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SUPPLY CHAIN OPERATIONS REFERENCE MODEL FOR U.S. BASED POWDER BED METAL ADDITIVE MANUFACTURING PROCESSES

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ABSTRACT

This paper focuses on modeling the supply chain of an additively manufactured, 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. 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.

1 INTRODUCTION

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 enhanced product customization that comes with an additive manufacturing process suits the best for the needs for the medical device segment. This paper 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.

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 (Centers for Disease Control and Prevention 2015). Currently, the implants that are being used commercially are traditionally manufactured, which offers practically no customization for the patient's unique bone structure. For every 100 THR surgeries, about 18 revision surgeries are performed (Katz et al 2007). Some of the major reasons for a revision surgery are:

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

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

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

It has been observed that 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 (Mahomed et al 2003). Customized implants built using AM processes are predicted to last much longer. This is particularly beneficial for younger people who have 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 length of time for the surgery (and 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 paper will examine future manufacturing practices assuming a shift from traditional to AM production processes. A tool, called SCOR (Supply Chain Operations Reference model) 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.

1.1 Objectives

The objective of this research is to develop a SCOR based model for a medical application and production of 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 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 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 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.

2 LITERATURE REVIEW

2.1 SCOR Modeling

A SCOR model is a process reference model with standardized terminology and processes which are developed and maintained by the Supply Chain Council (SCC) (Persson and Araldi 2009). 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.
There are three basic pillars on which SCOR is based (Handbook of Supply Chain Management 2006):

- 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.

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.

3 METHODOLOGY

This section focuses 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

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.

3.1 The As-Is Model

Presently, the hip stems are being manufactured by the method of forging. Figure 1 shows the SCOR based model for the As-Is model.

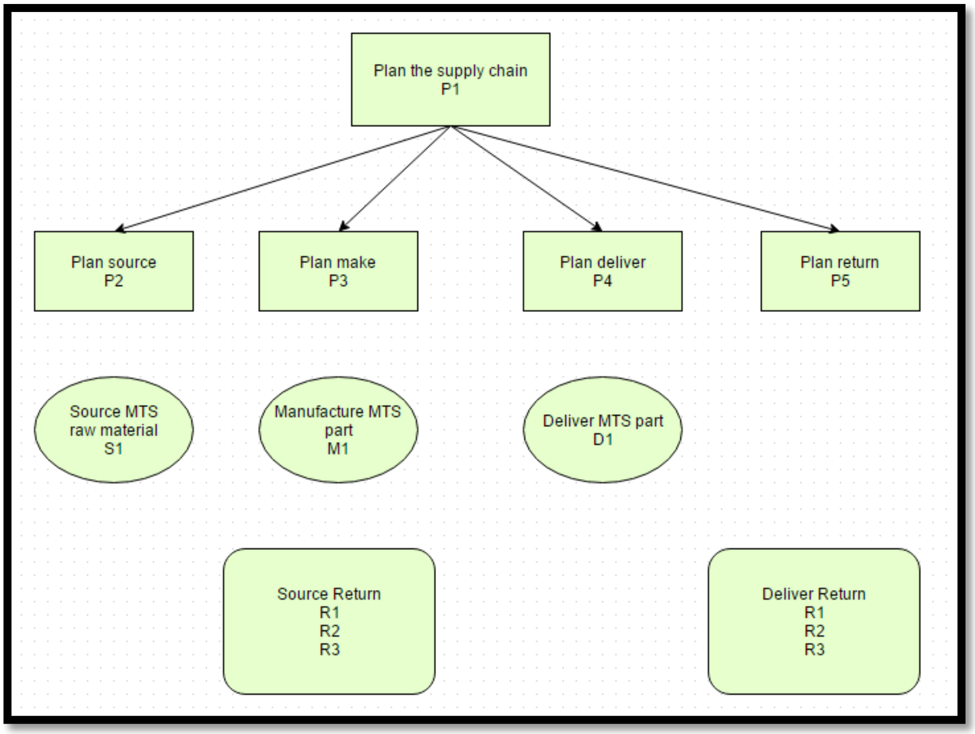

Figure 1 As-Is: SCOR model for current manufacturing process.

Level 1

Plan: Level 1 consists of P1, P2, P3, P4 and P5 process categories.
P1 – Plan the Supply Chain
P2 – Plan Source: 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.
P4 – Plan Deliver: After the hip stems are built, they are packaged appropriately 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 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 it from different suppliers are defective, need MRO (Maintenance, Repair and Operations) or are simply sourced in in excess. The other point where returns could occur 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 occur from/to any of the nodes.

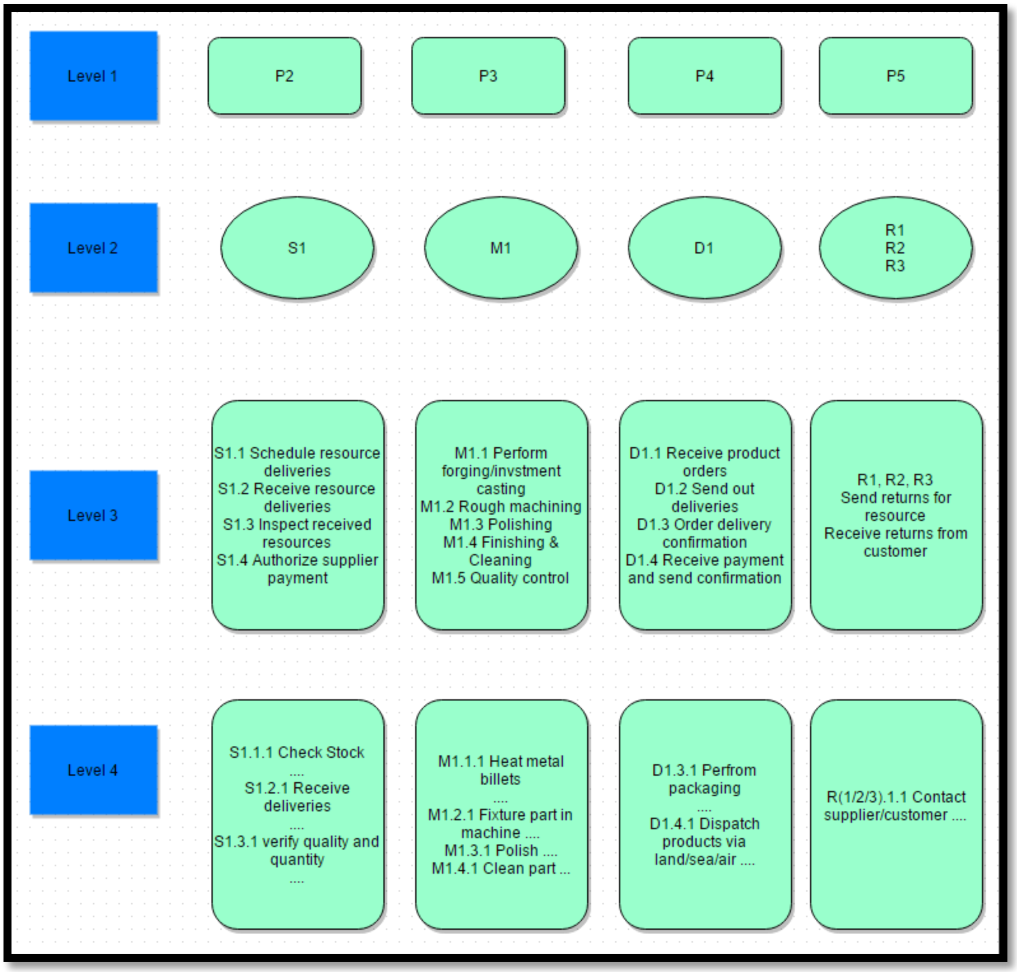

Figure 2 Various levels of SCOR As-Is Model.

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 approach, manufacturing is governed by the forecast 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 follows:

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 Figure 2.

3.2 The To-Be Model

To additively manufacture a 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 (usually Geomagic or 3-Matic). 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 3 shows the SCOR model for this 'to-be' state.

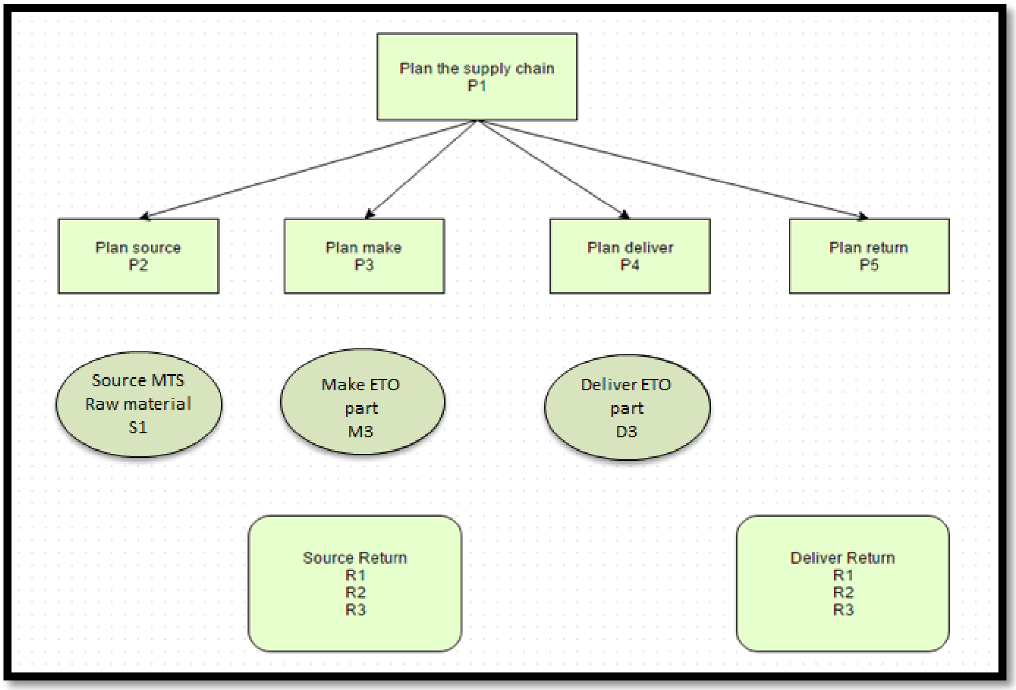

Figure 3 To-Be: SCOR model for additive manufacturing of hip stems.

Level 1

Plan: Level 1 consists of P1, P2, P3, P4 and P5 process categories.
P1 – Plan the Supply Chain.
P2 – Plan Source: To additively manufacture a hip replacement, the important resources are medical engineers (CAD and FEA), technicians, CT scanner, EBM machines, medical grade Cr and Cu alloy powder/Ti powder, EBM and CNC operators and machine tools etc.
P3 – Plan Make: The process planning for the manufacturing needs to be done beforehand.
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 is ordered and manufactured but is no longer required happens when the patient dies during the manufacturing process.

Level 2

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. Level 3 and Level 4 process for Source, Make, Deliver and Return processes are a disintegration of processes and differ between organizations.

3.3 Simulation Model

The SCOR models provided in the previous sections provide a foundation for building a simulation model from the supply chain information. The simulation model is manually built using the information from the SCOR model. Arena is chosen as the simulation language as it translates the activities of SCOR into a network based simulation system. SCOR model has nodes and process flow models similar to Arena and hence it is easier to translate the SCOR model into an Arena simulation model. As a basis for the simulation, there are about 332,000 hip replacement surgeries every year in the U.S. Revision surgeries are primarily performed due to aseptic loosening of the hip stem. This information will serve as the basic demand, where we assume that in the future half of these surgeries will utilize custom hip stems, 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 for our model of 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. The model created here is only simulated to determine resource capacities. The structure of a simulation model is shown in Figure 5.

To build this simulation, following assumptions were made:

1. The processing times for each operation has been assumed to have a triangular distribution and te arrival rate of patients into the system has been assumed to be random exponential.
2. A success rate of 95% has been assumed for the FEA analysis of the part and a 99% success rate has been assumed for the quality control node.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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.
8. 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%.

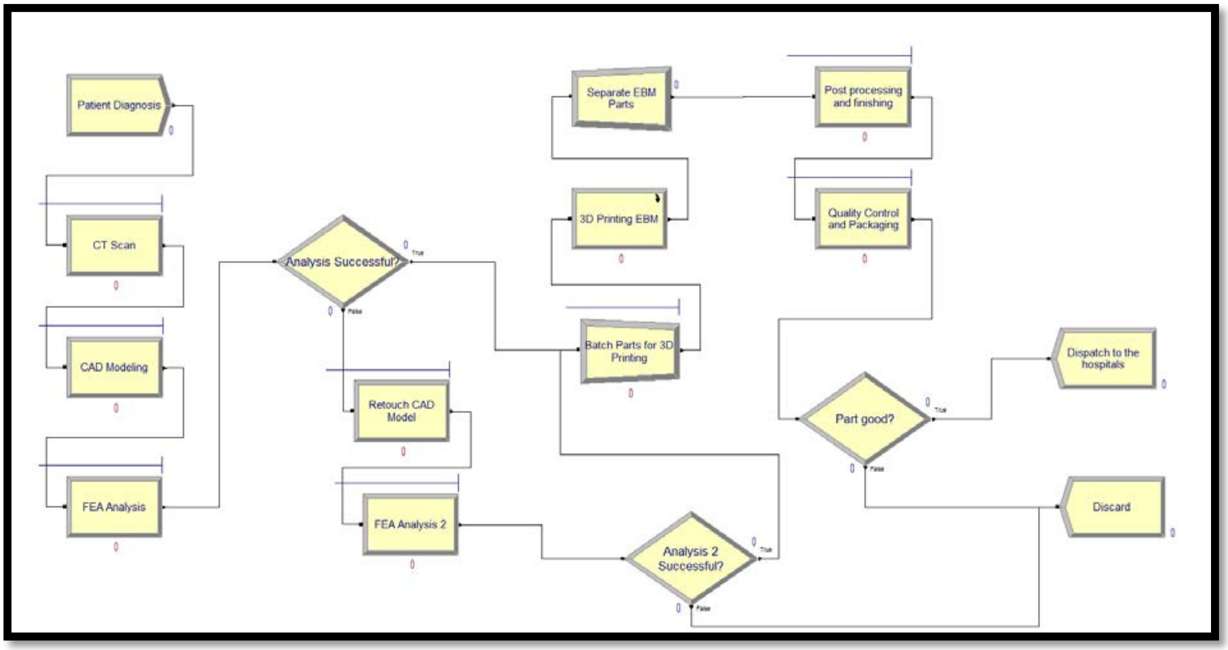

Figure 4 Simulation model for additive manufacturing of hip stems.

The simulation model was created using Arena. The processing time for each operation was taken as triangularly distributed with liberal assumptions. As this simulation was built, we realized that the main bottlenecks in this operation are the powder capacity, the number of EBM machines for the build, and the skilled medical engineers and EBM/CNC operators required. The metal powder was 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.

4 RESULTS AND DISCUSSIONS

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. 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.

4.1 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 judgment 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 (BioCrossroads 2009). Zimmer, DePuy (wholly owned subsidiary of Johnson & Johnson), Biomet are the three major companies in this market in Indiana. Figure 6 shows a map of the general idea of how the "As-Is" supply chain looks like.

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 the patient's geometry, completely relying on experience and judgement.

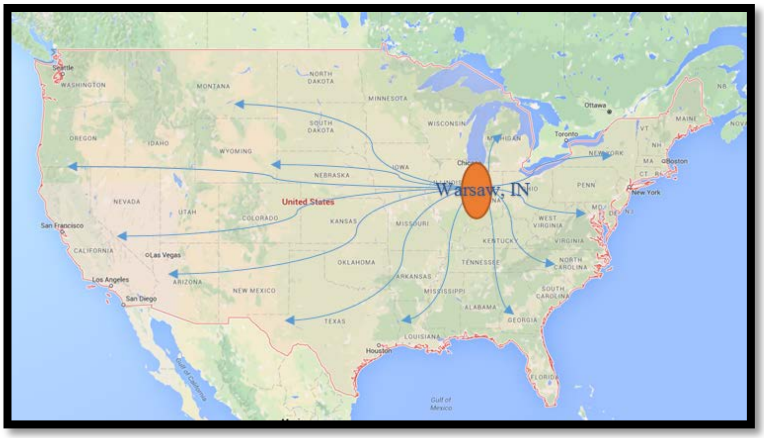

Figure 5 The As-Is supply chain.

For the "To-Be" supply chain, this research discusses 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 7 represents how the "To-Be" supply chain will generally look like.

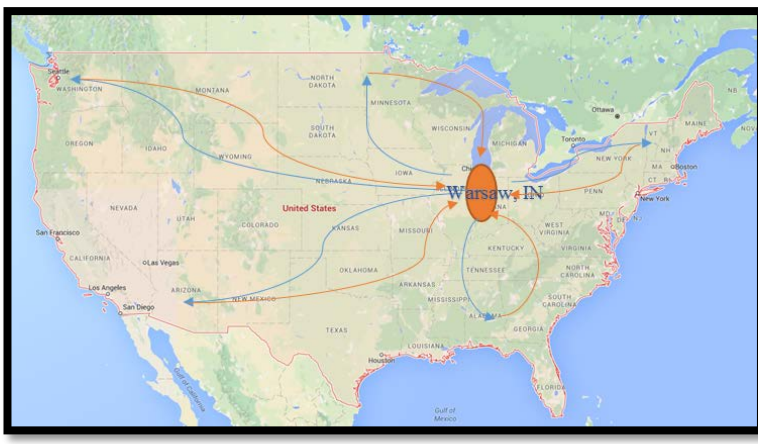

Figure 6 The To-Be supply chain.

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.

4.2 Simulation Results

For the simulation model of the AM based manufacturing of hip stems, the EBM machines were run 24*7 for the entire year, while the other machines and processes were run 5 days a week and 9 hours per day, considering 200 working days. The aim is to find the required resource capacities to meet half of the yearly requirement (166,000) using the AM process. Table lists the capacities for the resources.

Table 1 Resource capacities for the AM model.

Resource Type	Capacity
Technicians	585
Medical Engineer CAD	1190
Medical Engineer FEA	585
EBM Operator	50
EBM Machines	110
CNC Operator	440
Quality Control Inspector	145
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.

4.3 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 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 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. 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 would 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 (Arcam 2015). 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.

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 might change the entire face of the current supply chain and make the AM based supply chain more time and cost efficient.

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