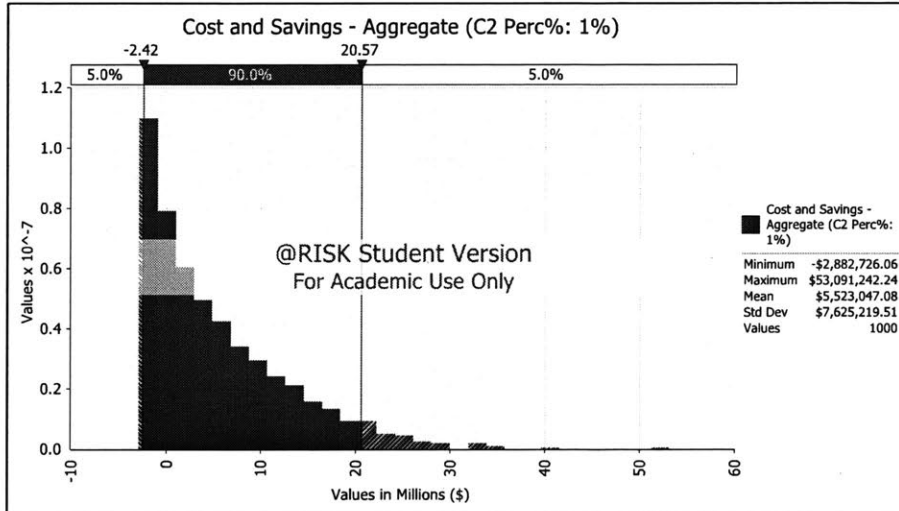


Figure 59: Probability distribution of Aggregate Benefit for Simulation 3

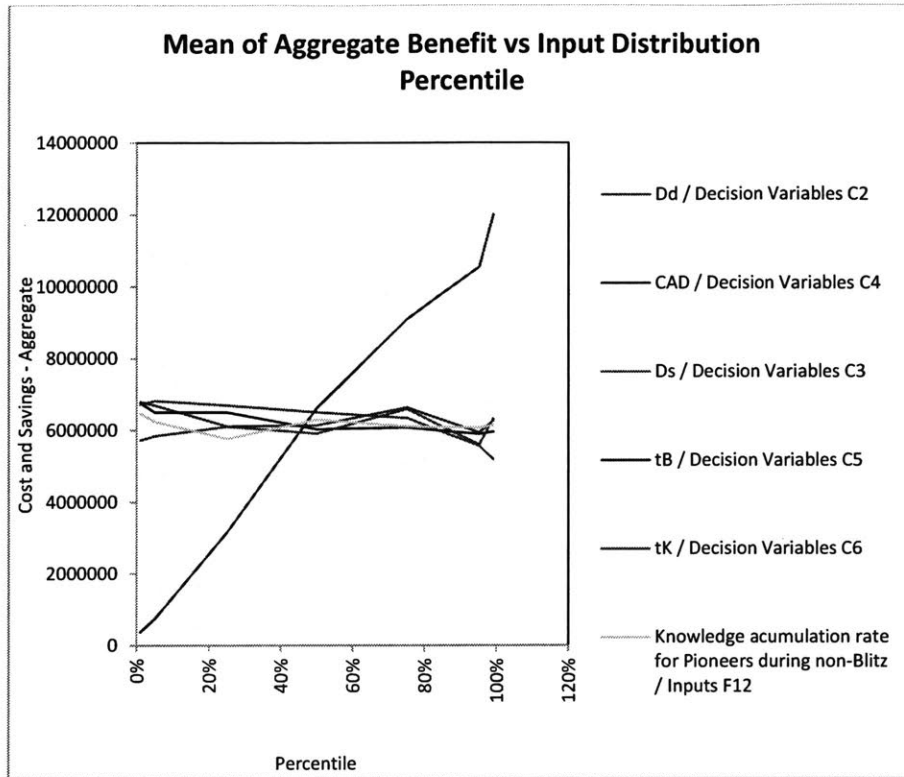


Figure 60: Sensitivity of Aggregate Benefit to various input ranges for Simulation 3

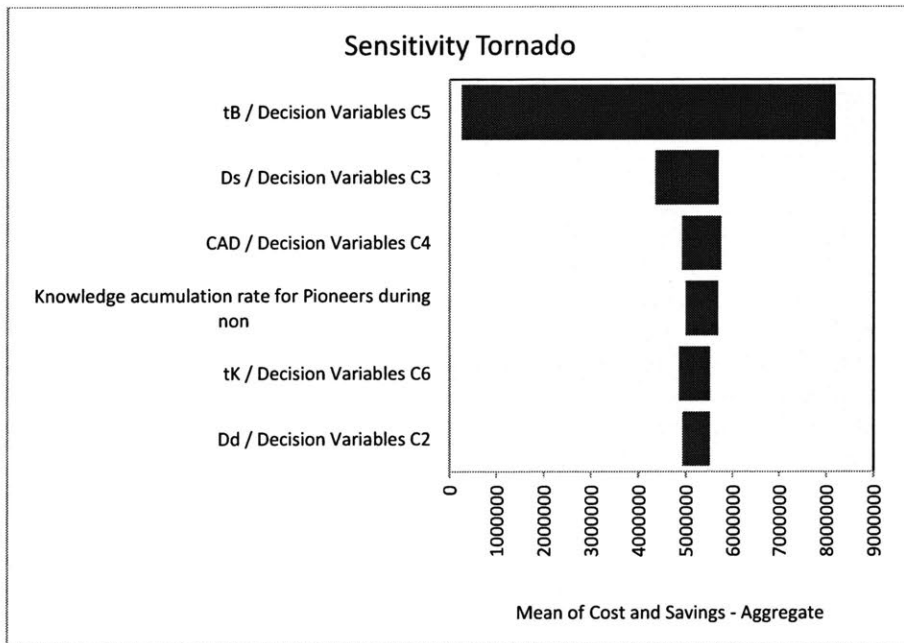


Figure 61: Ranking of input variable impact on program value over specified range for Simulation 3

6.4.4.4 Detailed results for Simulation 4

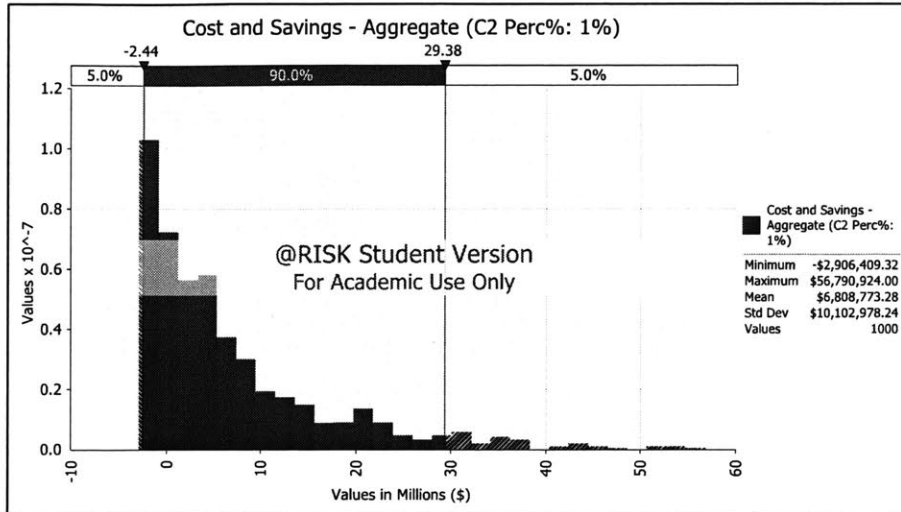


Figure 62: Probability distribution of Aggregate Benefit for Simulation 4

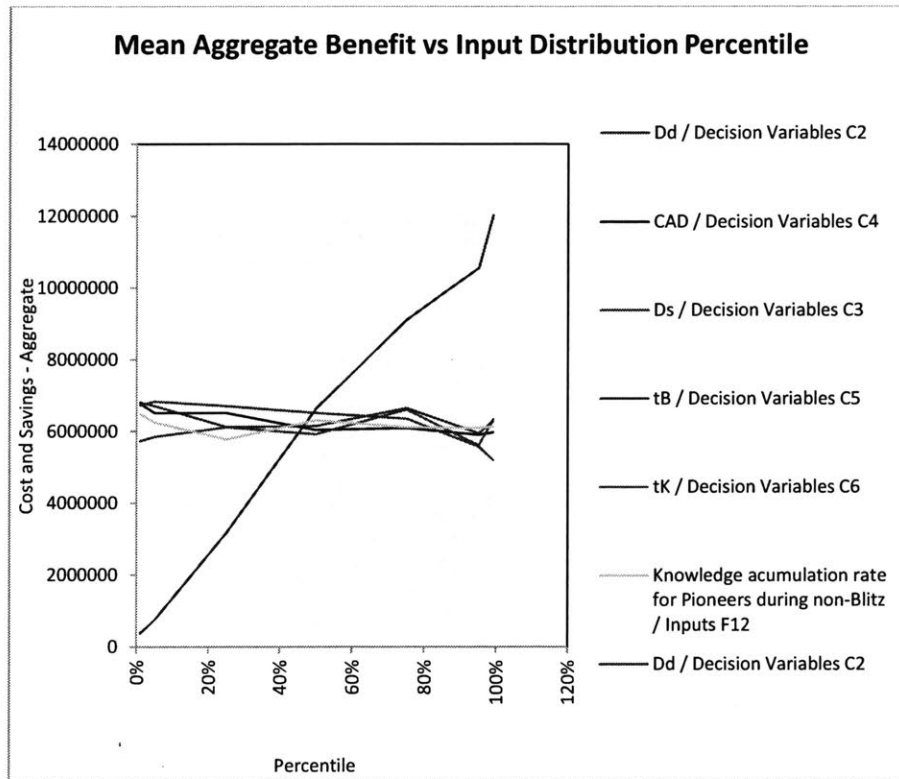


Figure 63: Sensitivity of Aggregate Benefit to various input ranges for Simulation 4

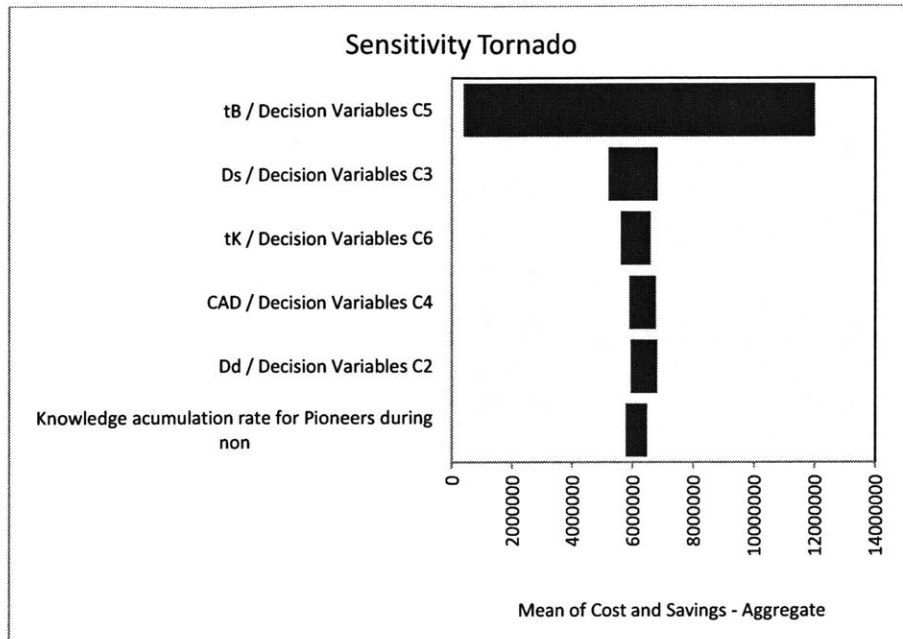


Figure 64: Ranking of input variable impact on program value over specified range for Simulation 4

7 References

- [1] "Our Credo | Johnson & Johnson." [Online]. Available: <https://www.jnj.com/about-jnj/jnj-credo>. [Accessed: 13-Feb-2017].
- [2] "FDA - technical considerations for AM devices." Food and Drug Administration.
- [3] P. Chung *et al.*, "Rapid and Low-cost Prototyping of Medical Devices Using 3D Printed Molds for Liquid Injection Molding," *J. Vis. Exp. JoVE*, no. 88, Jun. 2014.
- [4] Davis, Andrew, "Interview with Adrew Davis," 01-Nov-2016.
- [5] M. Zeiner, "Interview on 3D Printing Capabilities," 11-Oct-2016.
- [6] "Operations Strategy - Northwestern University," *Coursera*. [Online]. Available: <https://www.coursera.org/learn/operations-strategy/lecture/GaGBN/1-3-operations-strategy>. [Accessed: 27-Mar-2017].
- [7] B. Chandrasekaran, "Transformation of the Medical Device Industry," Frost and Sullivan, Nov. 2016.
- [8] "Johnson & Johnson 2015 Form 10-K."
- [9] "SEC Filings| Investors | Medtronic." [Online]. Available: <http://investorrelations.medtronic.com/phoenix.zhtml?c=76126&p=irol-sec>. [Accessed: 10-Feb-2017].
- [10] "GE 2015 Form 10k," General Electric.
- [11] "Siemens Annual Report 2016."
- [12] "Royal Philips Annual Report."
- [13] C. for D. and R. Health, "Overview of Device Regulation." [Online]. Available: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/>. [Accessed: 10-Feb-2017].
- [14] "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]." US Food and Drug Administration, 28-Jul-2014.
- [15] J. Disis, "Lawmakers say EpiPen hikes made Mylan executives 'filthy rich,'" *CNNMoney*, 21-Sep-2016. [Online]. Available: <http://money.cnn.com/2016/09/21/news/companies/mylan-epipen-house-oversight-committee/index.html>. [Accessed: 24-Mar-2017].
- [16] C. for D. and R. Health, "Classify Your Medical Device." [Online]. Available: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm>. [Accessed: 10-Feb-2017].
- [17] D. Mihov, "SOME BIOCOMPATIBLE MATERIALS USED IN MEDICAL PRACTICE." [Online]. Available: <http://www.uni-sz.bg/tsj/vol8,Suppl.2,2010/D.Mihov.pdf>. [Accessed: 24-Mar-2017].
- [18] L. McKeen, "Handbook of Polymer Applications in Medicine and Medical Devices," .
- [19] DePuy Synthes, "Corail Hip System Rationale." [Online]. Available: <http://www.corailpinnacle.net/sites/default/files/2016-12/corail-product-rationale-and-surgical-technique.pdf>. [Accessed: 24-Mar-2017].
- [20] "HCP | Ethicon." [Online]. Available: <http://www.ethicon.com/healthcare-professionals>. [Accessed: 06-Dec-2016].
- [21] "ETHICON SECURESTRAP Open Absorbable Strap Fixation Device - Hernia Solutions | Ethicon HCP." [Online]. Available: <http://www.ethicon.com/healthcare-professionals/products/hernia-repair-and-fixation/hernia-fixation/ethicon-securestrap-open-absorbable-strap-fixation-device>. [Accessed: 06-Dec-2016].
- [22] P. G. Smith and D. G. Reinertsen, *Developing products in half the time : new rules, new tools*. New York : Van Nostrand Reinhold, c1998., 1998.
- [23] Ortiz, Nicolas [EESUS], "NPD PM Manager Roles and Responsibilities." 04-Aug-2015.
- [24] Lukuc, Joanna, "Cadence Stage Gate Development Process." 11-Feb-2016.
- [25] T. Wohlers and T. Gornet, "History of additive manufacturing," *Wohlers Rep. Addit. Manuf. 3D Print. State Ind. Annu. Worldw. Prog. Rep.*, 2011.

- [26] PricewaterhouseCoopers, "The road ahead for 3-D printers," *PwC*. [Online]. Available: <http://www.pwc.com/us/en/technology-forecast/2014/3d-printing/features/future-3d-printing.html>. [Accessed: 31-Oct-2016].
- [27] "Wohlers Report 2016: 3D Printing and Additive Manufacturing State of the Industry Report," Wohlers Associates, 2016.
- [28] "ISO/ASTM 52900," ASTM, International Standard ISO/ASTM 52900.
- [29] "ULTEM 1010 resin | Stratasys." [Online]. Available: <http://www.stratasys.com/materials/fdm/ultem-1010>. [Accessed: 24-Mar-2017].
- [30] "SABIC ULTEM™ Resin and Stratasys FDM® Technology Enable Taylor-Deal Aviation to Produce Customized Parts Quickly and Cost-effectively." [Online]. Available: https://www.sabic-ip.com/gep/en/NewsRoom/PressReleasePrint/september_27_2012_sabicultemresinand.html. [Accessed: 24-Mar-2017].
- [31] "Technical Application Guide: Polyjet for Injection Molding." Stratasys, 2016.
- [32] I. Gibson, D. Rosen, and B. Stucker, "Binder Jetting," in *Additive Manufacturing Technologies*, Springer New York, 2015, pp. 205–218.
- [33] R. Januszewicz, J. R. Tumbleston, A. L. Quintanilla, S. J. Mecham, and J. M. DeSimone, "Layerless fabrication with continuous liquid interface production," *Proc. Natl. Acad. Sci.*, vol. 113, no. 42, pp. 11703–11708, Oct. 2016.
- [34] "Stratasys Direct Express: The World's Fastest Online 3D Printing Service." [Online]. Available: <https://express.stratasysdirect.com/sla-prototype.aspx>. [Accessed: 24-Mar-2017].
- [35] "3D Printing Aircraft Parts," *GE Global Research*. [Online]. Available: <http://www.geglobalresearch.com/innovation/3d-printing-creates-new-parts-aircraft-engines>. [Accessed: 01-Feb-2017].
- [36] "Directed Energy Deposition | Additive Manufacturing Research Group | Loughborough University." [Online]. Available: <http://www.lboro.ac.uk/research/amrg/about/the7categoriesofadditivemanufacturing/directedenergydeposition/>. [Accessed: 08-May-2017].
- [37] Yizhong Zhang, Chunji Yin, "Computational Hydrographic Printing."
- [38] I. T. Inc, "Why Nanovate." [Online]. Available: <http://www.integran.com/about-us/why-nanovate>. [Accessed: 01-Feb-2017].
- [39] Amelia Elliott, Sarah AlSalihi, "Infiltration of Nanoparticles into Porous Binder Jet Printed Parts." Oak Ridge National Laboratory.
- [40] "Using 3D printing in product design and development | Deloitte University Press," *DU Press*. [Online]. Available: <https://dupress.deloitte.com/dup-us-en/focus/3d-opportunity/3d-printing-product-design-and-development.html>. [Accessed: 31-Oct-2016].
- [41] E. Sachs, E. Wylonis, S. Allen, M. Cima, and H. Guo, "Production of injection molding tooling with conformal cooling channels using the three dimensional printing process," *Polym. Eng. Sci.*, vol. 40, no. 5, pp. 1232–1247, 2000.
- [42] "TRUMATCH® Personalized Solutions | DePuy Synthes Companies." [Online]. Available: <https://www.depuyshes.com/hcp/knee/products/qs/TRUMATCH-Personalized-Solutions>. [Accessed: 08-May-2017].
- [43] "Hype Cycle for 3D Printing, 2016." [Online]. Available: <http://www.gartner.com/document/3383717?ref=solrAll&refval=175802392&qid=8f0eee7faf7aa0e614fc525f1c38e382>. [Accessed: 31-Oct-2016].
- [44] "What is the 3D Printing vs Injection Molding Cost-per-Unit Breakeven? - Xometry." [Online]. Available: <https://www.xometry.com/blog/3d-printing-vs-injection-molding-breakeven/>. [Accessed: 13-Feb-2017].
- [45] Fabian Alvarez-Primo, "Wohlers Report - Material Properties," 2016. [Online]. Available: <http://wohlersassociates.com/materials2016.pdf>. [Accessed: 03-Jan-2017].
- [46] Geoffry S. Clark, "FDA - Shelf Life of Medical Devices."

- [47]“HP Multi Jet Fusion technology.” HP Development Company, Oct-2016.
- [48]J. R. Tumbleston *et al.*, “Continuous liquid interface production of 3D objects,” *Science*, vol. 347, no. 6228, pp. 1349–1352, Mar. 2015.
- [49]T. Rogers, “3D Printing vs Injection Molding.” [Online]. Available: <https://www.creativemechanisms.com/blog/3d-printing-vs-injection-molding>. [Accessed: 08-May-2017].
- [50]“Materials - Carbon 3D.” [Online]. Available: <http://www.carbon3d.com/materials/ce-cyanate-ester>. [Accessed: 17-Jan-2017].
- [51]Courtney Fox, Ph.D, “Functional Prototyping with Polymeric Materials.” [Online]. Available: https://www.nist.gov/sites/default/files/documents/mml/Session-4_1-Fox.pdf. [Accessed: 13-Feb-2017].
- [52]“HP Multi Jet Fusion.” HP Development Company.
- [53]“Internal J&J database of 3D Printed Medical Devices.”
- [54]K. Stephenson, “A Detailed Five-Year Review of Medical Device Additive Manufacturing Research and its Potential for Translation to Clinical Practice,” p. V003T14A014, Aug. 2015.
- [55]C. Scott, “Stryker is Committing to 3D Printing with Upcoming Multimillion-Dollar 3D Printing Manufacturing Facility,” *3DPrint.com*, 29-Jan-2016. .
- [56]“Stryker CEO: New 3-D Printing Manufacturing Plant will be in Ireland | MDDI Medical Device and Diagnostic Industry News Products and Suppliers.” [Online]. Available: <http://www.mddionline.com/blog/devicetalk/stryker-ceo-new-3-d-printing-manufacturing-plant-ireland-3-4-16>. [Accessed: 03-Jan-2017].
- [57]“Stryker Receives FDA Clearance for Tritanium® PL Posterior Lumbar Cage | Business Wire,” 04-Mar-2016. [Online]. Available: <http://www.businesswire.com/news/home/20160304005135/en/Stryker-Receives-FDA-Clearance-Tritanium%C2%AE-PL-Posterior>. [Accessed: 14-Feb-2017].
- [58]Andy Christensen, “Medical Imaging and Processing Software.”
- [59]“FDA - Custom Device Exemption Guidance.” Food and Drug Administration, 2017.
- [60]“FDA - technical considerations for AM devices.pdf.” .
- [61]“How Johnson & Johnson Is Poised to Transform Healthcare With 3D Printing Technologies | Johnson & Johnson.” [Online]. Available: <http://www.jnj.com/How-Johnson-Johnson-Is-Poised-to-Transform-Healthcare-With-3D-Printing-Technologies>. [Accessed: 15-Feb-2017].
- [62]Kohn, David, “Interview on 3DP with David Kohn,” 07-Oct-2016.
- [63]S. J. Spear and S. J. Spear, *The high-velocity edge : how market leaders leverage operational excellence to beat the competition*. New York : McGraw-Hill, c2009., 2009.
- [64]T. Mai, “Technology Readiness Level,” *NASA*, 06-May-2015. [Online]. Available: http://www.nasa.gov/directorates/heo/scan/engineering/technology/txt_accordion1.html. [Accessed: 27-Mar-2017].
- [65]“@RISK: Risk Analysis Software using Monte Carlo Simulation for Excel - at risk - Palisade.” [Online]. Available: <http://www.palisade.com/risk/>. [Accessed: 09-May-2017].
- [66]J. H. Choi, J. S. Kim, E. S. Han, H. P. Park, and B. O. Rhee, “Study on an Optimized Configuration of Conformal Cooling Channel by Branching Law,” in *ASME 2014 12th Biennial Conference on Engineering Systems Design and Analysis*, 2014, p. V001T06A007–V001T06A007.
- [67]T. Ruffner, “Case Study Success with Conformal Cooling Using Direct Metal Laser Sintering.”
- [68]W. R. Morrow, H. Qi, I. Kim, J. Mazumder, and S. J. Skerlos, “Environmental aspects of laser-based and conventional tool and die manufacturing,” *J. Clean. Prod.*, vol. 15, no. 10, pp. 932–943, 2007.
- [69]R. Toops, “Interview on Conformal Cooling,” 06-Oct-2016.
- [70]S. Patel, “3D Printed Injection Mold Inserts with Conformal Cooling.” .
- [71]S. Patel, “3D Printed Cavity Steel Results (J&J internal).” .
- [72]“Dynacast Metal Injection Molding (MIM) Process.” Dynacast, Inc.

- [73]“Evaluation of DMLS (Direct Metal Laser Sintered) moulds with Conformal Cooling lines for MIM Parts.” 03-Oct-2016.
- [74]“Market Guide for 3D Print Service Bureaus, 2015.” [Online]. Available: <http://www.gartner.com/document/3031517?ref=solrAll&refval=175824874&qid=3abafa55f3d3c81b43250bec57e6cfc9>. [Accessed: 31-Oct-2016].
- [75]“Predicts 2016: 3D Printing Disrupts Healthcare and Manufacturing.” [Online]. Available: <http://www.gartner.com/document/3171223?ref=solrAll&refval=175802355&qid=8f0eee7faf7aa0e614fc525f1c38e382>. [Accessed: 31-Oct-2016].
- [76]“Interview with Peter Ostiguy,” 29-Aug-2016.
- [77]Dr. Janos Sztrik, *Basic Queueing Theory*. University of Debrecen.
- [78]“Materials Matter: Selecting the Right Materials for 3D Printing.” [Online]. Available: <https://www.protolabs.com/resources/whitepapers/2016/materials-matter-3d-printing/>. [Accessed: 17-Jan-2017].
- [79]T. Tabi, N. K. Kovacs, I. E. Sajo, T. Czigany, S. Hajba, and J. G. Kovacs, “Comparison of thermal, mechanical and thermomechanical properties of poly(lactic acid) injection-molded into epoxy-based Rapid Prototyped (PolyJet) and conventional steel mold,” *J. Therm. Anal. Calorim.*, vol. 123, no. 1, pp. 349–361, Jan. 2016.
- [80]“Rigid Polyurethane Resin Material for 3D Printing: 3D printing resin for CLIP technology.” [Online]. Available: <https://www.sculpteo.com/en/materials/clip-resin-material/rigid-polyurethane-clip-resin-material/>. [Accessed: 17-Jan-2017].
- [81]J. C. Ferreira and A. Mateus, “Studies of rapid soft tooling with conformal cooling channels for plastic injection moulding,” *J. Mater. Process. Technol.*, vol. 142, no. 2, pp. 508–516, Nov. 2003.
- [82]K. Salonitis, “Design for additive manufacturing based on the axiomatic design method,” *Int. J. Adv. Manuf. Technol.*, vol. 87, no. 1–4, pp. 989–996, Oct. 2016.
- [83]L. Zonder and N. Sella, “Precision Prototyping: The Role of 3D Printed Molds in the Injection Molding Industry.” Strataysys, 2013.