ABSTRACT

SHOUCHE, SURABHI. Supply Chain Operations Reference Model for U.S. Based Powder Bed Metal Additive Manufacturing Processes. (Under the direction of Dr. Richard A. Wysk).

This thesis focuses on modeling the supply chain of an additively manufactured product, specifically a uniquely customized Total Hip Replacement implant. It explores how the supply chain could be modeled for hip components which are customized for individual patients and produced using additive manufacturing processes. The concept of the SCOR (Supply Chain Operations Reference) model is used to create a formal model of this system for analysis. It captures the basic structure for interactions between customers, products, and the market. This model also provides valuable information about the new technology in terms of procuring the raw materials or supplying components to the manufacturer or the customer.

The parts built by the AM processes are rough and require finishing for effective functioning of the part. The aggregate model is divided into finer sections dealing with: 1) patient-diagnosis, 2) CAD modeling of the uniquely customized implant, 3) the AM-build process, 4) post-processing operations, which are followed by delivery of the implant to the desired hospital. The SCOR model is used to compare the traditional and the AM supply chain on the basis of different performance metrics. The formal supply chain model is used to extract operational activities so that a computer simulation model of the system can be developed. The simulation is used to model system performance so that bottleneck operations can be identified and source needs determined along with a sensitivity analysis to analyze how change in times and resources affect production quantities. A cost-analysis is done to determine the feasibility of the AM-based supply chain. For a uniquely customized implant,

the device cost is higher, but there is a decrease in the surgical cost, mitigation cost and post-discharge costs.

© Copyright 2016 Surabhi Shouche

All Rights Reserved

Supply Chain Operations Reference Model for U.S. Based Powder Bed Metal Additive
Manufacturing Processes

by
Surabhi Shouche

A thesis submitted to the Graduate Faculty of
North Carolina State University
in partial fulfillment of the
requirements for the degree of
Master of Science

Industrial Engineering

Raleigh, North Carolina
2016

APPROVED BY:

Dr. Richard A. Wysk
Committee Chair

Dr. Russell E. King

Dr. Ola Harrysson

DEDICATION

To my parents, Dr. Shobha and Sanjay Shouche, for their unconditional love

&

The Almighty, for all the blessings

BIOGRAPHY

Surabhi Shouche was born in Ratlam (Madhya Pradesh), India. She spent her early years in the holy city of Ujjain and went for college to Vellore Institute of Technology, VIT University to study Mechanical Engineering. After an internship in the industrial sector, her interests towards Industrial Engineering grew and she decided to pursue her Master's studies at North Carolina State University, Raleigh in the Department of Industrial & Systems Engineering. She began working on her research in the field of Supply Chain and Additive Manufacturing under the guidance of Dr. Wysk, Dr. Harrysson, and Dr. King.

ACKNOWLEDGEMENTS

I am very thankful to my advisor, Dr. Richard A. Wysk for his constant support and encouragement. It has been a big learning curve under his direction and this research would not have been possible without his guidance and faith in me. I would also like to thank Dr. Ola L. Harrysson and Dr. Russell E. King for their invaluable comments and time, which helped shape this research.

I would also like to thank my wonderful parents for all the love and support from half way across the world. Huge thanks to my brother, Sudeep and sister-in-law, Samiksha for always reminding me that I can. A special mention to my grandfather, Ram Chandra Shouche who has always showered his blessing on me.

I am very grateful to my friends at NCSU: Bhavya, Utsav, Poorva, Rohit, Vedant, and Rutuja for sharing, caring and laughing together. Last but definitely not the least, a big thanks to my friends in India: Paridhi, Utkarsh, and Paritosh for being available through all time zones and patiently listening to my rants.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1	1
INTRODUCTION	1
1.1 Background	1
1.2 Motivation	3
1.3 Objectives.....	5
1.4 Summary	6
CHAPTER 2	8
RELEVANT WORK	8
2.1 Introduction	8
2.2 Medical Modeling of Uniquely Customized Devices	8
2.3 Statistics associated with Total Hip Replacements	14
2.4 Computer Simulation and SCOR Modeling	17
2.4.1 SCOR Model	17
2.4.2 SCOR Methodology	20
2.4.3 Automatic Simulation Model Generation.....	20
2.5 Summary	21
CHAPTER 3	23
METHODOLOGY	23
3.1 Introduction	23
3.2 SCOR Model	23
3.2.1 The As-Is Model	26
3.2.2 The To-Be Model	31
3.3 Simulation Model.....	36
3.4 Summary	40
CHAPTER 4	41
RESULTS AND DISCUSSIONS	41

4.1 Introduction	41
4.2 Comparisons between ‘As-Is’ and ‘To-Be’ Model: Performance Metrics	42
4.3 Comparing the supply chain of “As-Is” and “To-Be” Models.....	46
4.4 Simulation Results.....	49
4.5 Sensitivity Analysis.....	51
4.6 Cost Analysis.....	55
4.7 Summary	57
CHAPTER 5	59
CONCLUSIONS AND SCOPE OF FUTURE WORK	59
5.1 Introduction	59
5.2 Limitations	59
5.3 Conclusions	60
5.4 Scope of Future Work	62
REFERENCES	63
APPENDICES	66
Appendix A: As-Is Model	67
Appendix B: To-Be Model.....	71

LIST OF TABLES

<i>Table 1 Error analysis report between the STL file and the RP model</i>	<i>13</i>
<i>Table 2 Error analysis report between human femur bone and RP model</i>	<i>13</i>
<i>Table 3 Reported sources of model inaccuracies at various stages of CT image production</i>	<i>14</i>
<i>Table 4 Complication rate % for selected outcomes within 90 days of primary and revision Total Hip Replacement.....</i>	<i>15</i>
<i>Table 5 Distribution of device cost and surgical cost for Total Hip Replacement surgery</i>	<i>17</i>
<i>Table 6 SCOR level 2 process categories.....</i>	<i>24</i>
<i>Table 7 Thirteen performance metrics for SCOR</i>	<i>25</i>
<i>Table 8 List of resources for "To-Be" model.....</i>	<i>31</i>
<i>Table 9 List of critical resources considered in this simulation</i>	<i>38</i>
<i>Table 10 List of performance measures which are improved in the AM "To-Be" model</i>	<i>44</i>
<i>Table 11 Resource capacities for the AM model.....</i>	<i>50</i>
<i>Table 12 Resource capacities to meet 25% of the annual demand using AM methods</i>	<i>52</i>
<i>Table 13 Resource capacities to meet 75% of the annual demand using AM methods</i>	<i>53</i>
<i>Table 14 Resource capacities to meet 100% of the annual demand using AM methods</i>	<i>53</i>
<i>Table 15 Resource requirements for AM methods to meet 50% of the demand.....</i>	<i>54</i>
<i>Table 16 Device and surgical cost for a THR surgery</i>	<i>55</i>

LIST OF FIGURES

<i>Figure 1 (Left) The individual components of a total hip replacement. (Center) The components merged into an implant. (Right) The implant as it fits into the hip.</i>	3
<i>Figure 2 Procedure for design and manufacture of implants, surgical aid tools and medical devices</i>	10
<i>Figure 3 A framework of preparative planner for custom hip implant</i>	12
<i>Figure 4 Percentage of costs for a Total Hip Arthroplasty in which a patient is discharged to home</i>	16
<i>Figure 5 SCOR Process Framework</i>	19
<i>Figure 6 As-Is: SCOR model for current process for manufacturing hip stems</i>	27
<i>Figure 7 Traditional Make process for ‘As-Is’ Model</i>	28
<i>Figure 8 Various Levels of SCOR ‘As-Is’ Model</i>	30
<i>Figure 9 To-Be: SCOR model for additive manufacturing of hip stems</i>	32
<i>Figure 10 AM-build process</i>	33
<i>Figure 11 Levels of SCOR ‘To-Be’ Process</i>	35
<i>Figure 12 Simulation model for AM manufacturing of hip stems</i>	39
<i>Figure 13 Push system for ‘As-Is’ Model</i>	41
<i>Figure 14 Pull System for ‘To-Be’ Model</i>	42
<i>Figure 15 The “As-Is” supply chain</i>	47
<i>Figure 16 The “To-Be” Supply Chain</i>	48
<i>Figure 17 Number out in the simulation model</i>	49
<i>Figure 18 Total time spent by the hip stem in the system</i>	51

CHAPTER 1

INTRODUCTION

This chapter is intended to provide a brief overview of additive manufacturing (AM), and then introduce one possible use of this technology (total hip replacements). The chapter then moves toward the modeling and development of what the Supply Chain Model (SCM) for this complex system might look like in the near future. The SCM is important because it can be used to determine bottlenecks and constraints for the use of this new method of producing highly customized medical parts. A detailed model of both the engineering and medical portions of the total hip replacement process will be discussed along with the potential benefits of using AM parts for joint replacement.

1.1 Background

Additive manufacturing (AM), also known as 3D printing provides engineers the capability of producing objects of virtually any shape or geometry by depositing successive layers of suitable material using computer control. AM is currently being used for low volume production and building prototypes; however, AM is slowly moving to commercial products requiring personal customization. The industries which have been impacted the most by AM technology are healthcare, aerospace and automotive. Considering the overall market size for all the AM technology like printers, materials and printing services; the AM industry has been estimated at \$4.1 billion in 2016 [1].

AM technology can have a huge impact on the manufacturing industry from design to production. Transportation and storage could be significantly reduced and made less expensive as the manufacturing could be done on-site. With the advent of additive manufacturing, the future supply chain will be faster, cheaper and more compact. Parts whose shipments are typically expedited will potentially be manufactured in-house, eliminating delivery, inventory and order charges. The future supply chain will have fewer completed parts in storage and product flow. One of the future supply chain foci will be to move from part supply to material and machining supplies for additive manufacturing.

The enhanced product customization that comes with an additive manufacturing process suits the best for the needs for the medical device segment. The devices can be uniquely customized according to the patient's needs, which results in better fit and lesser surgical complications. This thesis focuses on creating a formal model of the supply chain for an AM produced part, using a Total Hip Replacement (THR) implant as the example product. It also evaluates how responsive is the entire supply chain from the patient's diagnosis with a need for an implant to the accomplishment of actual surgical procedure.

Total Hip Replacement surgery, also known as Total Hip Arthroplasty (THA), is the process of removing damaged bone and cartilage and replacing it with prosthetic components [2].

- The damaged femoral head is removed and a metal stem is substituted, which is used to support a synthetic cortical head.
- A metallic or ceramic cortical head is used at the top of this stem which takes place of the damaged femoral portion of a hip.

- An acetabulum, which is the damaged pelvis component, is replaced by metal socket.
- A spacer which is made up of plastic, ceramic or metal is inserted between the ball and the socket to allow smooth movement between the surfaces.

Figure 1 (Left) The individual components of a total hip replacement. (Center) The components merged into an implant. (Right) The implant as it fits into the hip. [2]

Source: <http://orthoinfo.aaos.org/topic.cfm?topic=a00377>

1.2 Motivation

Medical devices are viewed as one of the largest markets for AM parts because future devices can potentially be customized specifically for individual patients. To demonstrate how the future supply chain of an AM built product would look, this thesis will examine a single product; hip stem for a Total Hip Replacement (THR) implant; for analysis and

formulation of a detailed production and medical implant simulation model. Approximately, 332,000 Total Hip Replacement surgeries are done per year in the United States alone [3]. Currently, the implants that are being used commercially are traditionally manufactured which offer practically no customization according to the patient's bone structure. For every 100 THR surgeries, about 18 revision surgeries have to be performed [4]. Some of the major reasons for a revision surgery are:

- Aseptic Loosening (75%)
- Infection (8%)
- Dislocation (6%)
- Fracture (5%)
- Technical errors (3%)
- Other reasons (3%)

If an additively manufactured implant is used in place of a regular implant, following improvements are anticipated, owing mostly to the better fit on the uniquely customized implant:

- Lesser chances of aseptic loosening and dislocations
- Lesser surgical and post-discharge costs
- Decrease in pain experienced by the patient
- Enhanced life time of the implant

It has been observed that the revision surgeries have far worse functional outcomes than primary surgeries. Surgeries that are performed using a traditionally manufactured implant tend to last for 15-20 years, after which the patient is required to undergo a revision surgery.

The mortality rate, which is defined as the risk of death in the first 90 days of the surgery, is nearly 1% for a primary THR surgery as opposed to a 2.5% for a revision surgery [5]. A uniquely customized implant built by AM processes are predicted to last much longer. This is particularly beneficial for younger people who have to undergo this procedure.

It is our opinion that by customizing the hip stem, two major positive medical outcomes will be realized: 1) the surgical time will be shortened as the prosthetic will better fit the patient's bone geometry (thus, reducing the risk of infection and the total cost of the procedure), and 2) aseptic loosening for patients will be significantly reduced as a function of the geometric match with the femur medulla. This thesis will examine future manufacturing practices assuming a shift from traditional to AM based processes. A tool, called SCOR (Supply Chain Operations Reference) is used to create a process reference model which explores how the supply chain will react if half of the traditionally manufactured implants are produced using AM processes.

1.3 Objectives

The objective of this research is to develop a SCOR based model for medical application and production of a uniquely customized hip stems for Total Hip Replacement implants. A SCOR model consists of five distinct management practices, namely Plan, Source, Make, Deliver, and Return. It captures the 'as-is' state of a process and derives the desired 'to-be' future state. The 'as-is' state is described by the traditional manufacturing process, while the 'to-be' state in this model is composed of uniquely customized implants. The SCOR model contains levels of process detail which enables the transition of the supply chain from 'as-is' state to

its desired 'to-be' state. The utility of components such as a hip stem is highly increased if they are made uniquely customized. As the future of this supply chain will move from traditional to AM processes, it is crucial to have a formal model that can analyze the new chain and extract important operational activities.

A simulation model is developed in Chapter 3 that uses the SCOR model to imitate the operations of the AM based supply chain. The model is developed using Arena and reasonable assumptions are made to identify resource capacities for the future. Resource capacities include the amount of powder required to build these hip stems, number of machines required to build these implants and number of medical engineers needed for the design and engineering. The bottlenecks for manufacturing are also determined using this simulation model.

A cost-analysis is performed to compare the costs of the traditional and uniquely customized implants. As this cost-analysis is done, a trade-off is observed between cost and time for manufacturing Vs ease and effectiveness of the surgery.

1.4 Summary

The first chapter in this thesis provided an introduction of what this research proposes to accomplish. The chapter begins with an overview of the engineering impact of the AM processes and its effect on the supply chain of the future. It explains the surgical procedure for the medical operations involved in a Total Hip Arthroplasty. The chapter describes the motivation behind the selection of a hip stem for building a SCOR and a simulation model. The chapter concludes with the explanation of objectives for this research. The next chapter

in this thesis consists of the literature review, which will talk about the relevant work that has already been done in this field.

CHAPTER 2

RELEVANT WORK

2.1 Introduction

In this chapter, the previous work that has been done in this field of research is presented. This chapter begins with describing medical modeling of uniquely customized devices. A lot of notable work has been done to develop patient-specific implants with the help of technologies like Computed Tomography (CT) and Magnetic Resonance Imaging (MRI). The techniques of computer simulation and SCOR modeling are also introduced in this section.

2.2 Medical Modeling of Uniquely Customized Devices

‘Patient-Specific Instrumentation’ (PSI) have been gaining popularity in the recent years because of its superior fit and design. Maniar and Singhi studied a lot of cases on PSI Total Knee Arthroplasty (TKA) and compared the performance details of PSI as compared with conventional and navigated TKA [6]. There were some intraoperative advantages for the use of a patient-specific implant. The length of incision in a PSI surgery is much smaller than the conventional surgery. The number of steps in the surgery were also reduced, which results in lesser number of open trays. This results in a reduction in the theatre time, sterilization time and personnel cost. The postoperative alignment was better for PSI jigs. These jigs were placed for a better or comparable restoration of mechanical/kinematic axis and individual component alignment compared with conventional jigs. The arrangement of the incision cut with PSI was independent of outside landmarks to align the jigs and was expected to provide

a better restoration of the planned axis. There were improvements in the postoperative rehabilitation in terms of length of the hospital stay and blood loss. Since the introduction of PSI shortened the surgery with smaller incision and better alignment, it meant less blood loss and faster postoperative rehabilitation. PSI also provided cost-effectiveness as there was a decrease in total cost due to reduction in the number of trays, reduced number of personnel engaged, and decrease in cost of maintenance of inventory of both implants and instruments. Hieu et al investigated the rapid prototyping for medical applications (medical RP) and reverse engineering (RE) methods based on medical imaging data. Their work suggested that for the successful transfer of medical RP technology to hospitals, a good link between the medical and engineering sites should be established [7]. One of the main applications of RP technology was in the design and manufacturing of bio models, surgical aid tools and implants. The four main steps that are involved in the medical RP processes are: data acquisition, data registration and processing, geometrical modeling and design and medical application development. To process CT/MRI images and perform manipulations of the STL data, MIMICS and Magics RP software were used. To manipulate RE data (points, triangle mesh) and geometrical modeling processes, software like CopyCAD & PowerShape (Delcam Inc.), Pro Engineer (PTC), UG (Unigraphics Solutions), and Solidworks (SolidWorks Corp.) are used. The model is tested using Finite Element Analysis (FEA) and other mechanical testing methods by both the designers and the engineers. Thus, medical RP can help meet both clinical and geometrical restraints. Figure 2 shows a flowchart for the procedure for design and manufacture of implants, surgical aid tools and medical devices.

Figure 2 Procedure for design and manufacture of implants, surgical aid tools and medical devices [7]

Hosni and Harrysson worked on the design and manufacture of customized implants and came up with a procedure that estimated a 40% decrease in bone removal [8]. The process delivered minimized bone removal with maximum fit and usability. CT scans were used to develop a CAD model which was further used to make castings for the implant. The paper talked about the future scope of creating ‘clean models’ which could be directly used as implants. Problems like muscle and joint stiffness along with rehabilitation period was anticipated to be greatly reduced. Brown et al stated that 3D solid models of complex

fractures were made overnight using CT based modern RP software (Materialise, Ann Arbor, Michigan) and equipment (3D Systems, Valencia, California and Z-Corporation, Burlington, Massachusetts) [9].

Medical application and rapid prototyping is possible for prosthetics application and was a potential tool for the development of novel medical technologies. Rengier et al worked on the medical application for prosthetics using imaging data in 3D printing [10]. One of the pivotal roles was carried out by radiologists in the process chain of connecting engineering to the health care RP applications. A close association and collaboration between radiologists, computer scientists, material scientists and clinicians was expected to integrate the whole workflow into a clinical routine.

Jun and Choi proposed a methodology for the manufacturing of a patient-specific implant, specifically a Total Hip Replacement, from the patient's medical data [11]. Figure 3 shows the flowchart for the steps involved in this process. The first step in the methodology is to reconstruct a 3D femur from the sets of CT images. The parameters of the 3D geometry of the patient's hip bone are extracted from the 3D femur model. An initial shape for the implant is determined using these extracted parameters. A static/dynamic analysis is performed on this model to see if any change is necessary. A final patient-specific implant is determined after the required analysis. This model is evaluated using finite element analysis to seek the advantages that could be provided by a patient-specific implant close to the geometry of the hip joint. The main function of the patient-specific implant is to transmit the major load evenly to the hip bone, FEA is typically used to validate the design results. If the

results of the analysis show that there is excessive interface stresses or stress concentration at the joint, the geometry of the initial implant is modified accordingly.

Figure 3 A framework of preparative planner for custom hip implant [11]

Truscott et al analyzed the errors in the process route from CT scan of the original bone to the .stl data to RP model produced for elbow prototypes built on EOS P380. A touch probe scanner was used to inspect 500,000 data point positions [12]. Table 1 presents the error analysis report between the STL file and the RP model. 50% of the errors had a magnitude below 0.2333mm, 85% of errors had a magnitude below 0.4152mm and 96% of the errors had a magnitude below 0.5972mm. Table 2 presents the data for error analysis report between the human femur bone and the RP model. 50% of the errors has a magnitude below

0.8324mm, 91% of the errors had a magnitude below 1.2097mm and 97% of the errors had a magnitude below 1.5869mm, which was approved by the surgeon involved in the research.

Table 1 Error analysis report between the STL file and the RP model [12]

Mean Error	0.2333 mm
Max Error	1.5513 mm at point 113200
Standard Deviation	0.1820 mm

Table 2 Error analysis report between human femur bone and RP model [12]

Mean Error	0.8324 mm
Max Error	4.3380 mm at point 105592
Standard Deviation	0.3773 mm

Viceconti et al developed a new hybrid environment for the design of custom-made hip prosthesis and names it HIDE (HIPCOM design environment) [13]. The system was developed so that a custom-made hip prostheses could be developed from the CT scan data. This paper evaluated the efficacy of the design by using variation of the time necessary to design a custom-made implant. The average design time was recorded when using HIDE system and compared with the conventional procedure. Custom-made prostheses provided better primary stability and induced less stress shielding as compared to standard cementless designs. The HIDE system has adopted a set of procedures that allow a certain amount of automation in the design process. This helps in the reduction of the very high cost of the custom-made solutions. The design phases which were directly affected by the program were reduced by 50%. A total reduction of 23% was observed in the entire design process. Noteworthy is that this improved efficiency did not compromise the accuracy. A separate

study was conducted to demonstrate that the accuracy and repeatability of HIDE-based design procedure improved significantly as compared to previous procedures.

A study had been conducted by Krishnan et al for Total Knee Replacements which claimed that up to 20 steps in the entire surgical process are reduced when PSI guides are used [14]. When PSI implants were used, there was a significant reduction in the number of instrument trays (mean 4.3 Vs 7.5, $p < 0.0001$) and surgical time (mean 121.4 minutes Vs 128.1 minutes, $p=0.048$) as compared to the conventional technique. Table 3 displays the source of model inaccuracies at various stages of CT image production.

Table 3 Reported sources of model inaccuracies at various stages of CT image production [14]

CT scan stage	3D model reconstruction stage	Stage of production and curing of rapid prototyped (RP) models
1. Slice thickness	1. Selecting the threshold value	1. Residual polymerisation and transformation of RP materials
2. Pitch	2. Topological defects – tessellation, triangle edge and closure errors	2. Creation and removal of support structures (to avoid unsupported or weakly supported structures)
3. Gantry tilt	3. Decimation ratio for surface smoothing	3. Laser diameter
4. Tube current and voltage	4. Methods of interpolation	4. Laser path
5. Patient movement		5. Thickness of layer
6. Metal artefact of other prostheses		6. Mathematical modelling for surface finish
7. Slice image construction algorithm used		

2.3 Statistics associated with Total Hip Replacements

Several studies have been conducted to determine the immediate and postoperative outcomes of primary and revision total hip replacements. Mahomed et al used the Medicare claims submitted by the hospitals or by physicians and outpatient facilities under Medicare Part A and Part B respectively to identify individuals who had a primary and revision hip

replacement surgery [15]. Table 4 shows the crude risks of select outcomes within 90 days after primary and revision total hip replacement surgery.

Table 4 Complication rate %for selected outcomes within 90 days of primary and revision Total Hip Replacement [5]

	Complication Rate %	
	Primary THR	Revision THR
Death	0.97	2.6
Readmission to hospital	4.6	10
Pulmonary embolus	0.93	0.79
Wound infection	0.24	0.95
Hip dislocation	3.1	0.84

Mortality rate, i.e. the risk of death in the first 90 days of the surgery is nearly 1% for primary surgeries and it grows up to 2.6% for revision surgeries. The data shows that revision surgeries have worse functional outcomes as compared to primary surgeries. Figure 4 depicts the breakdown in percentage cost of a Total Hip Arthroplasty in which the patient is discharged to home. The cost of a Total Hip Arthroplasty consists of the following components [16]:

- Hospital Cost
- Device Cost
- Surgeon Cost
- Post-Discharge Cost

Figure 4 Percentage of costs for a Total Hip Arthroplasty in which a patient is discharged to home

According to a report by BlueCross BlueShield on the study of cost variations for knee and hip replacement surgeries in the U.S., the cost of a Total Hip Replacement surgery varies from \$16,398.95 in Montgomery, Alabama to \$73,987 in Boston, Massachusetts [17]. The average cost of a Total Hip Arthroplasty is \$30,124. 60% of the cost is covered by CMS (Centers for Medicare & Medicaid Services) which provides coverage to most citizens above 65 years of age.

A Total Hip Replacement surgery typically lasts for 15-20 years after which a patient has to undergo a revision surgery. For every 100 replacements done, there are 18 revision surgeries performed. There could be many reasons which could lead to the requirement of a revision surgery, namely:

- Aseptic loosening 75%
- Infection 8%
- Dislocation 6%

- Fracture 5%
- Technical Error 3%
- Others 3%

About 75% of the revision surgeries are done because of aseptic loosening of the primary THR. Table 5 represents the minimum, median and maximum cost of a THR surgery in terms of device and surgical costs.

Table 5 Distribution of device cost and surgical cost for Total Hip Replacement surgery [18]

	Device Cost	Surgical Cost
Minimum	\$2,392	\$7,152
Median	\$6,072	\$12,548
Maximum	\$12,651	\$23,051

The minimum device cost was \$2,392 and the maximum device cost was \$12,651; while the minimum surgical cost was \$7,152 and the maximum surgical cost was \$23,051 [19].

2.4 Computer Simulation and SCOR Modeling

A Supply Chain Operations Reference Model (SCOR) is a process reference model with standardized terminology and processes which are developed and maintained by the Supply Chain Council (SCC) [20]. A SCOR template is a simulation-based tool for analysis which is used to capture the subtleties of the operations of a supply chain. Persson and Araldi presented the first version of this template.

2.4.1 SCOR Model

There are three basic pillars on which SCOR is based [21]:

- Process modeling and re-engineering
- Performance measurements
- Best practices

Process Modeling and re-engineering: Any supply chain can be described by using process modeling as the fundamental blocks. SCOR consists of five distinct management processes: Plan, Source, Make, Deliver, and Return.

- Plan: It is a process or a set of processes that balance the demand and supply to create a path, which when followed satisfies the production, delivery and sourcing requirements.
- Source: These are the processes that procure goods and services to meet the demand.
- Make: It refers to the processes that transform the product to a finished state to meet the demand.
- Deliver: It is the process that provide finished goods and services to meet the demand. It includes order management, transportation management and distribution management.
- Return: It refers to the process associated with returning or receiving returned products for any reason. Products can be returned certain reasons such as – defects in products, MRO (Maintenance, Repair, Operations) required for the products, products procured in excess etc.

Figure 5 SCOR Process Framework [22]

Source: <http://courses.ischool.berkeley.edu/i243/s06/lectures/20060206/243-20060206.htm>

Performance Measurement: There are about 150 key indicators that could be used to evaluate the performance of a supply chain. There are three levels of metrics associated with SCOR, namely Level 1, Level 2, Level 3. Level 1 metrics are the used so that the performance of the total supply chain can be evaluated by the decision makers. Level 2 metrics are high level measures which are primarily used across various SCOR processes. Level 3 metrics are the secondary attributes which do not necessarily relate with Level 1 processes.

Best Practices: Best practices are the ones which are current, structured, proven and repeatable. It is used for organizational strategy, enabling technology and preparing business models in a broad sense.

2.4.2 SCOR Methodology

There are four main steps that are involved in the implementation of a SCOR-based working environment: (i) Examine the basic competition, (ii) construct the supply chain, (iii) align performance levels, practices and systems, and (iv) implement supply chain processes and systems. The second step consists of modeling the chain using standardized processes using level 1 and level 2 alone, whereas level 3 defines the tasks in level 2. Sometimes, a level 4 is introduced which is unique for each business and defines the tasks in level 3. It is very generic and usually left untouched. This tool has been developed by practitioners to identify and implement supply chain improvements, select and manage changes within organization and provide a basis for education and training in the field of supply chain.

2.4.3 Automatic Simulation Model Generation

Son and Wysk worked on creating a methodology for automatic simulation model generation that could be used to directly control a manufacturing system [23]. The static and dynamic information for the simulation model is obtained from shop floor resource model and shop level control model respectively. The simulation model created using traditional systems analysis could be used to perform high-level control activities in the manufacturing system using Ethernet communication. The simulation is generated in Arena and was validated using six different manufacturing systems. The manufacturing systems considered here are discrete-part manufacturing systems consisting of robots, automatic storage systems, CNC machines and an automated transporter, e.g., a guided vehicle system or a programmable conveyor system.

Sprock et al worked on applying model-based systems engineering (MBSE) to create SCOR based supply chain reference framework using OMG SysML™ [24]. The paper illustrated the construction of a Domain Specific Language (DSL) from SCOR and then combining it with a set of patterns to create a reference architecture. This reference architecture is used to construct an Analysis Model in the discrete event simulation environment. The time required to develop, validate and test system models is reduced because the single model of the system of interest provided access to multiple analyses. Their research developed an object-oriented, SCOR compliant reference architecture detailed in SysML.

The literature discussed in this section is beyond the scope of this thesis, but it be used in future to extend the SCOR model developed here to construct tools that can automatically build new systems for manufacturing.

2.5 Summary

This chapter provides: 1) an overview of the earlier work in medical modeling of implants, 2) an introduction to SCOR 3) various facts related to Total Hip Arthroplasty as an example product domain, and 4) using SCOR or formal state models to develop simulation models of complex systems. As the AM technology becomes more affordable, it will be used in more surgeries. There is evidence that this will provide advantages for using AM technology in implant medicine, and that we will see tailor-made 3D printed implants become a standard procedure. This research focuses on combining these areas together to create models (SCOR and Arena) to analyze the future supply chain of uniquely customized implants to assess

resource capacities and related economics. The next chapter describes about the methodology that has been used to prepare the SCOR model and build a simulation around it.

CHAPTER 3

METHODOLOGY

3.1 Introduction

This chapter explains the methodology of building a SCOR model for hip stems customized for individual patients. It describes the various levels of process details for traditional as well as additive method of manufacturing. The SCOR model is used to create a simulation model to assess capacities for additive manufactured hip stems. The last section of the chapter deals with cost-analysis for patient-specific hip stems and compares the economics with the traditional method of manufacturing and implantation.

3.2 SCOR Model

This section will focus on building two states of SCOR model 1) ‘As-Is’, and 2) ‘To-Be’. The As-Is state refers to the traditional method of manufacturing hip stems which consists of a series of operation from forming to finishing. The To-Be state refers to the additive manufacturing of patient-specific hip stems. SCOR helps in comparing the two states and thereby, transferring from current to the desirable future state.

SCOR contains three levels of process detail. **Level 1** defines the supply chain using five distinct management processes – Plan, Source, Make, Deliver, and Return.

These processes are categorized into **Level 2** configuration. It is the configuration level which defines various process categories. The operation strategy for an organization is chosen on the basis of this configuration. It consists of planning the process, executing it and

enabling the relationship between them. A level 2 process is classified by each type of product as follows:

- 1 – Make-to-Stock (MTS)
- 2 – Make-to-Order (MTO)
- 3 – Engineer-to-Order (ETO)
- 4 – Retail Product

The SCOR model provides 22 process categories which are defined in Table 6. Any configuration of a supply chain can be represented by using these process categories.

Table 6 SCOR level 2 process categories

Notation	Process Category
P1	Plan supply chain
P2	Plan source
P3	Plan make
P4	Plan deliver
P5	Plan return
EP	Enable plan
S1	Source make-to-stock products
S2	Source make-to-order products
S3	Source engineer-to-order products
ES	Enable source
M1	Make-to-stock
M2	Make-to-order
M3	Engineer-to-order
M0	Make infrastructure
D1	Deliver stocked products
D2	Deliver made-to-order products
D3	Deliver engineer-to-order products
ED	Enable deliver
R1	Return defective product
R2	Return MRO product
R3	Return excess product
ER	Enable return

Level 3 is the process element level that decomposes the processes. It defines an organization's ability to compete effectively in its selected market. It consists of process element definitions, information about inputs and outputs, best practices and process performance metrics. It provides detailed process element information for each Level 2 process category.

Level 4 provides a description of Level 3 tasks and is unique to each business and organization. It is required to manage the supply chain on a day-to-day basis.

In the next two section, the SCOR models are presented for traditional and additive method of manufacturing.

There are thirteen performance metrics which are endorsed by the SCOR model. Table 7 lists these metrics/parameters. A company cannot excel in all the 13 categories, and hence companies usually focus on four to six performance parameters which are important for their business. Usually companies focus on five defining categories: reliability, responsiveness, flexibility, costs, and efficiency in managing assets.

Table 7 Thirteen performance metrics for SCOR

SCOR model performance metrics	
Delivery reliability	Cost
Delivery performance	Cost of goods sold
Fill rates	Total supply chain management cost
Perfect order fulfillment	Value-added employee productivity
Responsiveness	Warranty/return processing costs
Order fulfillment lead times	Assets
Flexibility	Cash-to-cash cycle time
Supply chain response time	Inventory days of supply
Production flexibility	Asset turns

In the following sections, SCOR models for the traditional as well as additive method of manufacturing hip stems will be created and described.

3.2.1 The As-Is Model

Presently, the hip stems are being manufactured by the method of forming. Most hip replacements are made from Cobalt or Chromium alloys, or Titanium. Metal billets are heated in a furnace at 1200°C. Three stamps of different sizes are used successively for forming to give the shape of a hip stem to the metal billet. This part is subjected to post-processing finishing operations to achieve required dimensions and tolerances. Sand blasting is done to polish the part. The part is then bathed in a water-based citric solution to remove the powdered metal and clean the part. The quality control department inspects the hip stem for functional accuracy. The hip stems are then shipped to the desired locations. Figure 6 shows the SCOR based model for the As-Is model.

Figure 6 As-Is: SCOR model for current process for manufacturing hip stems

Level 1

Plan: Level 1 consists of P1, P2, P3, P4 and P5 process categories.

P1 – Plan the Supply Chain: The entire process is reviewed and demand and supply factors are taken into account to plan deliveries and source raw materials.

P2 – Plan Source: To manufacture a hip replacement, the important resources are –

- Engineers
- Medical grade Chromium and Copper alloys or Titanium

- Heat furnace
- Forging machine/Investment Casting machine
- CNC machine
- Machine tools
- Sand blasting machine
- Water-based citric solution

Engineers are foremost required for process planning, design and engineering, and to maintain the equipment and quality of the product. Raw materials for hip stems have to be procured. Other equipment as mentioned above like a heating furnace, forging machine casting system with sand blasting, and CNC machines and tools for finishing have to be acquired and maintained in working condition. Water-based citric solution is to be sourced in for cleaning the part. P2 (Plan Source) plans for the sourcing in of these resources. The plans for ordering the equipment and materials, and gathering the workforce are made in the Plan Source Level 1. P3 – Plan Make: The process planning for manufacturing needs to be done beforehand. Figure 7 shows the process plan for Make.

Figure 7 Traditional Make process for 'As-Is' Model

P4 – Plan Deliver: After the hip stems are built, they are packaged in appropriate packaging and dispatched to the hospitals. The transportation could take place by USPS, UPS or other

methods depending upon the company policies. This could depend on cost factors, urgency of the part and other related factors.

P5 – Plan Return: Returns could be made because of a variety of factors. It could be because the material/product is defective, needs repair, or is purchased in excess. Returns could be made at two points in the process. Once, at the source node, where the raw materials or equipment that are brought in from different suppliers are defective, need MRO (Maintenance, Repair and Operations) or are simply sourced in excess. The other point where returns could be made is at the customer-end. The hospitals or the purchasing company could return the hip stem because of any of the above mentioned reasons. The industry prepares a plan of action, in case returns have to be made from/to any of the nodes.

Level 2

This level classifies the processes as – Make-to-Stock (1), Make-to-Order (2), Engineer-to-Order (3), and Retail Product (4). For the traditional method of building hip stems, the manufacturing is governed by the forecasted demand. All the resources are kept in stock. The hip stems are also manufactured as Make-to-Stock. The delivery and return of these Make-to-Stock components happen via the company's logistic systems.

The Level 2 processes look as following:

S1: Source MTS parts

M1: Manufacture MTS parts

D1: Deliver MTS parts

R1, R2, R3 represent Return defective product, return MRO, and return excess product respectively.

The Level 3 and Level 4 process for Source, Make, Deliver and Return are described in Appendix A.

Figure 8 Various Levels of SCOR 'As-Is' Model

This section presented the 'as-is' model, which is the model representing traditional method of manufacturing a hip stem. The next section will talk about a similar kind of model for the 'to-be' i.e. the additive manufactured model of the hip stem.

3.2.2 The To-Be Model

To additively manufacture a uniquely customized hip stem, a CT scan is taken of the patient's hip and femur. These CT scans are essentially 2D images which are converted into a CAD model using specialized software. These CAD models are subjected to FEA analysis to determine faults in the model. When the model passes the FEA tests, it is fed into an EBM machine to be built. This is followed by support removal and other post-processing and finishing operations. Figure 9 shows the SCOR model for this 'to-be' state.

Level 1

Plan: Level 1 consists of P1, P2, P3, P4 and P5 process categories.

P1 – Plan the Supply Chain: The entire process is reviewed and demand and supply factors are taken into account to plan deliveries and source raw materials.

P2 – Plan Source: To additively manufacture a hip replacement, the important resources are listed in Table 8.

Table 8 List of resources for "To-Be" model

Resources	
Medical Engineers (CAD and FEA)	CNC Machine
CT Scanner	Machine Tools
Medical grade Cr and Cu alloy powder or Ti powder	EBM and CNC operators
EBM Machine	Technicians

Figure 9 To-Be: SCOR model for additive manufacturing of hip stems

Specialized medical engineers are required for the process planning, design and engineering, and to maintain the equipment and quality of the product. Raw materials for hip stems have to be procured. Other equipment as mentioned above like a CT scanner, machine for sand blasting, and CNC machine and tools for finishing have to be acquired and maintained in working condition. Water-based citric solution is to be sourced in for cleaning the part.

P2 (Plan Source) plans for the sourcing in of these resources. The plans for ordering the equipment and materials, and gathering the workforce are made in the Plan Source Level 1.

P3 – Plan Make: The process planning for the manufacturing needs to be done beforehand.

Figure 10 shows the processes involved in an AM-build.

Figure 10 AM-build process

P4 – Plan Deliver and P5 – Plan Return sections are the same as the ‘As-Is’ model. The probability of R3 (Return excess product) from the buyer is very low. The probability that the hip stem was ordered and manufactured but is no longer required happens in the event when the patient dies during the manufacturing process.

Level 2

This level classifies the processes as – Make-to-Stock (1), Make-to-Order (2), Engineer-to-Order (3), and Retail Product (4). For the additive manufacturing of hip stems, the manufacturing is governed by the actual demand. The manufacturing is not initiated unless an order is received. Since, the manufacturers cannot estimate the exact demand at any time, all the resources are kept in stock. The components are manufactured as Engineer-to-Order. This creates a “pull system” for all product orders. It also means that there is only one customer for each customized product. The delivery and return of these Engineer-to-Order components happen via the company’s logistic systems.

The Level 2 processes look as following:

S1: Source MTS parts, where S stands for Source and 1 stands for MTS

M1: Manufacture ETO parts

D1: Deliver ETO parts

R1, R2, R3 represent Return defective product, return MRO, and return excess product respectively.

Level 3 and Level 4 process for Source, Make, Deliver and Return processes are listed in Appendix B.

Figure 11 Levels of SCOR 'To-Be' Process

This is a comprehensive model of the 'To-Be' desirable state of the chain. To move from 'As-Is' to 'To-Be', SCOR helps in describing supply chain configurations and thus enables the industry to compare performances and process efficiencies.

3.3 Simulation Model

In the above sections, SCOR provided a fundamental composition of building an analytical model from the supply chain information. Now, a simulation is described that will evaluate the system for its efficiencies and capacities. A simulation model is manually built using the information from the SCOR model. Arena is chosen as the software of choice as it translates the activities of SCOR into a network based simulation system. There are about 332,000 hip replacement surgeries that happen every year in the U.S. Revision surgeries are primarily performed due to aseptic loosening of the hip stem. This section builds a simulation model to determine resource requirements if half of the original capacity, i.e. 166,000 hip stems are manufactured using AM methods.

For this research, a single central AM facility that will produce all uniquely custom hip stems is assumed to model the MAKE portion of the SCOR model. This facility receives orders from hospitals that will include a CT scan and the style of stem that will be used. The facility will complete the design of the hip stems using the CT scans for each patient. The hip stems will then be 3D printed and finished at this facility. Finally the hip stems will be inspected and autoclaved for packaging into aseptic transport containers.

To build this simulation, following assumptions were made:

1. The processing times for each operation has been assumed to have a triangular distribution.
2. The arrival rate of patients into the system has been assumed to be random exponential.
3. A success rate of 95% has been assumed for the FEA analysis of the part.
4. A 99% success rate has been assumed for the quality control node.

5. The hip stems are not built in the 3D printer one by one. The parts get batched (5 parts per batch) before the build, so that the machine is not run for just one part alone (efficiency). 10 hip stems could be placed in a single build for optimum results, but considering the stochastic nature of the demand, a batching of 5 parts is used on average, and during higher demand periods the build can be increased to up to 10 hips stems per build.
6. The part can be built using any powder bed metal 3D printer, but this simulation assumes that an EBM (Electron Beam Melting) machine for the build. A DMLS printer could be used instead of an EBM, but a DMLS printer often faces the issue of part-warping. This increases the need of a lot of sacrificial supports on the base, attaching a considerable portion of the part to the base plate. Hence, it is reasonable to assume that an EBM would be a preferable choice over a DMLS.
7. The EBM is a warm-bed machine. The heat treatment of the part is “heat treated” in the machine during its cool down. An overnight cool-down period is introduced. For longer build times, this cool down time becomes even longer. This cool-down period has also been included in the simulation to accommodate the heat treatment part.
8. 332,000 hip replacement surgeries are performed in a year in the USA. This simulation was aimed at manufacturing half of this quantity (166,000) per year. It was assumed that the EBM machines ran 24 hours, 7 days a week while the activities like CT scanning, CAD modeling, FEA analysis and finishing operations take place on 5 days of the week, 8 hours per day. It is a reasonable assumption since the EBM machines do not require an operator to work on it during the build process. Hence, the machine can be kept running during the nights and the weekends.

9. The *3D printing EBM* process in the simulation is sub modeled such that only the preparatory processes and the removal process require and EBM operator.
10. Typically a hip stem weighs ~1.5 pounds. Keeping in mind, the material for stem and the supports, one hip stem would require ~2 pounds of metal powder. It is assumed that the metal powders provide a utilization of 85%.

The model created here is only simulated to determine resource capacities. The cost component for these resources are not utilized to do a cost simulation. A rough cost-analysis is done in the next section to represent how the changes in device cost, surgery cost, post-discharge costs etc. affect the total cost of THA.

The structure of a simulation model is shown in Figure 12. The resources that are being considered for this system are listed in Table 9.

Table 9 List of critical resources considered in this simulation

Resources	
Medical Engineers (CAD and FEA)	EBM Machine
CT Scanner	CNC Machine
Medical grade Chromium and Copper alloy powder or Titanium powder	Technicians or Operators for CT Machines
EBM Operators	CNC Operators

Figure 12 Simulation model for AM manufacturing of hip stems

The simulation model was created using Arena software. The processing time for each operation was taken as a triangular distribution with liberal assumptions. As this simulation was built, we realized that the main bottlenecks in this operation are the powder capacities and the number of EBM machines for the build. Skilled medical engineers and EBM/CNC operators are also required. The metal powder were used with ~85% efficiency. The other resources were run at ~60-65% utilization. The simulation was run many times, adjusting the capacities of resources each time to produce approximately 166,000 hip stems in a year. The aim of this simulation model is to determine the resource requirements for the future and determine bottlenecks in the system. A detailed discussion about the results and conclusions of this simulation will be presentation in the next chapter.

3.4 Summary

This chapter presented a methodology for building simulation model from a SCOR-based model for the hip stems. The ‘As-Is’ and ‘To-Be’ models were created and detailed. A simulation model was also built which would assist in determining resource requirements for the future. In the next chapter (Chapter 4), the traditional and additive models will be compared to discuss about the shift of manufacturing from ‘As-Is’ to the desirable ‘To-Be’ state. The results of the simulation model will be used to discuss about the resources in the future. A cost-analysis will also be presented to compare the two methods of manufacturing and their economic impacts.

CHAPTER 4

RESULTS AND DISCUSSIONS

4.1 Introduction

The previous chapter discussed the methodology for building the SCOR model of a THR system and the simulation around it. In this chapter, we will discuss the significance of these models and try to understand how the simulation might be used in order to investigate the supply chain performance and resource requirements. By making comparisons between the SCOR models, it becomes easier to determine the pros and cons of each manufacturing method. The simulation results also tell us about the capacities of different resources. A cost-analysis is done to compare the costs of both the manufacturing methods and determine various trade-offs. The main difference between the two models is in terms of the inventory model it uses. The ‘As-Is’ system is a push inventory model while the ‘To-Be’ system is a pull inventory model. Figure 13 and 14 illustrates this difference.

Figure 13 Push system for 'As-Is' Model

Figure 14 Pull System for 'To-Be' Model

In the following sections, we compare the two models on different performance measures and prepare simulation model for sensitivity analysis related to resource capacities and cost analysis related to feasibility.

4.2 Comparisons between 'As-Is' and 'To-Be' Model: Performance Metrics

The Level 2 of the SCOR model identifies 13 major performance attributes that the companies focus on. These attributes are divided into five categories: Reliability, Responsiveness, Flexibility, Cost, and Assets. Not each metric out of these thirteen are relevant for these models. The relevant metrics are discussed below and some new metrics are devised to compare the two models more appropriately.

Order Fulfillment Lead Times: It is defined as the average lead time that is reliably attained from customer's approval of purchase order to the order completion at the customer's end. The 'To-Be' supply chain prepares ETO (Engineer-to-Order) products, hence the order fulfillment lead times for this model is higher than the 'To-Be' model.

Production Flexibility: It can be categorized into – Upside flexibility and Downside flexibility. Upside flexibility is defined as the number of days it takes to sustain an unplanned 20% increase in production. Downside flexibility is defined as the percentage order reduction

sustainable at 30 days prior to delivery with no inventory or cost penalties. For the ‘As-Is’ supply chain, the upside flexibility is better as the manufacturing process is faster. For the ‘To-Be’ supply chain, the downside flexibility is better as there is no inventory. The production process starts only after an order is placed.

Cost of Goods Sold: This is the sum of the direct and the indirect costs. The cost related with purchasing of the raw materials and manufacturing of the finished goods. The ‘To-Be’ model uses additive manufacturing method for the production of hip stems, hence the cost goes up.

Warranty Costs/Returns Processing Cost: It is defined as the cost required for materials, problem diagnosis, labor and other resources to discard/repair defective products. The number of defects/returns for an AM based supply chain (‘To-Be’ model) is significantly smaller than the ‘As-Is’ model. Hence, the warranty/ returns processing cost for ‘To-Be’ model is lesser than ‘As-Is’ model.

The above mentioned performance metrics indicate that the AM based supply chain is not very flexible. However, there are some metrics other than the above 13, which suggests the benefits of the AM ‘To-Be’ Model. Table 10 lists the parameters which make the AM supply chain as the supply chain of the future.

Table 10 List of performance measures which are improved in the AM "To-Be" model

Performance Measure
Product performance
Inventory: Push Vs Pull
CODP
Product life
Cash tied up in inventory
Material wastage
Mechanical properties
Returns
Time: surgery, post-discharge, rehab
Obsolescence

Product performance: The AM implant is uniquely customized for each patient's geometry which increases its performance. The better fit of the hip stems will reduce the pain experienced by the patient and provide better mobility.

Inventory (Push Vs Pull): The traditional method of manufacturing a hip stem is a push system where the inventory depends on demand forecasting. The AM supply chain is based on a pull inventory strategy because each hip has a unique geometry. A pull inventory model refers to a system where the orders to make products are requested by the customer. The AM model contains no inventory of finished goods as the hip stems are sold even before they are manufactured.

Customer Order Decoupling Point (CODP): CODP is the point in the supply chain of a product, where the product will be linked to a particular customer. The CODP for an AM implant is very high up in the supply chain. The product is designed and manufactured for a specific customer. While this brings variability in the supply chain, it improves performance and moves the chain from mass production to mass customization. More and more people,

especially people with different geometries, are able to take advantage of the technology and get better results.

Product life: The need for a revision surgery arises 10-15 years after the primary surgery. The need for a revision surgery arises due to aseptic loosening of the implant. The AM implant is uniquely customized and hence, provides better fit. The probability of aseptic loosening can be reasonably assumed to decrease by a 50%. This increase the product life on an average.

Cash tied up in inventory: The AM supply chain does not keep inventories for the manufactured hip stems. The orders are delivered as soon as they are manufactured. Hence, there is no cash tied up in the inventory of finished goods. However, an AM facility would require other inventories like metal powder and the surgical facilities would require specialized surgical sets for trials. The inventory costs of these items might be significant.

Material wastage: The metal powder used in the additive manufacturing of the hip stem can be recycled. There is less material waste as compared to traditional manufacturing methods.

Mechanical properties: Several experiments have been conducted to test the material properties of metal AM parts. It has been shown that the metal additive process produce superior properties as compared to their traditional manufacturing counterparts [25]. It is expected that the AM hip stems will have better mechanical properties (tensile strength, yield strength, hardness, and elongation) as compared to the traditionally manufactured hip stems.

Returns: The AM implants are manufactured with reference to a patient's hip geometry. Therefore, it is highly improbable that a return is made because of fitting issues. Returns are

rare event in the “ToBe” system, where the patient would likely die or become severely diminished because of a disease or trauma during the manufacturing process.

Time (Surgery, post-discharge and rehabilitation): The fit and functionality of a uniquely customized implant made by AM processes decrease the surgical time, post-discharge time and the average rehabilitation time for the patient. It makes the process relatively painless for the patient.

Obsolescence: The manufacturing of an AM hip stem is initiated only after an order is placed. Hence, there is no question of the product being obsolete.

As we look at the above performance measures, it is evident that the AM model comes with its own set of advantages. It is however, limited by the resource capacities, flexibility and the cost factors. In the next part, we use a simulation model to determine our resource requirements for the future. A cost analysis will be performed in the later section to compare the costs of both the models and determine the feasibility.

4.3 Comparing the supply chain of “As-Is” and “To-Be” Models

In the current “As-Is” manufacturing, the ‘few sizes for many’ rule is the service model. The hip replacements are manufactured in certain sizes and shapes and the surgeons use their better judgement to identify the suitable hip stem for their patients. Most of the hip replacements that are manufactured in the U.S. come from Warsaw, Indiana. It is also referred as *The Orthopedic Capital of the World*. One third of the \$32 billion Global Orthopedic Industry is headquartered in Warsaw, IN [26]. Zimmer, DePuy (wholly owned

subsidiary of Johnson & Johnson), Biomet are the three major companies in this market in Indiana. Figure 15 shows a map of the general idea of how the “As-Is” supply chain looks like.

Figure 15 The “As-Is” supply chain

The hip replacements are manufactured in certain sizes and shapes and shipped to the surgical centers across the U.S. During the surgery, the surgeon identifies the correct hip stem according to the patient’s geometry, completely relying on experience and judgement.

For the “To-Be” supply chain, this thesis discusses about a vision where a centralized Additive Manufacturing facility fulfills the entire demand. At present, there is no infrastructure developed for commercial AM produced medical device industry. Figure 16 represents how the “To-Be” supply chain will generally look like.

Figure 16 The “To-Be” Supply Chain

In Figure 16, the orange arrows represents that the CT scan, order and other patient information that is sent to the AM device modeling facility from the hospitals. The blue arrows represent the hip stem being shipped to the concerned facilities. Since the majority of orthopedic implants are manufactured in Warsaw, it is not be a bad assumption to centralize the AM based supply chain in Warsaw, IN as well. In both the “As-Is” and “To-Be” models, there will be occasional arrows for the returns. For optimum results for capacities and resource utilization, the EBM machines should be kept running

The “As-Is” supply chain is essentially a *push* system, while the “To-Be” supply chain is a *pull* system. The “To-Be” supply chain for uniquely customized hip stems waits for patient information about geometry and physical condition before manufacturing and thus, produces implants with better fit and functionality.

4.4 Simulation Results

In Chapter 3, a simulation model was built for the AM based manufacturing of hip stems. The EBM machines were run 24*7 around the year, while the other machines and processes were 5 days a week and 9 hours per day, considering 200 working days. The aim of this simulation is to find out resource capacities to meet half of the yearly requirement (166,000) using AM uniquely customized process.

A hit and trial approach was used to find resource capacities which generate approximately 166,000 hip stems in a year. Figure 17 shows the Arena screenshot for the number of hip stems dispatched for a year.

Figure 17 Number out in the simulation model

A utilization of 60-65% has been assumed for all other resources. After several hit and trials, the resource capacities were able to produce the desirable number of hip stems. Table 11 shows the screenshot for various resource capacities.

Table 11 Resource capacities for the AM model

	Type	Capacity
1	Technicians	585
2	Medical Engineers CAD	1190
3	Medical Engineers FEA	585
4	EBM Operator	50
5	EBM Machine	110
6	CNC Operator	440
7	QC Inspector	145
8	CNC Machine	440

For this model to be successful, about 585 technicians, 1190 medical CAD engineers and 585 medical FEA engineers who are skilled in the medical modeling field will be required. 110 EBM machines and 50 operators solely dedicated to producing hip stems so that we are able to hit our demand would be required. 440 CNC machines and operators are required who are able to carefully machine the devices. There must be a quality department which check for the quality of the device before dispatching it to the hospitals, but it does not seem to be a bottleneck in the production.

Each hip stem requires ~2 pounds of metal powder for the build. Considering 85% utilization of the powder, approximately 390,896 pounds of metal powder is required each year to meet 50% of the present demand by uniquely customized AM hip stems.

The AM hip stems have better functionality but there is a trade-off with the manufacturing time. Figure 19 shows the screenshot for total time spent by the entity in the system. On an average, it takes about ~39 hours to build a hip stem from scratch. This is significantly higher than the time required by the traditional manufacturing processes.

Total Time	Average
Entity 1	39.1606

Figure 188 Total time spent by the hip stem in the system

The resources have been utilized at ~60-65% which is a reasonable assumption based on the industrial experience.

In this section, the simulation results related to time constraints, output, resource capacities and their utilization are examined. At present, there are a few facilities which produce uniquely customized hip stems. This simulation explains the demands of the future if a focus is set on the AM methods for patient specific implants.

4.5 Sensitivity Analysis

The above section discussed the results of the simulation model when the production quantity was around 166,000 hip stems per year. This is roughly half of the present demand. In this

section, a sensitivity analysis is done for this model. The resource capacities will be determined by assuming the production quantity to be 25%, 75% and 100% of the current demand for hip stems. It is also expected that the AM and CAD modeling processes will become more efficient in the future. Hence, sensitivity analysis is also done for the case where the processing times and efficiencies are improved.

Case I: Changing percentage of the annual demand

Table 12, 13 and 14 indicate the resource capacity requirement for meeting 25%, 75% and 100% of the annual demand for hip stems using AM processes. To meet 75% and 100% of the total demand using AM methods, the production should be 249,000 and 332,000 per year respectively.

Table 12 Resource capacities to meet 25% of the annual demand using AM methods

Resource Name	Capacity 25%
Technicians	293
Medical Engineer CAD	595
Medical Engineer FEA	293
EBM Operator	25
EBM Machine	55
CNC Operator	220
QC Inspector	73
CNC Machine	220

Table 13 Resource capacities to meet 75% of the annual demand using AM methods

Resource Name	Capacity
Technicians	878
Medical Engineer CAD	1785
Medical Engineer FEA	878
EBM Operator	75
EBM Machine	165
CNC Operator	660
QC Inspector	218
CNC Machine	660

Table 14 Resource capacities to meet 100% of the annual demand using AM methods

Resource Name	Capacity
Technicians	1170
Medical Engineer CAD	2380
Medical Engineer FEA	1170
EBM Operator	100
EBM Machine	220
CNC Operator	880
QC Inspector	290
CNC Machine	880

To meet 25% of the annual demand, the production should be about 83,000 hip stems per year. 195,294 pounds of medical grade metal powder is required per year. To meet 75% of the annual demand with uniquely customized hip stems, the production quantities should reach 249,000 per year which can be achieved by resource capacities mentioned in Table 13. 585,882 pounds of medical grade metal powder will be required for this production quantity. Similarly, Table 14 indicated the resource capacities to meet entire demand with uniquely customized implants. A quantity of 781,176 pounds of medical grade metal powder is required to produce these many hip stems.

As it is evident, the bottlenecks in the production are the metal powders and the number of EBM machines that are available for commercially manufacturing hip stems.

Case II: Changing process parameters

In the future, AM processes will be more time-efficient and less expensive. In the coming 10 years or so, the processing time for AM methods have been anticipated to be reduced by 30%. It is also expected that the processes will require lesser material than before. The efficiency of the CAD modeling processes, FEA analysis, finish of AM process etc. will improve. Arcam has been working to create EBM machines which have a cool down chamber outside the machine. This could be helpful in increasing the availability of EBM machines for the build. Table 15 shows the old and new resource capacities for meeting 50% of the annual demand for uniquely customized hip stems. A simulation was run to incorporate better processing times and determine resource capacities.

Table 15 Resource requirements for AM methods to meet 50% of the demand

Resource Name	Old Capacity	New Capacity
Technicians	585	440
Medical Engineer CAD	1190	610
Medical Engineer FEA	585	485
EBM Operator	50	20
EBM Machine	110	65
CNC Operator	440	220
QC Inspector	145	145
CNC Machine	440	220

As the old and new capacities are compared, it is observed that the number of critical resources like EBM machines and CNC machines have gone down significantly. It is evident

that with the advancement in AM technology combined with the benefits of uniquely customized implants, the industry will move from mass production to mass customization.

4.6 Cost Analysis

Cost is one of the most important factors when comparing two methods of production. This section describes the costs associated with a Total Hip Replacement surgery. The costs of the entire surgery including the device cost for a traditional hip stem and a uniquely customized hip stem made by AM processes are compared.

The main components of the cost of a total hip replacement surgery consist of: hospital cost, device cost, surgeon cost, post-discharge cost, and revision surgery cost. Precise information related to these costs are not available, hence a rough cost model is developed to compare the two supply chains. Table 16 shows the minimum, median and maximum device and surgical cost for a traditional hip replacement surgery. The cost of a total hip arthroplasty ranges from \$11,327 (Alabama) to \$73,987 (Massachusetts) with an average cost of \$30,124.

Table 16 Device and surgical cost for a THR surgery

	Device Cost	Surgical Cost
Minimum	\$2,392	\$7,152
Median	\$6,072	\$12,548
Maximum	\$12,651	\$23,051

The variation in device cost is mainly because of the difference in hospital characteristic or the patient characteristic (age, gender, and physical condition). By using uniquely customized hip stems, it is expected that the percentage of revision surgeries will decrease from 18% to ~10%. Major reduction in the requirement of the revision surgery will be due to decrease in

cases of aseptic loosening and dislocations. Revision surgeries are more expensive than the primary ones and have worse functional outcomes. The cost of a Total Hip Arthroplasty can be written as:

$$C = C(h) + C(d) + C(s) + C(m) + C(pd)$$

Where,

C is the total cost of THA

$C(h)$ is the hospital cost

$C(d)$ is the device cost

$C(s)$ is the surgical cost

$C(m)$ is the mitigation cost

$C(pd)$ is the post-discharge cost

For a uniquely customized AM hip stem, the device cost increases while the hospital cost, surgical cost, mitigation cost and post-discharge cost are reduced. The cost of a revision surgery is more than the primary surgery. For a patient using a traditional hip stem, the average cost of a revision THA is around \$50,000. For a patient with a uniquely customized hip stem, the chances of requiring a revision surgery. The revision surgery rates are expected to drop from 18% to ~10%. Much information has not been available about the cost of revision surgery using a uniquely customized AM implant. Hence, the cost of revision surgery for traditional hip stem is used here for calculation purposes.

Using a traditional hip stem

$$C(d) + C(s) + C(m) = \$6,072 + \$12,548 + 0.18(\$80,000) = \$33,020$$

$$\text{Median cost of a THA surgery} = C(h) + C(d) + C(s) + C(m) + C(pd)$$

$$= C(h) + \$33,020 + C(pd)$$

Using a uniquely customized AM hip stem

The cost of manufacturing a uniquely customized hip stem using AM process varies from \$15,600 to \$20,100.

$$C(d) + C(s) + C(m) = \$20,100 + \$9,000 + 0.10(\$80,000) = 37100$$

$$\begin{aligned} \text{Median cost of a THA surgery} &= C(h) + C(d) + C(s) + C(m) + C(pd) \\ &= C(h) + \$37,100 + C(pd) \end{aligned}$$

$$\textbf{\textit{Difference in the costs}} = \textbf{\$4080}$$

Much information is not available as to how the hospital cost and post-discharge cost will be affected if uniquely customized AM implants are used but these costs are expected to go down. Comparing the two models, the median cost of a uniquely customized THA surgery is \$4,080 more than the traditional surgery.

In the future, the cost for AM process will go down which will significantly bring down the cost of THA surgery using a uniquely customized implant. As the AM processes become economically more viable, the number of patients opting for a uniquely customized hip stem will increase drastically.

4.7 Summary

In this chapter, we discussed the main results of this research. A comparison was made between the two methods of manufacturing. The simulation results were discussed to determine resource capacities and bottlenecks. A sensitivity analysis was done to analyze the

effect of variations in demand on the resource capacities. In the last section, a cost analysis was done to compare the two models to determine economic feasibility. The next chapter (Chapter 5) will consist of main conclusions drawn from this research. The chapter will conclude with the discussion of limitations of this research and scope of future work.

CHAPTER 5

CONCLUSIONS AND SCOPE OF FUTURE WORK

5.1 Introduction

Uniquely customized implants bring better fit and functionality to the patient which makes rehabilitation easier. The surgical times and costs are greatly reduced. Additive Manufacturing brings a lot of advantages to the table with respect to the functionality, compromising a little bit in manufacturing costs and time. This thesis has presented a methodology that used a SCOR model for metal based AM processes to compare and develop the supply chain for uniquely customized hip stems. In this chapter, we will look at the limitations and key conclusions of this research. We also will conclude the chapter with a little background about scope of future work.

5.2 Limitations

Certain assumptions were made during the simulation modeling and SCOR modeling. The limitations of this research are listed below.

1. For the simulation model, there were several assumptions taken regarding the process parameters and their distributions. This may have impacted the accuracy of the resource capacities. However, the resources capacities are not expected to be off by the order of a magnitude.
2. The model talks about a centralized system of “To-Be” supply chain. A centralized system is often not practical for an industry like medical devices. For a different

- supply chain footprint, there will be manufacturing centers located in more than a few locations and the CAD data and device delivery exchange between these locations and the surgical centers will happen in a differently organized manner.
3. The cost-analysis does not include the variations in different costs according to the patient and hospital characteristics. It is a rough model developed to do some initial comparisons.
 4. Details regarding surgical times/costs, post-discharge costs/time, hospital costs/time etc. are not sub modeled. Using these details could have brought more accurate results in the research.
 5. The uniquely customized hip stems will require special surgical instruments which are manufactured as a set for each surgery. This research does not talk about the surgical instruments and focuses only on the metal hip stems.

5.3 Conclusions

This research has shown a method to analyze how a commercial system of AM facility can be designed and analyzed. The two supply chain, “As-Is” and “To-Be” are very different in terms of manufacturing and logistics. A comparison was made between the two supply chains and good and bad metrics were identified. The “To-Be” supply chain of uniquely customized AM hip stems produced hip stems which gave better fit and functionality. Though these implants were expensive to manufacture, these hip stems provided better rehabilitation and post-discharge results. The surgical times were reduced owing to the better fit of uniquely customized implant in the patient’s geometry. There was lesser material

wastage and lesser costs associated with returns. The “To-Be” model is a *pull system* as compared to the “As-Is” system which is a *push system*. However, the AM based supply chain was less flexible to sudden change in demands. The manufacturing costs and times are considerably high as compared to traditional methods.

Using the simulation model, an estimate of required resource capacities was made. The bottlenecks in the production are the number of EBM machines and the quantity of metal powder required. To meet 50% of current demand with uniquely customized AM hip stems, there is a requirement of 390,896 pounds of medical grade Chromium or Copper alloy/Titanium powder per year. 110 EBM machines should be commercially used for manufacturing to meet this demand. The Arcam annual report for 2015 shows that they received an order for 58 EBM systems and they were able to deliver 50 systems [27]. It will obviously take a while before Arcam can deliver 110 commercial systems for hip stem applications, and this is only one of the many new AM applications.

The results of the rough cost analysis indicated that the median cost of a uniquely customized AM hip stem will be about 4,080 USD more than the traditional hip stem. There are reductions in surgical cost, post-discharge cost and hospital cost but the device cost for additive manufacturing and modeling is high enough to make it presently commercially uneconomical.

With the advancement of the additive manufacturing technology and CAD modeling, the process is expected to improve dramatically in the future in terms of costs and time. This will change the entire face of the current supply chain and make the AM based supply chain more time and cost efficient.

5.4 Scope of Future Work

The current work is just the start of exploring the new avenues in the development of an AM based supply chain. Currently, the development of a very basic SCOR model and simulation has been done. The new supply chain is assumed to be centralized. A centralized supply chain for such a device model is not the most realistic approach, especially when it caters to the needs of the population across the country. This thesis can be extended to create a distributed supply chain network with manufacturing locations, modeling centers and service centers located across the country.

In this model, basic capacities for the resources are determined. The efficiencies for these resources are expected to improve as the industry experiences technological advancements. New efficiencies and techniques could be incorporated to develop a more precise model in the future. The cost associated with AM processes, the requirement of post-processing operations and related technologies will be reduced. A revised model could be developed in the future which could accommodate these changes and provide more accurate results.

REFERENCES

- [1] "Wave of future: 3D printing industry to quadruple by 2020," 1 May 2015. [Online]. Available: <https://www.rt.com/business/253785-3d-printing-industry-growth/>.
- [2] "OrthoInfo Your connection to expert orthopedic information," American Academy of Orthopedic Surgeons, [Online]. Available: <http://orthoinfo.aaos.org/topic.cfm?topic=a00377>.
- [3] "Inpatient Surgery," Centers for Disease Control and Prevention, 29 April 2015. [Online]. Available: <http://www.cdc.gov/nchs/fastats/inpatient-surgery.htm>.
- [4] J. G. DELEE and J. Charnley. Radiological demarcation of cemented sockets in total hip replacement. *Clin. Orthop.* 121pp. 20-32. 1976.
- [5] N. N. Mahomed, J. A. Barrett, J. N. Katz, C. B. Phillips, E. Losina, R. A. Lew, E. Guadagnoli, W. H. Harris, R. Poss and J. A. Baron. Rates and outcomes of primary and revision total hip replacement in the united states medicare population. *J. Bone Joint Surg. Am.* 85-A(1), pp. 27-32. 2003.
- [6] R. N. Maniar and T. Singhi. Patient specific implants: Scope for the future. *Current Reviews in Musculoskeletal Medicine* 7(2), pp. 125-130. 2014.
- [7] J. Corney, L. Hieu, N. Zlatov, J. Vander Sloten, E. Bohez, L. Khanh, P. Binh, P. Oris and Y. Toshev. Medical rapid prototyping applications and methods. *Assem. Autom.* 25(4), pp. 284-292. 2005.
- [8] Y. A. Hosni and O. Harrysson. Design and manufacturing of customized implants. Presented at IIE Annual Conference. Proceedings. 2002.
- [9] G. A. Brown, K. Firoozbakhsh, T. A. DeCoster, J. R. Reyna Jr and M. Moneim. Rapid prototyping: The future of trauma surgery? *J. Bone Joint Surg. Am.* 85-A Suppl 4pp. 49-55. 2003.
- [10] F. Rengier, A. Mehndiratta, H. von Tengg-Kobligh, C. M. Zechmann, R. Unterhinninghofen, H. Kauczor and F. L. Giesel. 3D printing based on imaging data: Review of medical applications. *International Journal of Computer Assisted Radiology and Surgery* 5(4), pp. 335-341. 2010.

- [11] Y. Jun and K. Choi. Design of patient-specific hip implants based on the 3D geometry of the human femur. *Adv. Eng. Software* 41(4), pp. 537-547. 2010.
- [12] M. Truscott, D. De Beer, G. Vicatos, K. Hosking, L. Barnard, G. Booysen and R. Ian Campbell. Using RP to promote collaborative design of customised medical implants. *Rapid Prototyping Journal* 13(2), pp. 107-114. 2007.
- [13] M. Viceconti, D. Testi, R. Gori, C. Zannoni, A. Cappello and A. De Lollis. HIDE: A new hybrid environment for the design of custom-made hip prosthesis. *Comput. Methods Programs Biomed.* 64(2), pp. 137-144. 2001.
- [14] S. P. Krishnan, A. Dawood, R. Richards, J. Henckel and A. J. Hart. A review of rapid prototyped surgical guides for patient-specific total knee replacement. *J. Bone Joint Surg. Br.* 94(11), pp. 1457-1461. 2012. . DOI: 10.1302/0301-620X.94B11.29350 [doi].
- [15] N. N. Mahomed, J. A. Barrett, J. N. Katz, C. B. Phillips, E. Losina, R. A. Lew, E. Guadagnoli, W. H. Harris, R. Poss and J. A. Baron. Rates and outcomes of primary and revision total hip replacement in the united states medicare population. *J. Bone Joint Surg. Am.* 85-A(1), pp. 27-32. 2003.
- [16] I. E. Katatny, S. H. Masood and Y. S. Morsi. Evaluation and validation of the shape accuracy of FDM fabricated medical models. Presented at Advanced Materials Research. 2009, .
- [17] B. B. Shield, "A study of Cost variations for Knee and Hip Replacement Surgeries in the U.S.," The Health of America Report, 2015.
- [18] J. C. Robinson. Price variability for hip and knee replacement implants.
- [19] J. C. Robinson, A. Pozen, S. Tseng and K. J. Bozic. Variability in costs associated with total hip and knee replacement implants. *J. Bone Joint Surg. Am.* 94(18), pp. 1693-1698. 2012. . DOI: 1262702 [pii].
- [20] F. Persson and M. Araldi. The development of a dynamic supply chain analysis tool—Integration of SCOR and discrete event simulation. *Int J Prod Econ* 121(2), pp. 574-583. 2009.

- [21] J. B. Ayers. *Handbook of Supply Chain Management* 2006
- [22] U. Berkeley, "Models of Business Organization," University of California, Berkeley, 6 February 2006. [Online]. Available:
<http://courses.ischool.berkeley.edu/i243/s06/lectures/20060206/243-20060206.htm>.
- [23] Y. J. Son and R. A. Wysk. Automatic simulation model generation for simulation-based, real-time shop floor control. *Comput. Ind.* 45(3), pp. 291-308. 2001.
- [24] T. Sprock and L. McGinnis. Towards automated access to supply chain analyses. Presented at Proceedings of the 2014 POMS Annual Conference. 2014, .
- [25] J. Mazumder, "White Paper Title: Precision Additive Manufacturing of Medical Device," The POM Group Inc., Auburn Hills.
- [26] BioCrossroads, "Warsaw, Indiana: The orthopedics Capital of the World," BioCrossroads, 2009.
- [27] Arcam, "Arcam Annual Report -2015," Arcam, Sweden, 2015.
- [28] F. Persson. SCOR template—A simulation based dynamic supply chain analysis tool. *Int J Prod Econ* 131(1), pp. 288-294. 2011.

APPENDICES

Appendix A: As-Is Model

Level 3 – As-Is Model

Level 3 decomposes the process elements into definitions and information about inputs and outputs.

Source MTS (S1) can be decomposed into –

S1.1 – Schedule product deliveries

S1.2 – Receive product deliveries

S1.3 – Inspect received products

S1.4 – Authorize supplier payment

Make MTS (M1) can be decomposed into –

M1.1 – Perform forging or investment casting to get a basic shape for the hip stems

M1.2 – Rough machining

M1.3 – Polishing

M1.4 – Finishing and cleaning

M1.5 – Quality Control

Deliver MTS (D1) can be decomposed into –

D1.1 – Receive product orders

D1.2 – Send out deliveries

D1.3 – Order delivery confirmation

D1.4 – Receiver payment and send confirmation

Return MTS (R1) can be decomposed into –

Return can be done at two nodes.

R (1/2/3).1 – Return resource material to the supplier

R (1/2/3).2 – Receive returns from the customer

Level 4 – As-Is Model

These are the non-standardized or optional process which are often not defined as a hard guideline. Some of the examples of Level 4 processes are as follows:

Source

S1.1.1 – Check stock

S1.1.2 – Check pending items and any backorders

S1.1.3 – Contact suppliers and get a quote

S1.1.4 – Confirm schedules

S1.1.5 – Place orders

S1.2.1 – Receive deliveries from the supplier

S1.2.2 – Stock the items in the warehouse

S1.3.1 – Verify quality and quantity

S1.3.2 – Physically transfer stock to the machines

S1.4.1 – Contact supplier and authorize payment procedures

Make

M1.1.1 – Forging: Heat the metal billet in a furnace at 1200⁰C

M1.1.2 – Forge the metal billets in 3 stamps of different sized to achieve a standardized shape

M1.2.1 – Fixturing the part in a finishing machine

M1.2.2 – Select tooling and perform rough finishing

M1.3.1 – Polishing the part

M1.4.1 – Bathe part in a water-based citric solution

M1.4.2 – Clean the part

M1.5.1 – Perform a quality control on the finished hip stem

M1.5.2 – Sterilize the part and store packaged product in the inventory location

Deliver

D1.3.1 – Perform packaging

D1.4.1 – Dispatch product via land/sea/air

Return

R (1/2/3).1.1 – Contact supplier

R (1/2/3).1.2 – Send the stock to the supplier

R (1/2/3).1.3 – Negotiate for compensation or payment

R (1/2/3).2.1 – Contact buyer

R (1/2/3).2.2 – Understand causes of return

R (1/2/3).2.3 – Negotiate compensation or payments

R (1/2/3).2.4 – Receive the returned product and inspect for defects or repair needs

Appendix B: To-Be Model

Level 3 – To-Be Model

Level 3 decomposes the process elements into definitions and information about inputs and outputs.

Source MTS (S1) can be decomposed into –

S1.1 – Schedule product deliveries

S1.2 – Receive product deliveries

S1.3 – Inspect received products

S1.4 – Authorize supplier payment

Make MTS (M1) can be decomposed into –

M3.1 – Perform CT scan

M3.2 – Generation of a CAD model from CT scans

M3.3 – Additive manufacturing of the part

M3.4 – Finishing and cleaning

M3.5 – Quality Control

Deliver MTS (D1) can be decomposed into –

D3.1 – Send out deliveries

D3.2 – Order delivery confirmation

D3.3 – Receiver payment and send confirmation

Return MTS (R1) can be decomposed into –

Return can be done at two nodes.

R (1/2/3).1 – Return resource material to the supplier

R (1/2/3).2 – Receive returns from the customer

Level 4 – To-Be Model

These are the non-standardized or optional process which are often not defined as a hard guideline. Some of the examples of Level 4 processes are as follows:

Source

S1.1.1 – Check stock

S1.1.2 – Check pending items and any backorders

S1.1.3 – Contact suppliers and get a quote

S1.1.4 – Confirm schedules

S1.1.5 – Place orders

S1.2.1 – Receive deliveries from the supplier

S1.2.2 – Stock the items in the warehouse

S1.3.1 – Verify quality and quantity

S1.3.2 – Physically transfer stock to the machines

S1.4.1 – Contact supplier and authorize payment procedures

Make

M3.1.1 – Patient diagnosis

M3.1.2 – Consultation with medical engineers

M3.1.3 – Performing CT scan

M3.2.1 – Putting together 2D CT scan images using Mimics software to develop a CAD model of patient's bone structure

M3.2.2 – Performing FEA analysis on the CAD model to check for functional accuracy

M3.3.1 – Select process parameters for the 3D printing build

M3.3.2 – 3D print the hip stem

M3.3.3 – Removal of the part from the chamber

M3.4.1 – Removal of supports from the hip stem

M3.4.2 – Finishing using CNC methods

M3.4.3 – Polishing and cleaning

M3.5.1 – Perform a quality control on the finished hip stem

M3.5.2 – Sterilize the part and store packaged product in the inventory location

Deliver

D3.1.1 – Perform packaging

D3.1.2 – Dispatch product via land/sea/air

Return

R (1/2/3).1.1 – Contact supplier

R (1/2/3).1.2 – Send the stock to the supplier

R (1/2/3).1.3 – Negotiate for compensation or payment

R (1/2/3).2.1 – Contact buyer

R (1/2/3).2.2 – Understand causes of return

R (1/2/3).2.3 – Negotiate compensation or payments

R (1/2/3).2.4 – Receive the returned product and inspect for defects or repair needs