DESIGN FOR MASS CUSTOMIZATION OF MEDICAL DEVICES VIA PLATFORM METHODOLOGY

A Thesis Presented

by

Tathagat Siddharth Pathak

to

The Department of Mechanical and Industrial Engineering
in partial fulfillment of the requirements

for the degree of

Master of Science

in the field of

Industrial Engineering

Northeastern University
Boston, Massachusetts

August 2014
Abstract

The medical device industry seeks to deliver customized products to a vast variety of its customers. Medical device companies are looking for ways to decrease the product development cost and at the same time increase heterogeneity in products. In other words, the industry is looking for new methods and approaches to mass customize medical devices. This thesis presents a novel design methodology for mass customization of medical devices. The thesis proposes an approach to developing individualized devices to custom fit to the patient’s physiology. It applies techniques from mass customization to design medical devices to contain cost and handle large varieties of patient geometries. It uses the Design Structure Matrix (DSM), scalable product architecture and product platforms design processes to develop mass customized medical device concepts. The proposed method is demonstrated on hip and knee implant products to show its applicability to numerous medical devices. The hip and knee implants are divided into components and then analysed utilizing the DSM and product platform design techniques to generate scalable and modular implants each with different shape and size. The developed design implants are then analysed using finite element analysis to ensure that the new components can support the forces encountered by them once they are implanted in a human body.
Acknowledgements

First and foremost, I would like to express my most sincere gratitude to my advisors Dr. Abe Zeid, Dr. Sagar Kamarthi and Dr. Tucker Marion for their guidance and patience. I thank them for teaching me all the skills necessary to complete this journey.

I would also like to thank Andrew G. Wallace and Adam Medla for their help in the 3D Design of Hip & Knee Implant and special thanks to Donald W. Blanchet M.S.M.E for his help with the stress analysis of the implants.

I would like to thank my parents, Siddharth Pathak and Anokhi Pathak, my American family, Gretchen Bronke, Bob Bronke and Doris Neilson, my good friend Sandeep Lahiri and my mentors, Stoney Lingo and Helder Simoes for their endless support and patience. Without them I couldn’t have come this far. I thank them for always being there for me.

I am grateful to Northeastern University for supporting my research. This work was supported by Northeastern University Tier 1 Interdisciplinary Research Proof of Concept Grant, “Research Frontiers in Healthcare Mass Customization for Personalization of Diagnosis, Care and Cure”.

Thank You Very Much God. Jai Shri Krishna.
# Table of Contents

Abstract .................................................................................................................................................. i

Acknowledgements ................................................................................................................................... ii

Table of Contents .................................................................................................................................... iii

List of Figures .......................................................................................................................................... viii

List of Tables .......................................................................................................................................... xii

Chapter 1 Introduction ........................................................................................................................... 1  
1.1 Overview of Medical Devices ............................................................................................................. 1
1.2 Problem Statement .............................................................................................................................. 2
1.3 Proposed Solution ............................................................................................................................... 2
1.4 Thesis Contribution ............................................................................................................................. 3

Chapter 2 Tools for Developing Mass Customized Medical Devices ................................................. 4
2.1 Product Platform Methodologies ........................................................................................................ 4
2.2 Product Review ..................................................................................................................................... 6
2.3 Design Structure Matrix (DSM) .......................................................................................................... 7
2.4 Energy Material-Signal Diagram (EMS) .............................................................................................. 9
2.5 Interface Diagram .............................................................................................................................. 11
2.6 Design for Mass Customized Medical Devices (DMCMD) .............................................................. 11
Chapter 3 Hip Implant Customization

3.1 Product Review

3.2 Design Structure Matrix (DSM)

3.3 Energy Material-Signal Diagram (EMS)

3.4 Interface Diagram

3.5 Customized Designs

3.6 3-D Prototype of Designs

Chapter 4 Knee Implant Customization

4.1 Product Review

4.2 Design Structure Matrix (DSM)

4.3 Energy Material-Signal Diagram (EMS)

4.4 Interface Diagram

4.5 Customized Designs

4.6 3-D Prototype of Designs

Chapter 5 3D modeling of Hip and Knee Implants

5.1 Hip Implant Products Design

5.1.1 Acetabular Cup Design

5.1.2 Femoral Head Design

5.1.3 Plastic Liner Design

5.1.4 Femoral Stem Design
5.2 Hip Implant Assembly Setup ................................................................. 41
5.3 Knee Implant Products Design ............................................................... 41
5.3.1 Femoral Component 1 Design .............................................................. 42
5.3.2 Femoral Component 2 Design .............................................................. 42
5.3.3 Plastic Spacer Design ......................................................................... 43
5.3.4 Tibial Component 1 Design ................................................................. 46
5.3.5 Tibial Component 2 Design ................................................................. 46
5.4 Knee Implant Assembly Setup ................................................................. 47
5.5 Hip and Knee Implant Products Rapid Prototyping ............................... 48
6.1 Problem Setup: Assembly Analysis ......................................................... 51
6.2 Material Properties .................................................................................. 52
6.3 Contact Interactions ................................................................................ 53
6.4 Loading and Boundary Conditions .......................................................... 54
6.5 Meshing .................................................................................................... 54
6.6 Stress Analysis Results ............................................................................ 55
6.6.1 Hip Implant with Circular Interface ..................................................... 55
6.6.2 Hip Implant with Square Interface ...................................................... 56
6.6.3 Hip Implant with Elliptical Interface .................................................... 57
6.7 Displacement Results .............................................................................. 58
6.7.1 Hip Implant with Circular Interface: .................................................... 58
6.7.2 Hip Implant with Square Interface ................................................................. 58
6.7.3 Hip Implant with Elliptical Interface ............................................................. 59
6.8 Factor of Safety Results .................................................................................. 61
6.8.1 Hip Implant with Circular Interface ............................................................. 61
6.8.2 Hip Implant with Square Interface ............................................................... 61
6.8.3 Hip Implant with Elliptical Interface ............................................................ 62

Chapter 7 Finite Element Analysis of Knee Implant ................................................. 64
7.1 Problem Setup: Assembly Analysis ................................................................. 64
7.2 Material Properties ......................................................................................... 65
7.3 Contact Interactions ....................................................................................... 65
7.4 Loading and Boundary Conditions ................................................................. 66
7.5 Meshing .......................................................................................................... 67
7.6 Results ........................................................................................................... 68
7.6.1 Knee Implant customized products stress analysis ....................................... 68
7.6.2 Knee Implant customized products FEA displacement ................................ 71
7.6.3 Knee Implant customized products FEA Factor of Safety ............................. 73

Chapter 8 Discussion and Conclusion ................................................................. 76
8.1 Discussion ....................................................................................................... 76
8.2 Conclusion ...................................................................................................... 78

References ........................................................................................................... 80
Appendix: Hip implant analysis for different materials .................................................. 85
List of Figures

Figure 2.1: Module based product family development architecture .......................... 4
Figure 2.2: Sony Walkmans™ module based product .............................................. 5
Figure 2.3: Example of braun coffee makers modular products ................................ 5
Figure 2.4: Rolls Royce scalar product family ......................................................... 6
Figure 2.5: Example of DSM application on interaction of components ..................... 8
Figure 2.6: Steps for developing DSM for medical device X .................................... 8
Figure 2.7: EMS diagram ......................................................................................... 10
Figure 2.8: Interface diagram ................................................................................... 11
Figure 2.9: Proposed Design for Mass Customized Medical Devices (DMCMD) ........ 13
Figure 3.1: A hip and its implant ............................................................................. 15
Figure 3.2: DSM of hip implant product ................................................................. 16
Figure 3.3: EMS of a hip implant product ............................................................... 17
Figure 3.4: Interface diagram of hip implant ............................................................ 18
Figure 3.5: Present interface of the hip implant ....................................................... 18
Figure 3.6: New proposed square and elliptical interfaces ....................................... 18
Figure 3.7: Solidworks™ CAD module scale stem and head platform .................... 20
Figure 3.8: Solidworks™ CAD module scale hip products ..................................... 21
Figure 3.9: 3D Hip Implant Product Prototype ...................................................... 22
<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>A knee and its implant</td>
<td>23</td>
</tr>
<tr>
<td>4.2</td>
<td>Total knee replacement</td>
<td>24</td>
</tr>
<tr>
<td>4.3</td>
<td>DSM of knee implant product</td>
<td>25</td>
</tr>
<tr>
<td>4.4</td>
<td>EMS diagram of knee implant product</td>
<td>26</td>
</tr>
<tr>
<td>4.5</td>
<td>Interface diagram of knee implant</td>
<td>27</td>
</tr>
<tr>
<td>4.6</td>
<td>Present interface between plastic spacer and tibial component</td>
<td>27</td>
</tr>
<tr>
<td>4.7</td>
<td>Proposed two new common interfaces</td>
<td>27</td>
</tr>
<tr>
<td>4.8</td>
<td>Modular customized plastic spacer platforms of the knee implant</td>
<td>29</td>
</tr>
<tr>
<td>4.9</td>
<td>Modular customized knee implant products</td>
<td>30</td>
</tr>
<tr>
<td>4.10</td>
<td>Modular customized knee implant 3D prototype products</td>
<td>31</td>
</tr>
<tr>
<td>5.1</td>
<td>Acetabular cup sketch</td>
<td>33</td>
</tr>
<tr>
<td>5.2</td>
<td>Tapped hole sketch</td>
<td>33</td>
</tr>
<tr>
<td>5.3</td>
<td>Design tree and acetabular cup design</td>
<td>34</td>
</tr>
<tr>
<td>5.4</td>
<td>Femoral head sketch</td>
<td>34</td>
</tr>
<tr>
<td>5.5</td>
<td>Dowel hole for femoral stem with circular interface</td>
<td>35</td>
</tr>
<tr>
<td>5.6</td>
<td>Elliptical hole in the head for the stem with elliptical interface</td>
<td>35</td>
</tr>
<tr>
<td>5.7</td>
<td>Square hole in the head for the stem with square interface</td>
<td>36</td>
</tr>
<tr>
<td>5.8</td>
<td>Femoral heads for stems with various interfaces</td>
<td>36</td>
</tr>
<tr>
<td>5.9</td>
<td>Design tree of femoral head</td>
<td>36</td>
</tr>
<tr>
<td>5.10</td>
<td>Plastic liner sketch</td>
<td>37</td>
</tr>
</tbody>
</table>
Figure 5.11: Design tree and plastic liner design ................................................. 38
Figure 5.12: Base sketch for stem interfaces .............................................................. 38
Figure 5.13: Lofted femoral stem .............................................................................. 39
Figure 5.14: Design tree and stem with circular interface extruded ......................... 40
Figure 5.15: Stem with square and elliptical interface extruded ............................... 40
Figure 5.16: Hip implant assembly and mates ............................................................ 41
Figure 5.17: Femoral component 1 design ................................................................. 42
Figure 5.18: Femoral component 2 design ................................................................. 43
Figure 5.19: Plastic spacer platform 1 design ............................................................. 44
Figure 5.20: Plastic spacer platform 2 design ............................................................. 44
Figure 5.21: Plastic spacer platform 3 design ............................................................. 45
Figure 5.22: Plastic spacer platform 4 design ............................................................. 45
Figure 5.23: Tibial component 1 design ..................................................................... 46
Figure 5.24: Tibial component 2 design ..................................................................... 47
Figure 5.25: Knee implant assembly and mates ......................................................... 48
Figure 5.26: Dimension sst 1200es rapid prototyping machine ............................... 49
Figure 5.27: 3D prototypes of hip and knee implant designs ..................................... 50
Figure 6.1: Contact sets for FEA of hip implant products ........................................ 54
Figure 6.2: Loading and boundary conditions for hip implant stress analysis .......... 55
Figure 6.3: Module scale hip implant mesh .............................................................. 56
Figure 6.4: FEA of customized hip product with circular interface ........................................ 57
Figure 6.5: FEA of customized hip product with square interface ................................. 57
Figure 6.6: FEA of customized hip product with elliptical interface ............................ 58
Figure 6.7: Displacement of customized hip product with circular interface ............... 59
Figure 6.8: Displacement of customized hip product with square interface ............... 60
Figure 6.9: Displacement of customized hip product with elliptical interface .......... 61
Figure 6.10: Factor of safety of customized hip product with circular interface ....... 62
Figure 6.11: Factor of safety of customized hip product with square interface .......... 63
Figure 6.12: Factor of safety of customized hip product with elliptical interface ...... 64
Figure 7.1: Contact sets for FEA of knee implant products ............................................ 67
Figure 7.2: Loading and boundary conditions for knee implant stress analysis .......... 68
Figure 7.3: Modular knee implant mesh ........................................................................... 69
Figure 7.4: FEA of modular customized knee products .................................................. 71
Figure 7.5: Displacement of modular customized knee products .................................. 74
Figure 7.6: Factor of safety of modular customized knee products ............................... 76
Figure 8.1: Operation phases in DMCMD method .......................................................... 76
Figure A.1: Different material FEA results of hip product with circular interface ...... 86
Figure A.2: Different material FEA results of hip product with elliptical interface ...... 87
Figure A.3: Different material FEA results of hip product with square interface ...... 88
List of Tables

Table 6.1: Material Properties of Ti6Al4v ................................................................. 52

Table 6.2: Material Properties of Cross-Linked High Density Polyethylene .............. 52
Chapter 1 Introduction

1.1 Overview of Medical Devices

A medical device is a biocompatible artificial object utilized or inserted in the human body to diagnose, cure or avert a disease or a distinct condition or substituted for dysfunctional body unit [1]. Applications of medical devices are highly complicated due to complex human physiology. Illustrations range from simple devices such as thermometers and tongue depressors to cutting edge devices like implants and prostheses.

According to the Food and Drug Administration (FDA), medical devices are categorized into three classes: class 1, 2 and 3, based on the level of control required to prove their safety and effectiveness.

Class 1 devices, are subjected to the least regulatory control, they are not critical to support human life and are considered less likely to cause illness or injury. Elastic Bandages, nitrile gloves and surgical instruments are some of the examples of Class 1 Devices. About 47% of medical devices fall under this category out of which 95 % are exempted from the regulatory process [2].

Class 2 devices pose moderate amount of risks and that is why they are approved through the 510(k) FDA approval process. Examples of Class 2 devices include powered wheelchairs, pregnancy test kits, and hip and knee implants. Nearly 43% of medical devices fall under this category [2].

Class 3 devices pose the maximum amount of risk to human health and safety. Therefore
they are the most regulated devices by the FDA among all 3 classes of devices. These devices have to pass through the premarket approval (PMA) process in which the device manufacturer has to submit pre-clinical as well as clinical information to demonstrate its safety and effectiveness. These devices also require general as well as special controls [1]. Examples of Class 3 devices include implantable pacemakers, breast implants, and automated external defibrillators. Approximately 10% of medical devices fall under this category [2].

1.2 Problem Statement

Medical device companies either develop one-size-fits-all products or a highly customized product for very rare cases. This represents an opportunity for developing customized low cost products at the individual level. However, many companies are finding it difficult to customize medical devices at mass scale while still being dexterous in creating individualized devices. Additionally, firms are under pressure to produce successive generations of devices in order to reduce the product development time and cost. As documented by Dalgarno, et al. [3], companies are meeting the challenge by adopting mass customization strategies for creating individualized devices. Mass customization of devices, according to Marion et al. [4], is “the ability to design and manufacture a customized product at mass production speed and efficiency.”

1.3 Proposed Solution

The medical device industry can leverage product platform methodology for developing a variety of customized products. This will lead to a reduction in manufacturing costs and
process complexity, while increasing the variety of customized products. Ulrich and Robertson have mentioned that “by sharing components and production processes across a platform of products, companies can develop differentiated products efficiently, increase the flexibility and responsiveness of their manufacturing processes, and take market share away from those competitors that develop only one new product at a time.” [5].

1.4 Thesis Contribution

The purpose of this thesis is to develop a methodology for designing mass customized medical devices leveraging product platform techniques. This approach combines several established tools to form a unique methodology which will assist the design engineer to identify and arrange component architecture and interfaces. In the design process, since medical devices are complex compared to other consumer products, we add a dimension of the Design Structure Matrix (DSM) to understand the relationship of each part with other parts of a complex system [11]. Additionally, we use the concept of modularization to organize complex designs and process operations more efficiently by decomposing complex systems into simpler portions [12]. Combining DSM, mass customization, product platforms and modularity, a firm can economically develop a customized medical device for an individual.
Chapter 2 Tools for Developing Mass Customized Medical Devices

2.1 Product Platform Methodologies

There are two main custom platform based device development techniques:

**Module-Based Product Family Development:** In this approach several different products are created by adding, subtracting or replacing one or a combination of modules from the product platform [6] as shown in Figure 2.1.

![Module-based product family development architecture](image)

Figure 2.1: Module-based product family development architecture [6]

Following are some of the example of modular product families from the literature:

- Sony developed 250+ Walkmans™ in the 1980’s by leveraging modular designs in USA. Example of Walkmans™ is shown in Figure 2.2 [7].
**Figure 2.2:** Sony Walkmans™ module based product [7]

- Braun Family of Coffee Makers, this product family is another example of a modular platform as shown in Figure 2.3 [6]

**Figure 2.3:** Example of braun coffee makers modular products [6]

**Scale Based Product Family Development:** In this technique, one or more dimensions of the product platform is increased or decreased to develop a variety of products for various market niches [8]. Rolls Royce utilized a scalar platform to develop a variety of products delivering different horsepower and thrust by scaling its RTM 322 design example, as shown in Figure 2.4.
Integrating four different paradigms of research: DSM, product platforms in the form of energy material signal diagram, modularity and mass customization in the form of interface diagram and customized designs respectively. Combining these techniques leads to the formation of a unique methodology termed Design for Mass Customized Medical Devices (DMCMD). The remainder of this thesis applies the developed concept to customizing hip and knee implant products. Multiple designs are developed for each implant. Finite element analysis is performed on each design in the Solidworks™ CAD tool and each design is then critiqued. The method and model are discussed in chapter 7 and conclusions are drawn with implications for future work in chapter 8.

2.2 Product Review

It is necessary to understand the present design of the medical device product to begin the first phase of mass customized product development. The knowledge gained from this research will help one to develop a roadmap for a particular medical device. Next product
Platforms methodology is applied to develop the modular, scalar or module scale platform. Utilizing that platform numerous customized products are developed.

Tools covered in the remainder of this chapter have not been applied to medical implants. In this thesis they are applied innovatively to the customization of medical devices, specifically medical implants.

2.3 Design Structure Matrix (DSM)

According to Lindemann [13], a DSM is “a simple tool to perform both the analysis and the management of complex systems. It enables the user to model, visualize, and analyze the dependencies among the entities of any system and derive suggestions for the improvement or synthesis of a system”. It is also known as a problem solving matrix (PSM). The DSM is a square matrix which can be used in understanding various complex systems [15].

DSM-based design methodologies are applied in various disciplines. They are used for project scheduling and management in new product development [14]. A DSM helps one to analyze a particular system using powerful clustering algorithms. In this thesis a component-based DSM, which is also known as architecture DSM is used. Component-based DSM success has been proven by Pimmler and Eppinger [16] at Ford Motor Company for developing modular design for an automatic climate control system. Figure 2.5 shows an example of DSM. Utilizing the DSM in developing a customized medical
device platform is unique to the overall concept of Design for Mass Customized Medical Devices DMCMD.

A component-based DSM is useful to decompose, document and analyze the medical device X. Since medical devices are very complex assemblies, a DSM serves as a tool to manage and decompose the device. These are the steps we are going to follow for understanding the complexity of the medical device also shown in Figure 2.6:

(1) Decompose the device into elements
(2) Understand and document the interactions between the elements
(3) Analyze the potential reintegration via clustering

Figure 2.6: Steps for developing DSM for medical device X
2.4 Energy Material-Signal Diagram (EMS)

In order to apply mass customization, it is important to develop a framework for the device. During the design process, it is necessary to separate the components that interact with the customer/patient the most. Since some of the medical devices are fitted inside the patient’s body, it can be a challenge to understand the component interaction with the body parts as well as the other component/s of the device itself.

As defined by Fujimoto [17] product architecture is “the overall mapping to envision and identify product functions and distribute them through common elements and critical interfaces through which vital information and value creation are shared and realized.”

This will be useful in developing modular product architecture with platform-based design. Steps for the modular product architecture are as follows [17]:

1. Find the desirable functions of the product
2. Divide the functions depending on various components
3. Plan the interfaces among the component parts which interact

The Energy Material Signal (EMS) diagram is useful for developing a modular medical device architecture that is an extension of “black box” model, which is used for defining input and output of a system. It is a simple diagram used for visualizing the electromechanical system in addition to inputs and outputs to and from the system [18]. The EMS diagram is an augmentation of the function diagram; it is a visual tool for recognizing energy, material and/or signal flows, which are either hurtful or incompetent [19].
Figure 2.7: EMS diagram of a hip implant product

The EMS shown in Figure 2.7 is an example of how it can be used for developing a modular medical device platform. Various components are named starting from C1 to C5. As one can see in the Figure, the primary interface C1 could be an electric switch, which when pressed activates a motor to provide mechanical movement to C2. This in turn initiates the electrical input and oil transfer to C3 in addition to providing mechanical input to C4. Finally, C4 provides the mechanical input to C5. The dashed rectangular shapes in the Figure represent the possible platforms for the particular product. By utilizing EMS, one can also define a component or a platform, which can be mass customized [4]. By decomposing a medical device via EMS, one can develop platform architecture for the device in addition to identifying possible components for mass customization. EMS as described is used for understanding the flow between various components of the device. In this thesis, EMS is utilized in a different and distinct way in order to understand the connection between the medical device components.
2.5 Interface Diagram

The interface diagram can be developed using the information gained from the EMS diagram. Through the interface diagram one will be able to find common components or parts for mass customization [20]. As can be seen in Figure 2.8, there are a total of three platforms. The mass customized platform, which includes C2 and C3, does not interact with the customer but interfaces internally with components C1 and C4. The interface diagram was used to identify a mass customized platform as compared to mass customized components, thus contributing in the development of modular, scalar or module scale platform for customized device design.

![Interface Diagram](image)

Figure 2.8: Interface diagram

2.6 Design for Mass Customized Medical Devices (DMCMD)

The method described above as a combination of various tools is explained as a whole in this section. Utilizing the proposed tool, an engineer can mass customize any medical device with ease. The design for mass customized medical devices (DMCMD) is a new
product platform methodology to be applied in the development of customized medical device products leveraging the combination of product platform methodology described above. The DMCMD shown in Figure 2.9 starts with product research to identify the proper medical device $X$. Secondly the DSM is applied to understand the complexity of the medical device $X$ by decomposing, documenting and analysing the device. Step 3 defines the platform for the medical device using the EMS diagram in addition to identifying the mass customized component in the platform developed. Step 4 uses the Interface diagram to define various interfaces for the mass customized component identified. Step 5 generates a 3D design of the medical device $X$ using design software. Step 6: A 3D prototype is constructed to verify the design. Figure 2.9 show the steps of DMCMD.
Figure 2.9: Proposed design for mass customized medical devices (DMCMD) method
Chapter 3 Hip Implant Customization

3.1 Product Review

One of the most common implant operations among patients is the hip replacement using a hip implant. The hip implant has been chosen as one of the examples to show the impact of our method on medical devices. Hip implants [21] consist of a ball and socket joint in which the pelvis is the socket inside which the femur ball fits. Damage in the hip can be due to either osteoarthritis as shown in Figure 3.1(A) or wear and tear arthritis. The latter type of arthritis is caused by degeneration of cartilage over time which causes the bone ends to rub against each other.

Hip implants are common practice today. The artificial hip joint consists of 4 parts including femoral stem, femoral head, polyethylene liner and acetabular cup as shown in Figure 3.1(B).

There are various types of hip implants available in the market, based on the patient needs as listed below [22]:

1. Stem type with acrylic cement fixation
2. Stem type without cement fixation
3. Stem type with hybrid fixation
4. Bearing materials used in joint replacement
5. Metal on metal bearings
(6) Ceramic on ceramic bearings

(7) Hemi surface replacement for osteonecrosis

(8) Surface replacement of the hip

The proposed method concentrates on total hip replacement without cement fixation product which is, also known as "metal-on-plastic" hip implant as shown in Figure 3.1(C).

![Figure 3.1: A hip and its implant]
3.2 Design Structure Matrix (DSM)

Next, step 2 is applied to the hip implant product. The DSM is developed to understand the complexity of the medical implant product. From the DSM shown in Figure 3.2 it is clear that the femoral stem is connected to the femoral head. The femoral head and plastic liner are both connected in a manner which makes them very important components of an hip implant product. DSM helps one to determine which components to focus on. In this case it is the femoral head and the plastic liner.

![Hip Implant DSM](image)

Figure 3.2: DSM of hip implant product

Before advancing to step 3, it is important to understand how the two end components of the hip implant, the femoral stem and the acetabular cup, are connected to other bones. With the help of Figure 3.3(A) one learns that femur stem is connected to condyles which are further connected to the knee. The acetabular bone is connected to pelvic bone.
3.3 Energy Material-Signal Diagram (EMS)

As a third step, utilizing the EMS diagram, the hip implant is deconstructed as shown in Figure 3.3(B). It shows that all components are mechanically connected. Three different platforms have been developed: platform 1 for the stem, platform 2 for the head and liner, platform 3 for the cup. Figure 3.3(B) also indicates femoral head as the mass customized component. The next section demonstrates mass customization of this component in detail. Thus developing various platforms will be useful for further preparing the interface diagram.

![Figure 3.3: EMS of a hip implant device](image)

(A) End components connections[23]  (B) EMS diagram of hip implant

Figure 3.3: EMS of a hip implant device
3.4 Interface Diagram

As shown in Figure 3.4, one can observe that there is only one interface proposed in the new customized hip implant product. In this Figure it can be noticed that the plastic liner is not mentioned. The original hip implant product has the liner fixed with the cup and therefore they are combined to make one platform in the interface diagram as platform 3. The original circular interface is shown in Figure 3.5. The new interfaces developed are square and elliptical in shape as shown in Figure 3.6. Both the proposed interface models provide a better locking mechanism between head and cup.

![Interface Diagram](image1)

Figure 3.4: Interface diagram of hip implant

![Actual implant and CAD model](image2)

Figure 3.5: Present interface of the hip implant
3.5 Customized Designs

3D computer-aided-design (CAD) modelling of the customized hip implant has been performed using Solidworks™. In this design the diameter of the head is scaled, utilizing the information gained from the EMS diagram. The scalar customized platform of the femoral head is developed as shown in Figure 3.7. As noticed in Figure 3.7 the femoral head is scaled very similar to the Rolls Royce example [8]. By scaling the head itself one can develop numerous products of hip implant which would fit individual's hip with different physiologies. In addition, as in Figure 3.7, the modular stem is shown with square and elliptical interfaces. Each provides a better locking mechanism to the femoral head. Combining the modular stem and the scalar head makes a unique module scale hip implant product platform. Utilizing the developed module scale platform, more products can be generated in a manner similar to the scalar platform of the femoral head. Figure 3.8 shows a 3D model of customized hip implant products utilizing the combined module scale platform of stem and head with the assembly of acetabular cup and liner. The 3D design thus helps in observing the impact of DMCMD on the customization of the hip
implant product, which is further applied to the knee implant in the next section.

Figure 3.7: Solidworks™ CAD module scale stem and head platform
Lastly, in order to verify the design, a 3D prototype is developed as shown in Figure 3.9. The prototype helps in validating the design, thus proving that DMCMD is a useful technique for the medical device industry. This technique will provide patients requiring
customized products with individualized devices at the same price of mass production of a one-size-fits-all device.

Figure 3.9: 3D Hip Implant Product Prototype with square interface
Chapter 4 Knee Implant Customization

4.1 Product Review

Another very common implant operation among patients is knee replacement surgery. As per orthopaedic info, there are more than 600,000 knee replacement surgeries performed each year in the USA [24]. Knee replacement is a replica of a hinge joint with its movement very similar to the hinged door. As shown in Figure 4.1(A) the tibial plate and polyethylene part are fixed while the femoral component has the ability to bend and straighten [25]. Currently the market has around 150 varieties of knee replacement products sold by different manufacturers [25]. Due to arthritis as shown in Figure 4.1(B) or injury, it becomes difficult for a patient to do daily activities like walking and running. The patient may also experience pain while sitting or lying down. Thus to reduce pain and allow the patient to resume normal activities, knee replacement surgery is performed.

![Figure 4.1: A knee and its implant](image)

(A) Arthritic knee  
(B) Knee implant with various components
There are various different types of knee implant products available in the market as listed below [26]:

1. Total knee replacement
2. Unicompart mental (partial) knee replacement
3. Kneecap replacement
4. Complex or revision knee replacement

DMCMD method impact is demonstrated focusing on the total knee replacement product also known as "metal-on-plastic" knee implant as shown in Figure 4.2(A).

Figure 4.2: Total knee replacement components

(A) Total knee replacement components  (B) X-Ray of total knee replacement

4.2 Design Structure Matrix (DSM)

By applying the design structure matrix (DSM), the components internal interaction of the knee implant product can be understood. As demonstrated in Figure 4.3 there are two main connections: one between the femoral component and the plastic spacer and the
other between the plastic spacer and the tibial component. Analysing the DSM, it is realised that the plastic spacer is a very important component in the customized platform development. The reason for this is that the spacer is connected to both the hinged femoral component and the fixed tibial component. As shown in Figure 4.2(B), the tibial component is connected to the tibia and the femoral component is connected to the femur [27]. This connection will be useful in the development of the energy material signal diagram.

![Knee Implant DSM](image)

**Figure 4.3: DSM of knee implant product**

### 4.3 Energy Material-Signal Diagram (EMS)

As the next step in developing a customized platform, the EMS diagram is utilized to deconstruct the functions of the knee implant thus leading to the development of a better modular architecture as shown in Figure 4.4. The femoral component (platform 1), which replicates the knee of a patient is connected mechanically to the femur (bone) and plastic spacer (implant component) with a movement similar to a hinged door. The tibial component is also connected mechanically to the plastic spacer and tibia. Both the EMS and the DSM demonstrate the significance of the plastic spacer. Therefore the plastic spacer is chosen to be customized, shown in Figure 4.4 as the mass customized
component. Additionally, potential modular platforms are also shown in the EMS diagram inside square boxes.

![Figure 4.4: EMS diagram of knee implant product](image)

### 4.4 Interface Diagram

Utilizing the potential platforms information from the EMS diagram, the interface diagram is developed to identify a common interface. This goes further to the development of the customized modular platform. As shown in Figure 4.5 there is no new interface proposed between the femoral component and the plastic spacer, while a new interface is proposed between the plastic spacer and the tibial component. Figure 4.6 also shows that at present there is no interface between the plastic spacer and the tibial component: they are simply bonded with each other. A 3D CAD model of the two new proposed interfaces have been developed as shown in Figure 4.7. Both proposed interfaces shown in the Figure are similar in dimensions. The only difference is that the interface number 2 has a keyway. The reason for developing two separate interfaces is
explained in detail in the 3-D modelling of the knee implant in section 4.5.

Figure 4.5: Interface diagram of knee implant

Figure 4.6: Present interface between plastic spacer and tibial component

Figure 4.7: Proposed two new common interfaces
4.5 Customized Designs

3-D CAD models are developed utilizing the platforms and interfaces proposed in the previous steps. As shown in Figure 4.8 four different platforms are identified each of which can be used as a modular customized component to develop a range of knee implant products. Plastic spacer platform 1 is very similar to the knee implant product presently available on the market; the only difference is the interfaces shown in Figure 4.7. Plastic spacer platform 2 is customized by leveraging the same design as platform 1 but with more support for the femoral component, depending on the specific physiology of the individual. Plastic spacer platform 3 is customized by developing a keyway to the common interface proposed above, thus providing a locking mechanism between the plastic spacer and the tibial component of the implant. Plastic spacer platform 4 is customized by adding more material depth to platform 2 for patients who are heavy, since most of the knee implants need to be replaced within 5-10 years due to excessive wear and tear on the spacer. Figure 4.8 demonstrates that, numerous modular customized platforms can be easily developed in response to the individual’s specific needs using DMCMD concepts.
As a final step in Figure 4.9, the femoral components 1 and 2 (shown in two upper corners) are assembled with platform 1 and platform 2 (shown in the centre). These assemblies are then combined with the tibial components 1 and 2 shown in (two lower corners) to develop variety of customized products. As demonstrated in Figure 4.9, 8 different products starting from P1, P2, P3 to P8 are developed utilizing just 2 of the 4 modular customized platforms from Figure 4.8. A family of customized products for patients is developed with different physiologies. This will lead to a reduction in design cost and production cost as the same platform of plastic spacer can be used for creating 4 different products. With further femoral and tibial component designs more products could be developed utilizing the same common plastic spacer platforms.
Figure 4.9: Modular customized knee implant products
4.6 3-D Prototype of Designs

To verify the developed design, a 3-D prototype of the customized knee implant product is manufactured using a rapid prototyping machine. The prototypes of product P1 and P2 are shown in Figure 4.10. These prototypes are created to verify their application on real knee implant products.

![Figure 4.10: Modular customized knee implant 3D prototype products](image-url)
Chapter 5 3D modeling of Hip and Knee Implants

In this chapter, high level steps of various designs of the hip and knee implant products are discussed. 3D prototype of each design is also developed and shown for the verification of each design.

5.1 Hip Implant Products Design

Hip implant components are designed to exactly replicate the total hip replacement product as explained in detail in chapter 3.

5.1.1 Acetabular Cup Design

Acetabular cup is one of the four components of the hip implant product as explained in detail in chapter 3. This component is kept the same in the various hip implant products developed.

Step 1, Draw the sketch and then revolve it 360 degree to develop the acetabular cup, as shown in Figure 5.1.
Step 2, the hole is taped on top of the cup with size M6x1.0, as shown in Figure 5.2.

The design tree and acetabular cup design are shown in Figure 5.3.
5.1.2 Femoral Head Design

Femoral head is the second component of the hip implant. It is also the scalar platform for customizing the products based on patient’s physiology as demonstrated in chapter 3.

Step 1. Draw the sketch and then revolve it 360 degree to develop the femoral head, as shown in Figure 5.4.
Step 2, a dowel hole of diameter 12 mm is developed so that the femoral stem with circular interface could fit in the head, as shown in Figure 5.5.

![Figure 5.5: Dowel hole for femoral stem with circular interface](image)

Since in the design of the customized modular component, a locking mechanism is proposed, two more femoral heads are designed, one with elliptical hole and other with the square hole, to fit the appropriate customized modular femoral stem during the assembly process as shown in Figure 5.6 and 5.7 respectively.

![Figure 5.6: Elliptical hole in the head for the stem with elliptical interface](image)
Figure 5.7: Square hole in the head for the stem with square interface

Finally, the variety of designs of the femoral head is shown in Figure 5.8 to demonstrate the difference in the hole for holding the stem interface.

Figure 5.8: Femoral heads for stems with various interfaces

(B) elliptical interface  (A) square interface

The sample design tree of the circular femoral head design is shown in Figure 5.9.

Figure 5.9: Design tree and circular femoral head design
5.1.3 Plastic Liner Design

Plastic Liner is the third component of the hip implant product explained in detail in chapter 3. This component is also kept the same in the various hip implant products developed.

Step 1, Draw the sketch and then revolve it 360 degree to develop the plastic liner, as shown in Figure 5.10.

![Figure 5.10: Plastic liner sketch](image)

The design tree of the liner and the developed plastic liner are, as shown in Figure 5.11.
5.1.4 Femoral Stem Design

Femoral stem is the fourth component of the hip implant. It is also the modular platform for customizing the products based on patient’s physiology as demonstrated in chapter 3.

Step 1. Draw the sketch as shown in Figure 5.12 to develop a base for various extruded interfaces on the modular stem.
Step 2, create a loft to create exact replica of femoral stem that would fit in human femur bone, as shown in Figure 5.13.

Figure 5.13: Lofted femoral stem

Step 3, create an extruded boss base that would fit in the appropriate femoral head during assembly. Figure 5.14 shows, the stem extruded with the circular interface and the whole stem development design tree. The stems with square and elliptical extruded interface are, as shown in Figure 5.15.
Figure 5.14: Design tree and stem with circular interface extruded

(A) Square interface  (B) Elliptical interface

Figure 5.15: Stem with square and elliptical interface extruded
5.2 Hip Implant Assembly Setup

The assembly of the hip implant is as shown in Figure 5.16. There are a total of 12 mates between hip implant components: 3 concentric mates, 1 parallel mate and 8 coincident mates also shown in Figure 5.16.

Figure 5.16: Hip implant assembly and mates

5.3 Knee Implant Products Design

Knee implant components are designed to exactly replicate the total knee replacement product as explained in detail in chapter 4.
5.3.1 Femoral Component 1 Design

Femoral component 1 design is shown in Figure 5.17 with its design tree.

5.3.2 Femoral Component 2 Design

Femoral component 2 design is shown in Figure 5.18 with its design tree.
5.3.3 Plastic Spacer Design

Plastic spacer is the proposed modular platform in the knee implant product development. The design of the spacer is such that it can be easily customized per patient’s physiology. Plastic spacer platform 1 design is the simplest of all. Its design is shown in Figure 5.19 with its design tree.
Plastic spacer platform 2 is designed to provide more support. Its design is shown in Figure 5.20 with its design tree.

Figure 5.19: Plastic spacer platform 1 design

Figure 5.20: Plastic spacer platform 2 design
Plastic spacer platform 3 is designed to provide locking mechanism by creating keyway. Its design is shown in Figure 5.21 with its design tree.

![Figure 5.21: Plastic spacer platform 3 design](image)

Plastic spacer platform 4 is designed with more plastic for heavy patients. Its design is shown in Figure 5.22 with its design tree.

![Figure 5.22: Plastic spacer platform 4 design](image)
5.3.4 Tibial Component 1 Design

Tibial component 1 design is shown in Figure 5.23 with its design tree.

Figure 5.23: Tibial component 1 design

5.3.5 Tibial Component 2 Design

Tibial component 2 design is shown in Figure 5.24 with its design tree.
5.4 Knee Implant Assembly Setup

The assembly of the knee implant is shown in Figure 5.25. There are a total of 6 mates between hip implant components: 1 concentric mate, 1 parallel mate, 2 coincident mates and 2 distance mates, also shown in Figure.
5.5 Hip and Knee Implant Products Rapid Prototyping

Developed designs were converted to stl files in Solidworks™ software for 3D printing purpose. The products were 3D printed using the dimension sst1200es 3d printing machine shown in Figure 5.26, located in the mechanical and Industrial Engineering laboratory at Northeastern University. Dissolving method was used in printing. It took 24 hours to print the prototypes and 24 more hours for removing the dissolving support utilized in 3d printing. 3D prototypes of the hip and knee implant products developed utilizing this machine are as shown in Figure 5.27.
Figure 5.26: Dimension sst 1200es rapid prototyping machine
Figure 5.27: 3D prototypes of hip and knee implant designs
Chapter 6 Finite Element Analysis of Hip Implant

Over the past decade from November 2002 to July 2011, a total of 578 hip implants were recalled. Issues ranging from design flaws, early failure, manufacturing issues, cracking, and fracturing are some of the many reasons [28]. Recalls were done by well-known medical device companies like Stryker, Zimmer and J&J Depuy. Data suggests that some of the devices recalled were already implanted [28]. Looking at this analysis by safe patient project organisation, it is important to test the products that have been developed by leveraging DMCMD. In order to prove that the module scale customized hip implant products and platforms are robust and safe, static stress analysis is performed on them.

6.1 Problem Setup: Assembly Analysis

The customized module scale hip implant products developed in chapter 3 are converted to three dimensional finite element models. The finite element analysis is carried out utilizing Solidworks™ Simulation tool. Direct sparse solver is utilized for the Finite Element Analysis (FEA). In this study the same materials, contact interactions, meshing, loading and boundary conditions are used for all the developed module scale customized hip implant products. The present study emphasizes the variety of interfaces of the hip implant product.
6.2 Material Properties

As mentioned in chapter 3 we have focused on developing a "metal-on- plastic" hip implant products. In this study the metal material selected is Ti6Al4v. This is a biocompatible material with very high yield strength as shown in Table 6.1[29]. The material selected for plastic liner in this study is cross-linked high density polyethylene. This material is used by most of the medical device companies manufacturing hip implant products in the present market. Material properties for polyethylene are shown in Table 6.2 [30]. The acetabular cup, the femoral head and the femoral stem are considered to be made of Ti6Al4v in the analysis.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tensile strength, ultimate</td>
<td>138000 psi</td>
</tr>
<tr>
<td>Tensile strength, yield</td>
<td>128000 psi</td>
</tr>
<tr>
<td>Modulus of elasticity</td>
<td>16510 ksi</td>
</tr>
<tr>
<td>Density</td>
<td>0.160 lb/in³</td>
</tr>
<tr>
<td>Poisson's ratio</td>
<td>0.342</td>
</tr>
</tbody>
</table>

Table 6.1: Material Properties of Ti6Al4v

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tensile strength, ultimate</td>
<td>1450 - 6240 psi</td>
</tr>
<tr>
<td>Tensile strength, yield</td>
<td>1600 - 6240 psi</td>
</tr>
<tr>
<td>Modulus of elasticity</td>
<td>81.9-218 ksi</td>
</tr>
<tr>
<td>Density</td>
<td>0.0356 lb/in³^3</td>
</tr>
<tr>
<td>Poisson's ratio</td>
<td>0.46</td>
</tr>
</tbody>
</table>

Table 6.2: Material Properties of Cross-Linked High Density Polyethylene
6.3 Contact Interactions

This finite element model study has a total of 4 contact sets. Similar to the original hip implant product, the plastic liner is attached with the acetabular cup. The acetabular cup and the plastic liner are attached in the analysis with two separate bonded contact sets between them. Between the femoral head and plastic liner, there is free movement so the contact set selected between them has no penetration. Lastly in between the femoral stem and femoral head the contact set is kept as bonded to exactly replicate the scenario of hip implant in the body. All 4 contact sets are shown in Figure 6.1.

Figure 6.1: Contact sets for FEA of hip implant products

(A) Bonded contact 1 cup and liner  
(B) Bonded contact 2 cup and liner  
(C) No penetration between head and liner  
(D) Bonded contact head and stem
6.4 Loading and Boundary Conditions

According to the survey by the statistic brain website, the average male weight is 194.7 lbs [31]. The weight of the patient in our study is selected to be 250lbs, which is 50 lbs above the average male weight, equivalent to the force of 1112 N as shown in Figure 6.2(A). This force is applied axially on the acetabular cup considering that the patient is standing and immobile as shown in the X-ray image in Figure 6.2(B) [32]. The X-ray image of the hip implant inside the body as shown in Figure 6.2(B); it demonstrates that the femoral stem is fixed inside the body, thus the stem is fixed in the analysis.

![Figure 6.2: Loading and boundary conditions for hip implant FEA](image1)

![Figure 6.2: X-ray of hip implant](image2)

(A) Loading and boundary conditions for hip implant FEA  
(B) X-ray of hip implant

6.5 Meshing

Mesh for the hip implant product is automatically generated utilizing the Solidworks™ simulation tool. As demonstrated in Figure 6.3 the hip implant product has a complex geometry hence the curvature based meshing is utilized from the simulation tool.
Minimum and maximum element sizes of the mesh are 0.069 inches and 0.347 inches respectively. There are a minimum number of 8 elements in the mesh circle. The element size growth ratio is considered as 1.2.

Figure 6.3: Module scale hip implant mesh

6.6 Stress Analysis Results

6.6.1 Hip Implant with Circular Interface

As shown in Figure 6.4, the maximum stress 1,149.9 psi is seen at the interface that has been developed and it is very minimal, since the yield stress of the Ti6Al4v material is 128000 psi. Judging from these results the module scale customized product 1 can be said to be strong.
6.6.2 Hip Implant with Square Interface

As shown in Figure 6.5 the maximum stress 2373.1 psi is again seen at the interface that has been developed. It is very minimal but a little more than the implant with the circular interface, since the yield stress of the Ti6Al4v material is 128000 psi. Observing these results the module scale customized product 2 can also be said to be strong.
6.6.3 Hip Implant with Elliptical Interface

As shown in Figure 6.6 the maximum stress 3119.4 psi is again seen at the interface that has been developed. This is also much low, since the yield stress of the Ti6Al4v material is 128000 psi. Observing these results the module scale customized product 3 can also be said to be strong.

![FEA of customized hip product with elliptical interface](image)

Figure 6.6: FEA of customized hip product with elliptical interface

Comparing the results of the three different interfaces we conclude that the circular interface is the strongest, the square interface is somewhat less so, and the elliptical interface is the weakest of all these. However as demonstrated, all of them are certainly strong enough for implanting purposes. In the design phase it is proposed that the module scale hip implant product would have a locking mechanism. Therefore because the circular interface could not be locked, it is recommended to select the square interface in the product development phase.
6.7 Displacement Results

6.7.1 Hip Implant with Circular Interface

As shown in Figure 6.7 the maximum displacement is seen at the acetabular cup. The displacement value is very small for the force of 1100 N. Thus, it can be concluded that the hip implant customized product is safe and not prone to dislocation in the patient’s body under heavy loading conditions.

Figure 6.7: Displacement of customized hip product with circular interface

6.7.2 Hip Implant with Square Interface

As shown in Figure 6.8 the maximum displacement again is seen at the acetabular cup. The displacement value is very small for the force of 1100 N. Thus, it can be concluded that the hip implant customized product is safe and not prone to dislocation in the patient’s body under heavy loading conditions.
6.7.3 Hip Implant with Elliptical Interface

As shown in Figure 6.9 the maximum displacement is seen inside the acetabular cup. The displacement value is very small for the force of 1100 N. Thus, it can be concluded that the hip implant customized product is safe and not prone to dislocation in the patient’s body under heavy loading conditions.
Figure 6.9: Displacement of customized hip product with elliptical interface

Examining the results of 3 different interfaces it can be concluded that the acetabular cup with circular interface stem is the least prone to dislocation, the cup with elliptical interface stem somewhat more so, and the cup with square interface stem is most likely to dislocate among all of the 3 stem interfaces. However as demonstrated, all of them are showing very minute displacement for heavy loading conditions, therefore they are good enough for implanting purposes. In the design phase it is proposed that the module scale hip implant product would have a locking mechanism. Therefore because the circular interface could not be locked, it is recommended to select the elliptical interface in the product development phase. The result provides a different selection compared to stress analysis.
6.8 Factor of Safety Results

6.8.1 Hip Implant with Circular Interface

Observing the factor of safety results as shown in Figure 6.10, the hip implant with circular interfaced stem can be said to be safe. It can be noticed that there are few green colored area in the results but still the overall design can be considered safe for implanting.

![Figure 6.10: Factor of safety of customized hip product with circular interface](image)

6.8.2 Hip Implant with Square Interface

Observing the factor of safety results as shown in Figure 6.11, the hip implant with
square interfaced stem can also be said to be safe. It can be noticed that there are few green colored and few blue colored at the bottom end of the femoral stem in the results, but still, the overall design can be considered safe for implanting.

Figure 6.11: Factor of safety of customized hip product with square interface

6.8.3 Hip Implant with Elliptical Interface

Observing the factor of safety results as shown in Figure 6.12, the hip implant with circular interfaced stem can also be said to be safe. It can be noticed that there are few green colored and few blue colored at the bottom end of the femoral stem in the results, a little less than the square interfaced stem. The overall design can be considered safe for implanting.
Observing the results of the customized implants with 3 different interfaces, it is seen that the results of the products are very similar to each other. Thus, it can be concluded that all the developed hip implant products are safe for implanting purpose.
Chapter 7 Finite Element Analysis of Knee Implant

Over the past decade from February 2003 to May 2013, a total of 709 Knee implants were recalled. Issues ranging from faulty design, early wear and delamination, difficulty with plastic spacer inserts and manufacturing issues are some of the many reasons [33]. The issues as noticed are different from those of the hip implant described above. Recalls were done by companies well-known in medical device industry like Stryker, Zimmer, and J&J Depuy; the same companies that manufacture hip implants. Data suggest that some of the devices recalled were already implanted, a situation similar to that of hip implants discussed above. Looking at this analysis by safe patient project organization, it is important to test the products that have been developed by leveraging DMCMD. In order to prove that the modular customized knee implant products and platforms are robust and safe, static stress analysis is performed on the designed products.

7.1 Problem Setup: Assembly Analysis

The modular customized knee implant products developed in chapter 4 are converted to three dimensional finite element models. The finite element analysis is carried out in Solidworks™ Simulation. Direct sparse solver is utilized for the Finite Element Analysis (FEA). In this study the same materials, contact interactions, meshing, loading and boundary conditions are used for all the developed modular customized knee implant products. There are 8 different products designed, however testing of only 4 different modular customized products is done to prove the design is flawless. It was felt that if all
four designs tested were successful, it could be assumed that the remainder would also meet the standards. Our study is concentrated on the developed modular customized products of the knee implant rather than the interfaces as was the case in the hip implant stress analysis.

7.2 Material Properties

As mentioned in chapter 4 we have focused on developing "metal-on-plastic" knee implant products. In this study the metal material selected is Ti6Al4v. This is a biocompatible material with very high yield strength as shown in Table 6.1. The material selected for plastic spacer in this study is cross-linked high density polyethylene. This material is used in manufacturing by most of the medical device companies developing knee implant products in the present market. Material properties for polyethylene are shown in Table 6.2. The femoral component and the tibial component are considered to be made of Ti6Al4v in the analysis.

7.3 Contact Interactions

This finite element model study has a total of 4 contact sets. Similar to the original knee implant product the plastic spacer is attached to the tibial component. The plastic spacer and the tibial component are bonded together in this analysis with 3 different bonded contact sets. Between the femoral component and the plastic spacer there is free movement so the contact set selected between them has no penetration, to exactly replicate the scenario of knee implant in the body. All 4 contact sets are shown in Figure 7.1.
7.4 Loading and Boundary Conditions

The weight of the patient in this study is selected to be 250lbs, which is 50 lbs above the average male weight, equivalent to the force of 1112 N as shown in Figure 7.2(A). The force is applied axially on the femoral component assuming that the patient is standing and immobile as shown in the X-ray image in Figure 7.2(B) [34]. The X-ray image of the knee implant inside the body as shown in Figure 7.2(B), demonstrated that the tibial component is fixed inside the body. Thus the tibial component is fixed in the analysis.
Figure 7.2: Loading and boundary conditions for knee implant stress analysis

(A) Loading and boundary conditions for knee implant FEA  
(B) X-ray of knee implant

7.5 Meshing

Mesh for the knee implant product is automatically generated utilizing the Solidworks™ simulation tool. As demonstrated in Figure 7.3, the knee implant product also has a complex geometry similar to the hip implant, hence the curvature based meshing is utilized from the simulation tool. Minimum and maximum element sizes of the mesh are 0.069 inches and 0.347 inches respectively. There are a minimum number of 8 elements in the mesh circle. The element size growth ratio is considered as 1.2.
7.6 Results

7.6.1 Knee Implant customized products stress analysis

FEA results of the knee implant products can be observed in the Figure 7.4. Product 4 is the strongest while Product 5 is the least strong among all four products. Stress value of the rest of the 8 products is in between the range of Product 4 and 5 in terms of stress as observed in the results of stress analysis. All the products are strong enough for the purpose of implanting since the highest stress among all 8 products is just 626.235 psi, which is substantially low compared to the yield stress of Ti6Al4v, which is 128000 psi.
Product 1: Femoral component 1, Tibial component 1 and platform 1

Product 2: Femoral component 2, Tibial component 1 and platform 1

Product 3: Femoral component 1, Tibial component 1 and platform 2

Product 4: Femoral component 2, Tibial component 1 and platform 2
Product 5: Femoral component 1, Tibial component 2 and platform 2

Product 6: Femoral component 2, Tibial component 2 and platform 2

Product 7: Femoral component 1, Tibial component 2 and platform 1

Product 8: Femoral component 2, Tibial component 2 and platform 1

Figure 7.4: FEA of modular customized knee products
7.6.2 Knee Implant customized products FEA displacement

Displacement results of the knee implant products can be observed in the Figure 7.5. Examining the results, Product 3 shows the maximum displacement while product 4 shows the least among all eight products. Displacement results of the remainder of the 8 products are in between the range of product 3 and 4 in terms of displacement as observed in the results of the FEA displacement. All the products are good enough for the purpose of implanting since the highest displacement among all 8 products is .000729 inches which is very minimal. The product will surely not dislocate inside the patient’s body.

Product 1: Femoral component 1, Tibial component 1 and platform 1

Product 2: Femoral component 2, Tibial component 1 and platform 1
Product 3: Femoral component 1, Tibial component 1 and platform 2

Product 4: Femoral component 2, Tibial component 1 and platform 2

Product 5: Femoral component 1, Tibial component 2 and platform 2

Product 6: Femoral component 2, Tibial component 2 and platform 2
7.6.3 Knee Implant customized products FEA Factor of Safety

Factor of safety results for the customized knee implant products are as shown in Figure 7.6. The results show that all the customized products are fully safe. Product 2 is the safest while product for the least safe among the 8 knee product results. These results verify and validate that the designed customized knee are safe for implanting purpose.
Product 1: Femoral component 1, Tibial component 1 and platform 1

Product 2: Femoral component 2, Tibial component 1 and platform 1

Product 3: Femoral component 1, Tibial component 1 and platform 2

Product 4: Femoral component 2, Tibial component 1 and platform 2
Product 5: Femoral component 1, Tibial component 2 and platform 2

Product 6: Femoral component 2, Tibial component 2 and platform 2

Product 7: Femoral component 1, Tibial component 2 and platform 1

Product 8: Femoral component 2, Tibial component 2 and platform 1

Figure 7.6: Factor of safety of modular customized knee products
Chapter 8 Discussion and Conclusion

8.1 Discussion

As pointed out in the previous chapters, a combination of techniques from the fields of management and engineering has been recommended to develop a new methodology termed as DMCMD. It is then applied on two of the most common implanted medical devices, the hip implant and the knee implant. Figure 8.1 shows various operation phases of the DMCMD method.

After defining and reviewing the medical device product a specific type of product is selected, which is further customized utilizing product platform methodology. The use of DSM was fruitful in understanding various connections between the components of the hip and the knee implant products. Overall, as seen in Figure 3.2 and 4.3 both systems are not complex. But, this planned methodology would be very useful when implemented on a more complex medical device. In future research, the plan is to apply this methodology to more complex devices like artificial hearts and other complex implants.

Figure 8.1: Operation phases in DMCMD method
In the next phase, the EMS diagram was developed. This helped in deconstructing the hip and knee implant products in order to understand the connections between various components. In addition the mass customized component was identified using the EMS diagram. Three different platforms were proposed for the hip and the knee implants. The EMS diagram was leveraged to develop an interface diagram. From this, an interface with a better locking mechanism between the femoral stem and femoral head was created in the case of hip implant. In the case of the knee implant there were two interfaces proposed. The interface number 1 consisted of the circular taper while the interface number 2 was designed with the keyway on the taper to provide a locking mechanism between the plastic spacer and the tibial component. Then a module scale platform was developed for the hip implant and a modular platform developed for the knee implant. Utilizing the platforms designed, a family of products was created both for the hip and the knee implant. A benefit of this process is the identification of a mass customized element or platform. This allows the product development team to focus on increasing the robustness and quality of the engineering within those parts and developing numerous products out of them. Further research on more non-toxic material and/or a material subject to less wear and tear are the logical next steps in improving the design.

Lastly, we used Solidworks™ to develop a 3D model of the implant products with various mass customized modular and scalar platforms for the hip and the knee implant that could easily be customized based on the individual needs. Going further, the design was validated by making a prototype of the implant using a 3D printer. Digital design and rapid prototyping are increasingly being used to design and manufacture custom medical devices, not only for external uses, but also for internal devices such as skull fragments.
and dental implants. We view the inclusion of digital design and prototyping directly into the process, as essential in developing high variety and low cost mass customized devices. Finally, finite element analysis was performed on various products of the customized hip and knee implants. Then various different products were compared to find the best possible product among them.

8.2 Conclusion

In this thesis we have demonstrated the use of product platform, modularization and mass customization on the hip and knee implant products. We applied DSM on hip and knee implants to simplify the complexity of the devices. Furthermore, we used an EMS diagram to procure platform elements. The mass customized component was found using EMS. We then developed an interface diagram to obtain various interfaces for both the hip and the knee implant. Solidworks™ CAD was employed to develop a 3D model of the mass customized implant assembly, resulting in a well-defined interface for the mass customized component. In summary the DMCMD method applied on the implant examples demonstrate an amalgamation of tools like the DSM, product platform and mass customization can be employed with efficacy in healthcare. The stress analysis results prove that the family of products created using DMCMD are strong enough for implanting purpose.

Future work includes conducting cost benefit analysis on mass customizable medical devices that encompasses platform-based modular and/or scalar architecture. It will help us understand the actual impact of mass customization and the product platform methodologies. DMCMD will also be implemented on more complex medical devices.
and to expand its use in various other areas of healthcare to ensure its effectiveness. Further market segmentation can be used to modularize the platform based on various market niches for a particular product or device. Individualized medical devices can be developed by applying the shape commonalization technique on the X-ray images of multiple patients. A macro can be developed to find commonality indices from the patients X-ray images using which one can propose a tailor made medical device for a specific patient group type. The designs can then be developed in Solidworks™ which can be converted to stl files for developing a product using rapid prototyping.
References


23. Unit 6-The Hip, *Virginia Commonwealth University*. Available online at:
http://www.arthritisresearchuk.org/arthritis-information/surgery/knee-
27. Agarwal, S., Knee Replacement Surgery, *Cardiff Hip and Knee*. Available online at:
Union*, 9 September 2013. Available online at: http://safepatientproject.org/
29. Titanium Ti-6Al-4V(Grade 5, Annealed), *MatWeb*, 2014. Available online at:
b958e5f825ae85390&ckck=1 (accessed 12 April 2014).
30. High Density Polyethelene (Injection Molded), *MatWeb*, 2014. Available online at:
12a1bce53ebdc8 (accessed 12 April 2014).


Appendix: Hip implant analysis for different materials

Just out of curiosity, FEA was done on hip implant module scale products with three different types of materials. The three material considered in stress analysis were Ti6Al4v, Titanium Grade 4 and Stainless steel. The results obtained are compared in terms of materials in this appendix.

Comparing the results for hip with circular interface, it is observed from stress analysis that the hip product with Ti6Al4v material is the strongest while, the product with stainless steel is the least strong with titanium grade 4 hip product in between both of them. There is not a significant difference between the results as shown in Figure A.1.

(A) Hip material Ti6Al4v  (B) Hip material stainless steel
Figure A.1: Different material FEA results of hip product with circular interface

(A) Hip material Ti6Al4v

(B) Hip material stainless steel

(C) Hip material titanium
Comparing the results for hip with elliptical interface, it is again observed from stress analysis that the hip product with Ti6Al4v material is the strongest while, the product with stainless steel is the least strong with titanium grade 4 hip product in between both of them. There is not a significant difference between the results as shown in Figure A.2.
Figure A.3: Different material FEA results of hip product with square interface

(A) Hip material Ti6Al4v

(B) Hip material stainless steel

(C) Hip material titanium grade 4
Comparing the results for hip with square interface, it is again observed from stress analysis that the hip product with Ti6Al4v material is the strongest while, the product with stainless steel is the least strong with titanium grade 4 hip product in between both of them. There is not a significant difference between the results as shown in Figure A.3.