Bio-Surfaces and Geometric References for a Standardized Biomechanical Design Methodology for Mass Customization

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BIO-SURFACES AND GEOMETRIC REFERENCES FOR
A STANDARDIZED BIOMECHANICAL DESIGN
METHODOLOGY FOR MASS CUSTOMIZATION

by

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A dissertation submitted to the faculty of
Brigham Young University
in partial fulfillment of the requirements for the degree of

Doctor of Philosophy

Department of Mechanical Engineering
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of a dissertation submitted by

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This dissertation has been read by each member of the following graduate committee and has been found to be satisfactory.

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As chair of the candidates’s graduate committee, I have read the dissertation of Kimberly Jensen Nielsen in its final form and have found that (1) its format, citations, and bibliographical style are consistent and acceptable and fulfill university and department style requirements; (2) its illustrative materials including figures, tables, and charts are in place; and (3) the final manuscript is satisfactory to the graduate committee and is ready for submission to the university library.

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This dissertation presents a method for the design of customizable products that interface with the human body. The method presented involves first, a consistent method of capturing and representing the human model so that the model can be used with CAx tools and solid modeling techniques. Second, it provides a design methodology based on feature structure planning and assembly modeling that provides a consistent structure to the design process so that it can be reused and parameterized. Third, a strategy for identifying parametric variables that are referenced to the human body is introduced.

The core of this method is the definition of biomechanical products as an assembly model, where human data is defined as the base part. This research expands on traditional mating conditions in assembly model methods by identifying different ways products can interface with the human body. With the identification of these mating conditions, prod-
ucts can be designed to interact with the body in definable ways through the definition of parametric strategies. This dissertation also presents the necessary theoretical and numerical methods for implementation of these mating conditions in a CAD system.
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TABLE OF CONTENTS

CHAPTER 1 Introduction ........................................................................................................1

1.1 Motivation and Goals ..................................................................................................2

1.1.1 Current Practices in Bio-Interface Design .......................................................3

1.2 Problem Statement ...................................................................................................5

1.3 Organization of Dissertation ...................................................................................6

CHAPTER 2 Related Work ..................................................................................................9

2.1 Design Methodologies ..............................................................................................9

2.1.1 Traditional Mechanical Design .........................................................................9

2.2 Interface Criteria for Biomechanical Devices .........................................................11

2.3 Reference Datums and CAx Tools ..........................................................................13

2.3.1 Human Modeling ..............................................................................................14

2.3.2 Digital Anthropometric Landmarking of the Body .........................................15

2.3.3 Anthropometric Databases ................................................................................16

2.4 Scanned Data ...........................................................................................................18

2.4.1 Scanning Techniques ........................................................................................19

2.4.2 Polygonal Simplification Methods ....................................................................20

2.5 Anatomical Positions, Planes, and Directions .........................................................21

2.6 Virtual Environments ...............................................................................................23

2.7 Assembly Modeling and Design ..............................................................................24
2.7.1 Analysis and Computer Representation of Assemblies ........... 24
2.7.2 Generation of Sequences for Product Assembly ..................... 34
2.7.3 Integrated Computer Tools in Assembly Modeling .................. 35
2.8 Mass Customization and Parametric Strategies ......................... 36
2.8.1 Mass Customization ................................................................. 36
2.8.2 Parametric Strategies ............................................................... 38
2.9 Summary .................................................................................... 40

CHAPTER 3 Methodology ........................................................................................................ 41
3.1 Research Methods ........................................................................... 41
3.2 Dissertation Contribution .............................................................. 43

CHAPTER 4 Geometric References in Bio-Interface Design ................... 45
4.1 A Strategy for Geometric References attached to Scan Data .......... 46
4.1.1 Bio-Datum Planes .................................................................. 47
4.1.2 Key Bio-Points ....................................................................... 49
4.1.3 Bio-Axes ............................................................................... 50
4.1.4 Geometry Creation using Bio-references ................................. 51
4.1.5 Demonstration of Bio-References ........................................... 52

CHAPTER 5 Bio-Interface Design based on Assembly Model Techniques ....... 57
5.1 Expanded Top-Down Assembly Technique .................................... 58
5.2 Biomechanical Additions to Mating Conditions .......................... 60
5.3 Assembly Design Techniques for Bio-Interfaces .......................... 62

CHAPTER 6 Bio-Interface Constraint Equations ........................................ 65
6.1 Overview of Computer-Aided Graphics ......................................... 65
8.2.2 Shin Guards: System Level Design ...........................................123
8.2.3 Shin Guards: Detailed Design ..................................................125
8.3 Body Armor ....................................................................................128
8.3.1 Body Armor: Planning and Concept Development .................128
8.3.2 Body Armor: System Level Design .......................................130
8.3.3 Body Armor: Detailed Design .................................................131
8.4 Curriculum Development ................................................................136

CHAPTER 9 The Exploration of Mass Customization .................................139
9.1 Mass Customization Case Study: Safety Glasses ..............................140
9.1.1 Safety Glasses: Case 1 .............................................................142
9.1.2 Safety Glasses: Case 2 .............................................................143
9.1.3 Safety Glasses: Case 3 .............................................................146
9.1.4 Safety Glasses: Case 4 .............................................................147
9.2 Mass Customization Conclusions ....................................................149

CHAPTER 10 Reconfiguration Space for Bio-Interface Design ......................151
10.1 Degrees of Freedom in Reconfiguration Space ............................152
10.2 Parametric strategies in Reconfiguration Space ............................153

CHAPTER 11 Conclusions and Future Work ...........................................155
11.1 Summary and Conclusions ...........................................................155
11.2 Major Contributions .................................................................157
11.3 Limitations in CAx Tools ..............................................................158
11.4 Recommendations for Future Work ............................................158

References ..........................................................................................161
LIST OF FIGURES

Figure 2.1 Diagram of Anatomical Planes and Direction ..............................................22
Figure 2.2 Top Down Assembly example ......................................................................27
Figure 2.3 Contact Mating Conditions ...........................................................................30
Figure 2.4 Angular Mating Conditions ..........................................................................31
Figure 2.5 Distance Mating Conditions .........................................................................32
Figure 2.6 Four approaches to customization .................................................................37
Figure 3.1 Areas of Research in Bio-Interface Design ..................................................42
Figure 4.1 Human Body annotated with Anatomical Planes .........................................48
Figure 4.2 Head annotated with Basic Anatomical Datum Planes .................................49
Figure 4.3 Front View of Human Head annotated with Datum Planes .........................50
Figure 4.4 Side View of Human Head annotated with Datum Planes ............................51
Figure 4.5 Automatic Regeneration of an Extrusion ......................................................53
Figure 4.6 Automatic Regeneration of an Extrusion ......................................................53
Figure 4.7 Automatic Regeneration of a Revolution .....................................................54
Figure 4.8 Automatic Regeneration of a Blend ...............................................................54
Figure 4.9 Regeneration of a Blend ...............................................................................54
Figure 4.10 Automatic Regeneration of a Revolution ...................................................55
Figure 4.11 Automatic Regeneration of a Sweep ............................................................55
Figure 4.12 Automatic Regeneration of Sweep ...............................................................55
Figure 9.7  Front and Side Views of Scan Data for Case 3 .............................................. 146
Figure 9.8  Scan data for Case 3 annotated with Reference Planes ................................. 146
Figure 9.9  Issues in the Selection of Points for Plane Creation .................................... 147
Figure 9.10 Front and Side Views of Scan Data for Case 4 ............................................. 148
Figure 9.11 Annotation of Scan Data with Reference Plane for Case 4 ............................ 148
Figure 10.1  Illustration of Mapping Function ............................................................... 153
LIST OF TABLES

TABLE 5.1 Specification of Classes and Subclasses of the Mating Conditions ..........62
TABLE 7.1 Description of Key Characteristics for Ski Goggles...................................106
TABLE 7.2 Parametric Strategies for Ski Goggles Case Study .....................................107
TABLE 8.1 Key Characteristics for Safety Glasses ........................................................114
TABLE 8.2 Mating Conditions for Safety Glasses ........................................................115
TABLE 8.3 Key Characteristics for Shin Guard Case study ........................................123
TABLE 8.4 Parametric strategies for Shin Guard Case Study ........................................125
TABLE 8.5 Key Characteristics for Body Armor Case study ...............................131
TABLE 8.6 Mating conditions in Body Armor Case Study .........................................132
TABLE 9.1 Values extracted for Bio-References ....................................................141
Mechanical design methodologies have been developed and used for the design of mechanical products for many years. These standardized design approaches are currently used to develop a wide variety of mechanical devices spanning the spectrum of commodity, automotive, and aerospace products. These same methodologies, however, do not lend themselves well to the design of products that interface with the human body.

Many types of products interface, or come into contact, with the human body. Such devices are typically referred to as biomechanical devices and include helmets, protective equipment, prosthetics, and orthotics. Because these devices interface with the human body, they present unique design problems. The interfaces are typically complex surface-surface contacts that are not mathematically defined and involve bio-sensory feedback, such as pressures and pain thresholds. Because mechanical design methodologies do not take into account the specialized geometry and biomechanisms of the human body, there is a need to develop a general design methodology for products that interface with the human body.
Prior to 1980, first generation CAD techniques were used in electronic drafting applications [1]. Geometry was represented in a wireframe format and lines were used to represent the edges of three dimensional objects. During the 1980’s, second generation CAD emerged and used surface modeling techniques. Mathematical equations were used and allowed for the modeling of complex surfaces. Instead of representing the edges of objects using lines, the entire bounding surface could be represented. Although surface modeling techniques could represent complex surfaces, they were not robust and required a significant number or parameters to define the geometry of an object. Finally, in the 1990’s, solid modeling was introduced, using volumes and Boolean operators to represent geometry. The use of solid modeling brought more robust models, a full definition of the geometry of a part, and a reduction in the number of parameters needed to define the part. For example, instead of defining a cube through each individual face, described by its vertices and bounding lines, solid modeling allowed a cube to be described using three parameters: length, width, and height. Because of the reduction of parameters, parametric techniques and mass customization could also be explored using third generation CAD.

1.1 Motivation and Goals

Because of the uniqueness of each human body, mass customization and parametric modeling is an ideal strategy for biomechanical products. Although solid modeling has many benefits, not all three dimensional objects are easily articulated using the solid modeling techniques used in traditional mechanical design. Complex surfaces, such as bio-surfaces, can not always be well defined using volumes and Boolean operators. Because of this, biomechanical interface design has continued using second generation surface mod-
eling techniques and most attempts at mass customization have been strictly cosmetic. In addition, biomechanical interface design requires modeling complex surface geometry and accounting for bio-sensory feedback. Therefore, traditional mechanical design approaches need to be further developed to address the needs in biomechanical interface design. This development is necessary due to the following reasons:

1. Bio-surfaces and interfaces are more complex geometrically than traditional mechanical surfaces.

2. Current CAx tool approaches are developed for prismatic parts and are therefore insufficient for bio-interface design

3. Parametric strategies required for bio-interface design are more sophisticated due to complex surfaces and interfaces. It is difficult to define parameters associated with the human body.

1.1.1 Current Practices in Bio-Interface Design

Currently, devices that interface with the human body are designed using craftsman era design methods or traditional mechanical design techniques.

In craftsman era design, each product is designed and manufactured individually due to specific needs of a single customer. This method is used for products that require one-of-a-kind interfaces such as prosthetics or orthotics. They allow products to be designed for an individual, however, as a result, these products are generally expensive with long design cycle times and are generally not reproducible.
Biomechanical devices that do not require these individualized interfaces typically rely on traditional mechanical design methods. These methods result in products that are less expensive and have a faster concept-to-consumer cycle time. However, because traditional mechanical design tools such as CAD, CAE, and CAM (CAx tools), as well as design approaches, were developed for the design of exclusively mechanical products, they lack techniques and methodologies that address the human aspects required for biosurface and interface design, such as sensory requirements and pain thresholds. The most significant area for further development involves the lack of geometric tools for capturing and modeling human shape and form and the subsequent creation of interface geometry that meets biomechanical design criteria. CAx tools and systems do not provide adequate tools and there are not adequate methodologies using the existing tools and techniques to facilitate biomechanical design. As a result, these products, although faster than craftsman era products, still require lengthy design periods due to the difficulty in modeling products that interface with the body.

Another significant undeveloped area in biomechanical design involves the lack of adequate parametric strategies for products that interface with the human body. The issue here is the difficulty in defining parameters associated with human surfaces as inputs. It is not clear what forms are most appropriate for mathematically representing the human surfaces, let alone reducing the mathematical forms to a subset of consistent parameters. Consequently, it is not clear how to automate the design process. A great deal of work has been done to render current design tools parametric so they support automation and mass customization. However, since these tools and methods do not directly support biome-
chanical design, attempts at mass customization of biomechanical products are fragile and ineffective, and for the most part non-existent.

1.2 Problem Statement

This dissertation presents new strategies, methodologies, and techniques for implementing mass customization in products that interface with the human body using, for the most part, existing tools coupled with new planning and modeling methods. These strategies are based on four methods in design. First, a consistent method for capturing and representing the human body so that the model can be used with CAx tools and solid modeling techniques. Second, a design methodology based on feature structure planning that provides a consistent structure to the design process so that it can be reused and automated. Third, a strategy for identifying parametric variables tied to the human body that can be used to parameterize the design process. Fourth, the use of top-down assembly modeling techniques to identify model essential mating conditions for the designed product. To address the issues that exist in designing products that interface with the human body, this dissertation presents a strategy of using assembly modeling to represent biomechanical products and their interface to the human body. This results in a top-down design method for devices that have a product-human interface.

The identification and use of these strategies and design methods have resulted in three strategies for the design of products that interface with the human body, which will be further outlined in this dissertation.
1. A strategy for geometric references attached to human scan data

2. A strategy utilizing assembly model methods for bio-interface design

3. A strategy for the planning of reusable customizable products that interface with the human body.

Although these strategies, tools, and techniques promise to help in designing products that interface with the human body, they do not necessarily solve all problems associated with biomechanical design and do not attempt to address the forces or mechanics involved in biomechanical design. Instead, this dissertation focuses on tools and techniques for the modeling and design of products that interface with the human body using CAx tools as well as parametric strategies and techniques that allow the creation of reusable customizable products that interface with the body.

1.3 Organization of Dissertation

This dissertation presents a methodology for the design and creation of reusable and customizable products that interface with the human body by outlining tools, techniques, and an overall design method. The approach consists of integrating traditional mechanical design methods, CAx tools, and assembly modeling techniques.

Chapter 2 consists of an overview of past research that is relevant to this dissertation. Past research can be classified into the areas of human modeling, CAx tools and techniques, mass customization, design methodologies, and assembly modeling. Chapter 3 describes the methodology used in research and development of a bio-interface design
process. Chapters 4, 5, 6, and 7 outline the three strategies for bio-interface design presented in this dissertation, namely the introduction of bio-references attached to scan data, the expansion of assembly model methods to address bio-interface design needs, the constraint equations associated with the bio-interface assembly modeling additions, and a general methodology for the design of customizable products that interface with the body. Chapter 8 presents several cases studies that demonstrate the three bio-interface design theories developed in this research and chapter 9 explores the mass customization process by using several sets of scan data to update a parametric model. Chapter 10 explores the concept of reconfiguration space. Finally, chapter 11 reviews and summarizes the design process, discusses major contributions of this work, and makes recommendations for the continuation of this research in the future.
This chapter presents background information relevant to the research and methodologies presented in this dissertation. The background information can be categorized into eight different areas. These areas include design methodologies, assembly modeling, mass customization, and parametric strategies. To develop design techniques for products that interface with the human body, we must also look at the research done in the areas of human modeling, interface criteria for biomechanical design, anatomical positions, planes and directions, and virtual environments.

2.1 Design Methodologies

2.1.1 Traditional Mechanical Design

A process is a series of steps that change a set of inputs into a set of outputs. Thus, the product development process is a sequence of steps that transforms a set of customer inputs into an output such as a product. Ulrich and Eppinger [54] describe a generic development process with six phases. These phases are useful for quality assurance, coordina-
tion, planning, management, and improvement in the designed process as well as in the product.

- Phase 0: Planning
- Phase 1: Concept Development
- Phase 2: System Level Design
- Phase 3: Detail Design
- Phase 4: Testing and Refinement
- Phase 5: Production Ramp Up

Phase 0, or planning, typically begins with business strategy as well as an overall view of technologies in the target market. The output of this phase is the project mission statement, which addresses business goals, key assumptions, constraints, and the target market for the product.

Phase 1, the Concept Development phase, involves identifying the needs of the target market customers, developing and evaluating a variety of product concepts, and selecting a concept for further development and testing.

Phase 2, system level design, defines the product architecture and the subsystems of the product and its components. This phase typically develops a geometric layout for the product, the functional specifications for all parts of the product, and the flow diagram for the final assembly process of the part.

Phase 3, detailed design, involves the process of complete specification of the product. The geometry, materials, and tolerances of all the components of the product are defined as well as process plans, tooling, and purchasing information. Production cost and robust performance are also addressed in this phase of the design process.
Phase 4, the production ramp-up phase, is where the product is fabricated using the designed process. This phase tests the overall process for the product, is used to train the production force, and evaluates the product to find flaws.

The biomechanical design process for products that interface with the body, developed in the dissertation will follow this general design process. Phases 0, 1, 4, and 5 will proceed in the same manner. However, Phases 2 and 3 must be modified in order to develop the complete specification for biogeometric interfaces.

2.2 Interface Criteria for Biomechanical Devices

Comfort is essential in the design of biogeometric interfaces, however, comfort is subjective and difficult to evaluate. Comfort has been defined as the lack of discomfort [55] and more recently as feelings of relaxation and well-being [56]. Slater defined comfort as "a pleasant state of physiological, psychological, and physical harmony between a human being and the environment" [57].

Though difficult to analyze, Goonetilleke [35] proposes that comfort is a composite function that can be separated into terms of sensory qualities, aesthetics, smell, taste, and hearing. All of these components couple to create a comfortable product. Generally, biogeometric interface design focuses on the sensory qualities, although all components should be considered.

Sensory qualities can be grouped into four categories: Pressure, Flutter (light tapping), Stretching, and Vibration [35]. All sensory qualities can contribute to feelings of comfort or discomfort, however pressure on a human interface is typically considered a defining parameter. Appropriate pressure patterns for different parts of the human body
should be understood, but the ideal pressure distribution has not been defined. However, discomfort as a result of pressure can be quantified using peak pressure, pressure gradients, and the size of the contact area [33].

In designing to minimize discomfort, there are two key strategies that have been adopted in industry [34].

- Distribute the force uniformly [58]
- Concentrate force or load on stronger areas [59]

It appears that discomfort and injury can be avoided through pressure distribution and lowering pressure magnitude over the human surface, however, some devices use localized force to produce feelings of comfort, such as massage rollers, beaded car seats, or active cushions which operate using pressure waves [33]. Levels of comfort also increase in shoes when pressure is more concentrated on specific areas of the foot. Both strategies produce comfortable products, however, research has shown that comfortable products can become uncomfortable over a duration of time. Thus the duration of the pressure also influences the comfort/discomfort transition [34].

The spatial summation theory (SST) asserts that to arouse stimulation, simultaneous stimulation of many sensory receptors is required, or that the larger the stimulated area, the greater the sensory experience [33]. Thus a pressure over a large area can cause greater discomfort than the same pressure over a small area.

Research has also shown that three factors influence skin blood flow, which can contribute to discomfort: bone depths, ratios of loading area diameter, or "indentor" diameter, to bone diameter, and the percentage of tissue compression over the bone area [35]. This "indentor" is an influential factor that is often neglected.
Goonetilleke and Eng [60] demonstrated that the maximum pressure tolerance (MPT) is related to the probe, indentor size, or the contact area of the stimuli. In traditional design, MPT corresponds to either the yield or ultimate stress, depending on the product application.

Threshold Pressure ($P_{\text{crit}}$) and Threshold Force ($F_{\text{crit}}$) correspond to the maximum force or pressure where comfort is still experienced. This value varies depending on the part of the body, and the duration of the force or pressure. Some values for different $P_{\text{crit}}$ and $F_{\text{crit}}$ are available for different areas of the body, but in many cases this value may need to be identified for individuals and individual products.

Based on research, Goonetilleke made the following suggestions to designers of human-product interfaces:

- Identify the threshold pressure and threshold force ($P_{\text{crit}}$ and $F_{\text{crit}}$)
- If the pressure is below $P_{\text{crit}}$, distribute the forces

If the pressures are high and approach the MPT value, consider a more concentrated force for a short duration to relieve and reduce discomfort.

Although designing for comfort is objective, these guidelines can improve the ability to make more comfortable products and must be used in addition to traditional mechanical design criteria.

2.3 Reference Datums and CAx Tools

One of the key issues in developing design methods for biogeometric interface design is providing adequate reference data that can be used in the CAD environment. Reference models of the human body are needed that can be parameterized and incorpo-
rated into solid models. These reference models can be defined through human modeling, the anatomical landmarking of the body, and anthropometric databases.

2.3.1 Human Modeling

Human modeling includes the representation of human characteristics either through geometric models, engineering analysis, or mathematical equations [17]. Human characteristics can be in the form of geometric measurements of anthropometric landmarks, or measurable features on the human body that are present on all people, such as the nose, eyes, shoulder, etc. Human characteristics can be measured by size and shape.

Many different techniques have been used to model the human body. Anatomically-based methods generally simulate muscular structures and bones [30], [31]. These models require a significant amount of time to create.

Another approach to human modeling is fitting a B-spline surface to an unorganized point cloud. Ma et al.[32] used this method, and later built upon it by using a hybrid model based on B-spline surfaces and Catmull-Clark subdivision surfaces to represent an object.

The majority of methods for human modeling are based on acquiring high quality 3D digital scans of humans or mannequins. Wang et al. [3] used a mesh generation algorithm based on fuzzy logic to build a surface of a human from three-dimensional data points collected using a scanner.

Seo et al. [4] used a template approach to build human models where body geometry of individuals captured by digital scanners was fit to a standard human model. The template is composed of a standard skeleton model and a skin surface made up of a quad-
rilateral mesh. This mesh was then fit to the actual scan data using algorithms that calculated vertex displacement between the template and the scanned model. This approach results in final human models that have a specified number of vertices and points. This method for human modeling has been applied to animation, but not product design.

Wang et al. [12] developed a feature based approach to the human model which allowed for the parameterization of mannequins. A point cloud of a human was acquired using a scanner and the points were used to develop a parametric model that could then be altered and new models created based on that parameterization.

This research will make use of human models by importing them into CAD systems. Human models will allow designers to custom-fit products at bio-surface interfaces.

2.3.2 Digital Anthropometric Landmarking of the Human Body

Anthropometry, the study of human measurements, has identified landmarks that can be found on the majority of the human population. For scanned data points to be useful and applied to real life problems and solutions, measurements must be taken of these anthropometric landmarks. In using the human model, the scanned 3D image must be mapped with landmarks and sectioned in a meaningful way to allow designers to create products.

There have been many different techniques used to map anthropometric landmarks to scanned human models. For mass customization and large scale applications, automated methods for this landmarking is valuable. Many research groups have been working to develop automated feature extraction and landmarking techniques that use various algorithms and techniques to detect these landmarks.
Methods of feature extraction include techniques of taking cross-sectional slices of the scanned data and eliminating outlying points that fall outside a specified tolerance limit. Features are then extracted by examining each cross section for points or specific shape transitions between slices that represent the start of a feature. [3]

Other methods include placing optical markers on the body prior to scanning. These markers can be detected on the scanned data, allowing for the landmarking of anatomical features automatically through software methods [6].

Human body mapping from 3D scan data is another method of extracting anatomical landmarks on the human body. Software is being developed that uses human body templates [16]. These templates are created of a model in a standard anthropometric pose, with known landmarks at specified locations on the model. The actual scan data is then aligned to the template using algorithms which search for centers, outer convex hulls, inner convex hulls, and cusps that match between the actual scan data and the template model. When the template and scan data have been aligned, the location of anatomical landmarks on the model can be extracted using approximations provided by the template [16].

Methods for feature detection and anatomical landmarking are valuable in this research because they can lead to automated methods for the creation of anatomical datum points, axes, planes, and other references.

2.3.3 Anthropometric Databases

In designing for specific populations, a mannequin is generally designed that can statistically represent a population. This mannequin assures that the needs of the custom-
ers are met through proper fit or orientation of landmarks on the body. The use of incorrect models for a product can change the analysis or invalidate a design [17].

In order to help create a test subject for biomechanical design that is not custom-ized for individuals, there are several databases that provide anthropometric statistics for populations. A few of these databases include CAESAR, ANSUR, NHANES, and CPSC. Some databases are based on scan data while others are made up of data taken from actual measurements on live human bodies.

The CAESAR (Civilian American and European Surface Anthropometry Resource) Project is an anthropometric database of body measurements based on scanned data [5]. This project was a survey of 2500 people scanned in the United States, Italy, and the Netherlands in 2002. Measurements were taken from scan data using anthropometric landmarks on the human body. Markers were placed on specified landmarks prior to scanning.

The other databases, ANSUR, NHANES, CPSC, and HQL are databases of measurements taken from measuring actual people instead of taking measurements from scan data. ANSUR (Anthropometric Survey of US Army Personnel, 1988) is a database of physiological data on 3982 subjects between the age of 17 and 51 that were actively serving in the army [25]. The database contains statistics for men and women as well as for various races including White, Black, Hispanic, Asian/Pacific Islander, Native American, and others. NHANES (The Third National Health and Nutrition Examination Survey, 1988) is a survey of 33,994 people in the United States and takes data in five areas: Adult Household Data, Youth Household Data, Examination Data, Laboratory Data, and Dietary Recall Data [26]. NHANES has many components, including body measurements, bone
densitometry, demographic data, total nutrient intakes, as well as other data. CPSC (Consumer Product Safety Commission) performed a survey to create the Anthropometric Data of Children Database [27]. This database is the only public database of anthropometric data for children and is a valuable resource in product design. Other databases can also be found which contain anthropometric data for different races and age groups.

Anthropometric databases can be used in a biomechanical design methodology to create human models in the CAD system

2.4 Scanned Data

The use of scanners has allowed for the creation of three dimensional digitized human surface images [2]. Scanned data is imported into a system as a point cloud, or a set of three dimensional points. These scanned points are used to represent the outer surface of the scanned object by defining edges of the features of the object.

A scanned point is a discrete entity that has no topological indentifiers. A surface of scanned points has no references to a coordinate system or to other points in the surface. Therefore, to work with scanned data, references must be established that will allow for topological relationships such as dimensions.

Currently, the use of human scanned data in industry and research has been concentrated on textiles and clothing [2], [14], [28], [29]. In general, this research has focused on obtaining body measurements from scanned data. Parametric clothing patterns are created, but instead of referencing the actual human body, scan data is used to obtain measurements from the anatomical landmarks of the test subject. These measurements are then used to update the pattern for an individual. The use of scanned data has not been
used to create parametric devices which do not use the textile patterns of standard clothing manufacturing methods.

Scan data will allow modeling techniques, parametric strategies, and mass customization processes to be used in biogeometric interface design. With scan data, biogeometric interfaces can be modeled to fit the bio-data of a scanned person. In addition, scan data will allow for the creation of parametric models of devices that can be updated to new human models for mass customization purposes.

2.4.1 Scanning Techniques

Recent developments in technologies and scanning methods now allow high resolution scans of the human body. These scanners can acquire as many as 100,000 to 500,000 coordinate data points which allow for measurements to be taken on the body and used for applications such as clothing and pattern design [3].

Shadow-moire interferometry is an optical technique that uses interference fringes to measure out-of-plane displacements. A light source is projected through a thin glass plate that is etched with lines. These lines are projected onto a screen and, before scanning, calibrated at a certain distance. When an object is placed between the scanners, interference fringes are created. These fringes are calibrated such that the topological surface can be imported to the computer from the interference fringe measurements and a 3D points from the surface can be obtained.

Laser triangulation and other techniques can be used to acquire 3D point clouds representing outside surfaces of parts of human bodies.
Scanning techniques play an important role in determining how data for bio-surfaces will be obtained for use in solid modeling.

2.4.2 Polygonal Simplification Methods

Accurate human body modeling requires a detailed surface in order to create a realistic geometric model. Currently, due to the variety of scanning techniques, accurate human bodies can be captured and represented digitally, creating a valuable resource for designers [4]. Unfortunately, due to file size and various interference sources during acquisition, scanned data often requires significant simplification and noise reduction before the models can be used for product design or visualization.

Scan data comes into a system in the form of a point cloud. Scanners are capable of obtaining 100,000 to 500,000 coordinate data points for the surface of a human model [3]. This is a large amount of data, but gives little information about the surface [16]. The surface is constructed from these data points using an unstructured polygonal mesh. These points are connected by a polygonal model where each point is connected to two or three other points to form a mesh of triangles or quadrilaterals. This mesh can be rendered, creating a detailed surface of the model. In general, the greater the number of polygons, or the greater complexity of the polygonal model, the better the model appearance. However, the more detailed, the larger the file. This can cause problems in the amount of time it takes to manipulate and store the model [24].

Polygonal simplification methods offer solutions to such problems. These techniques seek to reduce render time without significantly reducing the visual details of the model. In the selection of a simplification algorithm, no single algorithm works best for all
cases. The algorithm used depends on the desired results. In some cases, preservation of geometric accuracy is desired while in other cases high visual fidelity is the main goal. In either case, the main purposes for mesh simplification are to eliminate redundant geometry, reduce the model size, and/or improve runtime performance.

There are a number of polygon simplification methods and algorithms that are used to convert models depending on the goal. However, all methods generally use one or more of four simplification mechanisms. These mechanisms are Sampling Algorithms, Adaptive subdivision, Decimation, and Vertex merging schemes. Methods for polygonal simplification must be investigated in order to create human models from the scan data that can be manipulated and referenced in the CAD systems.

2.5 Anatomical Positions, Planes, and Directions

Medical professionals often refer to sections of the body using established anatomical planes and directions. In human anatomy, the body is divided into sections by three planes, where the anatomical position of the body is defined as standing, with the palms of the hands facing forward [23].

The three main anatomical planes of the human body are the Midsagittal Plane, the Coronal Plane, and the Transverse Plane, shown in Figure 1.1. The Midsagittal Plane, also referred to as the Median Plane, is a vertical plane that divides the body into equal right and left halves [21]. The Median Plane runs through the middle of breastbone or sternum from front to back [23]. The Coronal Plane is a vertical plane that divides the body into front and back halves [22]. The Coronal Plane runs from side to side and follows the Coro-
nal Plate in the skull, which is on top of the skull just in front of the ears. Finally, the Transverse plane is a horizontal plane that divides the body into top and bottom halves. The Transverse Plane runs through the waist of the individual [20]. All vertical planes parallel to the Median or Midsagittal plane are referred to as Sagittal planes. Any plane dividing the body or a limb into upper and lower parts is a transverse plane.
Anatomical directions of the body are taken with respect to the defined anatomical planes. The medial and lateral directions are taken with respect to the Median Plane. Positions that are toward the Median plane are medial positions and lateral positions are away from the median plane. Posterior and anterior are defined with respect to the Coronal Plane. Posterior features or objects are on the back half of the Coronal Plane, while anterior features are on the front of the Coronal Plane. The superior and inferior directions are defined with respect to the Transverse plane where superior features are above the transverse plane, and inferior features are below the transverse plane [22], [23]. Proximal refers to being nearer or closer to a specified reference while distal refers to being farther from a specified point of reference [23]. Figure 1.1 illustrates the three anatomical planes, the anatomical position, and the anatomical directions of the human body.

Anatomical positions, planes, and directions are necessary to create anatomically meaningful geometric references on the human body that designers as well as medical professionals will recognize.

2.6 Virtual Environments

Although most designing for scanned data is based on measurements extracted from scanned models, research is being done to create virtual environments where a designer, generally for clothing, can build directly on the scanned model and gain insight from the model’s shape, size, curvatures, and overall surface [2].

Usoh et al. developed a paradigm for interactions where a designer can sweep a shape or surface and visually create an interpolated surface on a computer screen [7]. At all times, the designer has a virtual body representation, and can therefore create surfaces
on that representation. The system allows the designer to move, deform, stretch, and apply forces to the created surfaces. These virtual environments are not similar to the CAD system environments familiar to most mechanical engineers and do not provide regular solid modeling operations.

2.7 Assembly Modeling and Design

Assembly models are mock-ups of a final mechanical product in assembly form. Each part of the product is modeled and then assembled together to create the assembly model. Assembly models are essential in design and allow designers to evaluate interferences of parts in the assembly, review and specify assembly procedures, review the relative motion of parts, and simulate product appearance. To assemble parts into an assembly model, mating conditions are specified and dictate how geometry or reference datums are constrained in order to hold the product together in a logical fashion.

In general, assembly modeling research focuses on three areas which include analysis and computer representation of assemblies, the generation of sequences for product assembly, and integrated assembly design utilizing several tools and techniques. This research contributes to the analysis and computer representation of assemblies area by allowing a new technique for assembly design for products that interface with the human body. However, work in all three areas will be discussed next.

2.7.1 Analysis and Computer Representation of Assemblies

The analysis and computer representation of assemblies involves component modeling as well as the definition of mating conditions to articulate the assembly model of a
product. This section discusses computer representation of assemblies by discussing the theories in assembly modeling and the mating conditions used to define an assembly. As in mechanical design, there are two theories in assembly modeling. These approaches are the bottom-up and top-down methods to assembly modeling.

2.7.1.1 Bottom-Up Assembly Modeling

In the bottom-up design approach, each part of an assembly is modeled separately and has its own internal and private variables. Relationships are not established between the separate parts at this stage of the design. After the modeling of each part is complete, the separate parts are then imported into and arranged in an assembly model. In the parameterization of a bottom-up designed product, shared dimensions can be referenced during modeling; however, the parts still have their own proprietary dimensions and variables.

Currently, unless parametric relationships are defined in the CAD system, solid modeling programs rely on bottom-up design approaches. The solid models of each part in the assembly are created, followed by the definition of assembly relations and constraints between the completely defined components. Most assembly representations of the bottom-up approach involve the definition of component models and positioning the models in space.

2.7.1.2 Top-Down Assembly Modeling

On the other hand, top-down assemblies begin with the definition of an assembly file which provides a global reference frame for all parts in the file. Top-down assembly design shifts the focus from managing the design of individual parts to managing design in
terms of the mechanical interfaces between the parts [78]. Figure 2.2 demonstrates the
design of one of the components in a top down assembly process. Currently, CAD systems
allow for top-down assembly modeling capabilities once the parts in the assembly have
been modeled. Generally, these capabilities involve the definition of parametric relations-
ships between parts within the assembly. Also, these capabilities are used to simulate
assembly drawings and share geometric information between CAD and CAM oriented
activities [62], [63].

Several research groups have studied methods for the top-down design of assem-
bles. Popplestone introduced top-down assembly design using engineering entities
referred to as modules [64]. In this method, each module corresponded to mathematical
constraints. The designer then specified relationships between the modules to define the
overall product.

Mäntylä introduced a method of assembly modeling that can represent the assem-
bly information at several levels of abstraction as well as supporting hierarchical views of
the designed object, abstract geometry, geometric constraints for modeling the design
intent and the mating of parts of the assembly, and parametric design of feature models
[65].

Gui developed a methodology that is based on multi-graph data structure of assem-
bles [66], [62]. This structure represents both components and connectors where the com-
ponent performs the functions required for structural or kinematic requirements and the
connector performs the constraint functions required to make the components mate.
Figure 2.2  Top Down Assembly example. a) An interface is used to create a space for the creation of a new part. b) The new part is modeled off of the interface by using parameters from the assembly model. c) The new part is added to the assembly.
Gui and Mäntylä developed a top-down assembly modeling system based on function-based assembly modeling instead of feature-based assembly modeling [67]. This system utilizes the concept that modeling an assembly hierarchy is based on both structural and functional divisions. All information is contained in the "mechanical design prototype," which integrates design theory, functional modeling, features, knowledge engineering, decision support systems, bond graph theory, fuzzy logic, and analogical reasoning. This method links different types of geometric classes in a design process.

2.7.1.3 Modeling Assembly Topology

Many researchers have worked on methods to represent assembly topology to perform analysis or improve assembly design. In general, detailed descriptions of parts and their interactions are necessary to visualize and apply functional analysis methods [76]. Most researchers have developed and used graph structures in order to model an assembly.

Bourjault used a graph structure referred to as a liaison diagram to represent an assembly [69]. In the liaison diagram, a part is represented in the graph by a node. Joints connecting two parts are represented by arcs.

Lee and Gossard developed a method for representing assemblies by creating a two part assembly data structure [70], [71]. The first part of the data structure contains the topological and geometric information of the assembly while the second stores information on how the parts are connected. This method is represented in a tree structure.

Other research in modeling assemblies has been done by [72], [73], [66], [67], [80], and [68]. These methods work to capture and represent assemblies through compo-
2.7.1.4 Mating Conditions

In assembly modeling, parts interface, or mate, with other parts in a definable way to create a product. These mating conditions are generally based upon shared axes, faces, or distances between two parts. Mating categories in traditional mechanical assembly modeling include contact, angular, or distance conditions. Each category has several types of mating conditions. In assembly modeling, each part must have defining parameters that position it with respect to the other parts in the assembly.

Contact mating conditions include the mate, align, and tangent conditions. The mate condition places two mating faces coincident to each other, with normal vectors facing each other. The align condition is similar to the mate condition, however, instead of the normal vectors pointing toward each other, the vectors point away from each other. Finally, a tangent mating condition exists when the face of one surface contacts the tangent of a cylindrical or spherical part. The contact mating conditions are illustrated in Figure 2.3.

The angular mating conditions consist of parallel, perpendicular, or custom angle. The parallel mating condition places two faces or axes parallel to each other while the perpendicular mating condition places them at a perpendicular angle. The custom angle allows the axes or faces to be placed at an angle specified by the user. Examples of these mating conditions are found in Figure 2.4.
Distance conditions are used to position two non-coincident parts relative to each other. Distance conditions include the center condition or the specification of a distance between two faces. These conditions are illustrated in Figure 2.5.
2.7.1.5 Key Characteristics

In assembly modeling, the use of Key Characteristics (KC’s) has gained popularity among many companies as a method of focusing product design, assembly, and manufacturing around important product features [74], [77]. According to Lee and Thornton [77], KCs are "product features, manufacturing process parameters, and assembly features that significantly effect a product’s performance, function, and form." These key characteristics define top-level requirements and articulate requirements and relationships between

![Angular Mating Conditions](image.png)
parts that are most important in the assembly. They are geometric features and material properties that are highly constrained, and where small deviations from their nominal specifications would have a significant impact on the function or form of the product [78]. Typically, KCs relate features on different parts to each other. An assembly can be thought of as "a set of parts that work together as a system to achieve KCs" [75].

Figure 2.5 Distance Mating Conditions. a) Center b) Distance between faces
Key characteristics are classified into three fundamental categories [77]. These categories include product KC’s (PKC), manufacturing KCs (MKC) and assembly KC’s (AKC). PKCs are key characteristics that relate to the individual parts of the assembly that affect the product function or form as a whole. These KCs do not relate the interaction of parts, but basic part geometry and how they influence the products specification. MKCs are parameters for manufacturing machine processes and/or fixturing features. They significantly effect the realization of a product or assembly. Finally, AKCs are features of an assembly that effect the realization of the final product and include mating conditions and features that affect the assembly of the product.

In the design of an assembly using KCs, the design must first begin with a general description of the top level design requirements, which includes the definition of all key characteristics for the product. These requirements then flow down to the assembly and finally to the individual parts. Requirements must be in a measurable form. Thus, a KC is achieved when dimensions or metrics of the KC are within the specified tolerances [75].

2.7.1.6 Top-Down Assembly Modeling Methodologies using Key Characteristics

Several researchers have developed systems for the design of assemblies using key characteristics. These KCs are used to locate and define critical interfaces in the assembly at the beginning of the design process in order to ensure that the desired form and function of the product is satisfied.

In [79], Muske describes a top-down design methodology where key characteristics are translated into critical features on products and parts. His proposed method
describes how to choose assembly and fabrication methods and is applied to 747 fuselage sections.

Because products are complex and made up of many interacting parts, Whitney et al. introduced a technique for designing assemblies that is built upon the identification of key characteristics, the design of the assembly architecture that will satisfy the key characteristics, and finally conveying the architecture in the form of a liaison diagram and datum flow chain. The datum flow chain represents how the product parts relate to each other geometrically in order to satisfy and deliver the key characteristics in the final product. This approach is expanded in this dissertation to address the needs of biomechanical design.

2.7.2 Generation of Sequences for Product Assembly

An essential element of product design is the generation of sequences for product assembly. The choice of assembly sequences affect both the product and manufacturing layout, therefore it is an important aspect of assembly modeling in time and cost reduction. Assembly sequence design involves the identification of sub-assemblies, clearances, tolerances, factory layout, assembly forces, and surface interactions [62].

Several researchers have developed methods and techniques to generate assembly sequences. [81], [82], and [83] have developed techniques for assembly sequences that begin with all part descriptions in the assembly. While some of these researchers have worked to generate all possible sequences in the assembly model, others have worked to generate sequences that satisfy a specified constraint in the assembly. Some of these meth-
ods rely on user inputs to determine relationships between assembly parts, while others use CAD databases to obtain information.

Romney et al. [85] developed software to generate assembly sequences. This system automatically determined how to assemble a product given the geometric description of the assembly.

Baldwin et al. [84] developed a method of sequence generation that evaluated a product for the number of fixtures, reorientations, and subassemblies. This method used an integrated computer to evaluate the assembly sequence.

2.7.3 Integrated Computer Tools in Assembly Modeling

In assembly design, research has also been done using approaches that integrate analysis tools, database software, and CAD techniques to model assemblies. Most of these systems and techniques are based on bottom-up approaches to assembly modeling and require the full articulation of parts before they can be used in the assembly.

Huang and Lee [88] developed a system of assembly modeling that generated assembly plans from a CAD model using analysis techniques, such as predicate calculus and heuristics. Eversheim and Baumann [89] demonstrate the DEMOS system to optimize the assemblies, allowing the product structure and part geometry to change in order to develop a product. This research combined commercial solid modelers with data management tools to create the system. Hsu et al. [90] described a system based on integrated design planning, where feedback evaluation was used to redesign assemblies using criteria such as minimizing assembly time, operation reduction, and the ease of product assembly.
2.8 Mass Customization and Parametric Strategies

2.8.1 Mass Customization

Mass customization describes an approach to business where technology and business strategies are used to provide customized products to the customer through speed and specificity [50], as well as a flexible method for producing product variety and customization [51].

Gilmore and Pine [52] presented four approaches to mass customization, described below and illustrated in Figure 2.6.

1. Collaborative: The company works directly with the customer to create an individualized product that satisfies the needs of the customer.

2. Adaptive: The company creates a single product that can be customized or changed by the customer.

3. Cosmetic: The company uses different techniques to present the same product to customers.

4. Transparent: The company customizes products for the customer without the customer’s knowledge.

In addition to four different approaches to mass customization, there are also different levels, or degrees, to customization. Lampel and Mintzberg describe five levels for customization which range from little or no customization to a purely customized product [53]. The first level is pure customization where the company works with the customer to
create a product to satisfy the customer’s needs. The second level, tailored customization, involves altering a generic product to fit the needs of the customer. Customized Standardization, the third level of customization, is the custom assembly of generic or standard components. In segmented standardization, the fourth level, products are standardized, yet allow some customization for features. There are more choices available to the customer, however, the customer does not have a direct influence over the design. Finally, the fifth level is pure standardization where the product is not customizable, but has a broad target
market. Other studies apply methods of modularity, process design, manufacturing and template approaches to achieve mass customization.

Mass customization for biogeometric interfaces allows the creation of a biomechanical device to be customized for an individual.

2.8.2 Parametric Strategies

As discussed previously, parameterization is the process of identifying key parameters on which all relationships of the model or device are based. Thus, as these few key parameters are changed, the model can be updated allowing these parametric models to increase the efficiency of a design process. Although the initial "generic" parametric model may take some time to create, the reusability of the model allows for more innovation [38] and future derivative designs can be created with little design time. Because of this, the generic product definition, or the generic parametric model, along with standardized parametric design objects are the greatest advantage of parametric models [39]. Most work in parametric methods is in reference to CAD, where parametric capabilities are found in most of the CAD software packages [44].

The basic parametric strategy is to set up a base parametric model definition. The parametric model definition contains the key parameters and dimensions of the model as well as the relationships between the dimensions [42]. This definition can include a feature structure for the model along with a parameter scheme and relations [43]. The parameter scheme includes the dimensions for the model and relations are the relationships or associations between the dimensions. From the key parameters, feature structure, parameter scheme, and relations, a generic parametric model definition can be defined for the
model or product. In setting up a parametric model it is critical to understand the parameter limits and the envelope for which the model is valid. Hoffman and Kim [49] have researched this problem and have developed an algorithm that determines the valid range for each parameter in simple rectilinear polygons.

The next level in parametric strategies, after parametric definitions, can be either an interactive strategy or a programmatic strategy. In the interactive approach, parameterization of the model is achieved by using the parametric capabilities within the CAD system [44]. The parametric model is created within the software tool through point-and-click commands. Model relationships and parameters are defined by using the parametric capabilities of the software. Then, as parameters change by user input, derivative models can be created. In the programmatic approach, the use of a programming tool kit or application programming interface (API) is used to build batch files or create an executable program that can dynamically create the model as the program runs [38]. With the programmatic approach, the designer has more control in the methods for setting up the parametric model, can create more complex designs and processes, and can employ databases and data structures in the model [40], [41]. In addition, programmatic approaches can be used to create parametric models for artifacts besides solid CAD models. Drawing models, analysis models, manufacturing models, technical publication models, and manufacturing process sheets can all be set up parametrically where as the solid model or product changes, these artifacts can also be updated automatically [38],[40], [45], [46], [47], [48].

Using parametric strategies in biogeometric interface design will allow for mass customization applications and processes that are more time and cost effective. The rede-
sign of a product for an individual will require only an update to the parametric model instead of starting at the beginning of the design process for the new individual.

2.9 Summary

The research presented in this chapter presents background information useful in understanding the approach and development of the work described in the remainder of this dissertation. In order to improve biomechanical design techniques and allow the customization of these products, prior research in the areas of design methodologies, interface criteria for interfaces, geometric references, scan data, assembly modeling techniques and theories, and mass customization must be studied. This research helps form and develop design theories and methodologies to improve biomechanical design as well as allow the application of parametric techniques to products that interface with the body.
CHAPTER 3 METHODOLOGY

The unique demands of bio-interface design requires its own design process. However, in order to take advantage of the extensive research and development in design process tools and techniques, this methodology should be as similar as possible to the traditional mechanical design methodology. Consequently, the method for developing the proposed new bio-interface design process involves integrating biomechanical steps and techniques into the traditional design process.

3.1 Research Methods

In Chapter 1, the following reasons were identified as areas that must be addressed in order to allow the creation of customizable products that interface with the body.

1. Bio-surfaces and interfaces are more complex geometrically than traditional mechanical surfaces.

2. Current CAx tool approaches are developed for prismatic parts and are therefore insufficient for bio-interface design.
3. Parametric strategies required for bio-interface design are more sophisticated due to complex surfaces and interfaces. It is difficult to define parameters associated with the human body.

These undeveloped areas of mechanical design are addressed in this dissertation with three areas of research, illustrated in Figure 3.1. Research in geometric references, assembly modeling, and design methodologies all contribute to the development of a bio-interface design methodology that expands traditional methods and design tools.

In the development of a bio-interface design techniques and processes, the traditional mechanical engineering process was used as the starting point. This method has been used successfully in the engineering industry, so it was assumed that the biomechanical design methodology would be a derivative of this process. The traditional design process was then tested for deficiencies. As the methodology was tested, deficiencies and issues were addressed, leading to the integration of geometric references and assembly modeling techniques into the methodology. This resulted in the three design strategies developed in this research.
Testing for the biomechanical methodology was done through the assigning of class projects and the development of case studies. For several semesters, students in the Engineering Graphics course were assigned one project during the semester that focused on biomechanical design. The methodology was taught in the classroom and the students then designed and modeled a biomechanical device. Case studies, independent of the classroom, were performed by graduate students and research assistants.

For the most part, the developed bio-interface design methodology followed the traditional design process discussed in Section 2.1 Design Methodologies. Phases 0, 1, 4, and 5 proceed in the same manner. However, Phases 2 and 3 were modified in order to develop the complete specification for bio-interfaces. The new tasks in Phases 2 and 3 involve developing a process structure for the creation of the design geometry based on assembly modeling techniques and solid modeling operations or features that can form the backbone for a reusable design process and can be parameterized and automated. This reusable process structure is integrated into traditional design processes so as to take advantage of as much existing mass customization methods and tools as possible.

3.2 Dissertation Contribution

The main contribution of this dissertation is a design methodology for articulating a customizable product that interfaces with the body. This methodology is described and illustrated in detail in Chapter 7, however all strategies and techniques developed in this dissertation relate to and are essential in this design process. The bio-interface design methodology is illustrated in the following steps, where the bulleted items show the addi-
tions and modifications to the traditional design methodology that address the needs of bio-interface design.

1. Planning

2. Concept Development
   • Geometric Configuration

3. System Level Design
   • Liaison Diagram
   • Mating conditions
   • Parametric Strategies
   • Feature Structure

4. Detailed Design
   • Bio-reference definitions
   • Product geometry creation
   • Parameterization
   • Mass customization

5. Testing and Refinement

6. Production Ramp Up

The development of three design strategies, namely a strategy for attaching geometric references to scan data, top-down assembly modeling with the scan data as the base part, and strategies for identifying parametric variables associated with the human body all contribute to this design methodology for the design of customizable products that interface with the body and are described throughout this dissertation. The strategy for attaching geometric references to scan data is described in Chapter 4.
In biomechanical design, there must be a representation of the human body to accurately model products which interface with human surfaces. The body can be represented by using either anthropometric measurements, which reduce the body into parameter values, or through scanning techniques, which allow the creation of three-dimensional human models. While anthropometric measurements are useful in many mass customization cases, they still lack the full definition of the interface surfaces. In this work, we combine anthropometric measurement techniques with 3D scans of human surfaces to create products that interface with the human body.

Although scans and anthropometric data can create three-dimensional human models, it is difficult to create customizable products that interface with the human body without the use of solid modeling tools and parametric techniques. Solid modeling requires datum planes and axes in order to perform volumetric operations such as extrusions, revolutions, sweeps, and blends. Parametric modeling techniques require a clear specification of independent variables in a product model. However, in a 3D human model, datum planes and references are not defined, and independent variables are not easily identified.
due to the complexity of human surfaces. The independent variables for parametric design in these products should ultimately be scan data, however, due to the volume and complexity of the data, this is not practical. Therefore, in order for solid modeling and parametric techniques to be used for bio-interface design, the human scan data must be referenced and annotated in a logical way as to satisfy the need for datum planes and axes and create a strategy to identify parameters that can relate the product geometry to the body.

4.1 A Strategy for Geometric References attached to Human Scan Data

The first contribution of this research is a strategy for geometric references attached to human scan data. This approach provides tools and techniques that allow solid modeling with respect to human scan data as well as a method to define independent parameters to create parametric models for products that interface with the human body. As mentioned previously, the design methodology developed in this dissertation utilizes the following steps:

1. Planning

2. Concept Development
   - Geometric Configuration

3. System Level Design
   - Liaison Diagram
   - Mating conditions
   - **Parametric Strategies**
   - Feature Structure
4. Detailed Design

- **Bio-reference definitions**
- **Product geometry creation**
- **Parameterization**
- Mass customization

5. Testing and Refinement

6. Production Ramp Up

The steps of the design process that use bio-interface references are bolded in the methodology. The annotation of scan data with geometric references is important in System Level design in the development of parametric strategies for the mating conditions and the articulation of the feature structure where the product is decomposed into the CAD operations for geometry creation. In detailed design, geometric references are essential in geometry creation and product geometry creation.

The geometric references used in traditional CAD applications include datum planes, datum axes, and datum points. These three reference types are used to annotate human scan data to create references for solid modeling operations with respect to the human model, as well as references for later assembly work. Additionally, these references can also serve as parameters for creating parametric models that allow the designed product to be customizable to different human scans.

4.1.1 Bio-Datum Planes

Using recognized anatomical references from the medical field, discussed in Section 2.5, the scan data is annotated with datum planes and axes. These planes and axes
provide orientation references for solid modeling methods and assembly work, as well as variables for parametric models. Figure 4.2. shows the human body annotated with the anatomical datum planes from the medical field. Additional reference datums can then be made with respect to these initial anatomical datum planes using anthropometric measurements. These additional planes can be created parallel to existing anatomical planes and passing through an anthropometric measurement in the form of an anatomical landmark. A fully articulated model therefore consists of scan data representing the surfaces of the human body annotated with anatomical datums and any additional reference datums based off of appropriate anthropometric measurements. Figure 4.2 shows the base part of the

Figure 4.1  Human Body annotated with Anatomical Planes from Medical Field [86].
human head annotated with basic anatomical datum planes. Figure 4.3 and 4.4 show the human head annotated with datum planes based on anthropometric measurements.

4.1.2 Key Bio-Points

Three dimensional scan data comes in the form of a point cloud made up of points with x, y, and z coordinates. In this research, the points in the scan data are selected and used as geometric references referred to as key bio-points. By selecting points in the point cloud as datum references, solid geometry can be created that allows human/product inter-
faces with the complex surfaces of the body. Key datum points can be used alone, or to create reference curves and surfaces utilizing a network or series of key bio-points.

4.1.3 Bio-Axes

Anatomical axes are generally used in the field of biomechanics to analyze the motion of the human body. Generally, several axes are used in each joint of the body to describe the types and range of motion of limbs or other body parts. In this research, axes are used to create solid geometry. Therefore, anatomical axes based in the motion of
joints, axes created by the intersection of bio-planes, or a reference axis between two key bio-points can be used to create solid models of products.

4.1.4 Geometry Creation using Bio-references

After human scan data is annotated with bio-planes, key bio-points, and/or bio-axes, solid modeling techniques can then be used to create geometry that interfaces with the scan data in CAD systems. Techniques for creating this geometry is similar to the creation of products that do not have product-human interfaces. However, to create custom-
ized products for individuals, the product geometry must be directly referenced to these bio-references instead of through a fixed numerical dimension.

Every individual has a unique set of anthropometric measurements and anatomical landmarks. Therefore, because the bio-datum, bio-points, and bio-axes are based off of anatomical landmarks, each individual will have their own set of bio-references. By referencing geometry to these bio-references instead of creating fixed dimensions with respect to one set of scan data, as bio-references change, the product can regenerate to account for differences in human geometry.

In geometry creation for customizable products, solid or surface modeling operations can reference anatomical landmarks by either fixing sketches or volumetric operations to a specified landmark, or by specifying a relationship between geometry and a bio-reference. These relationships can be in the form of distances, angles, or ratios between anatomical references and parts. Sketches for the CAD primitives, such as extrusions, revolutions, blends, and sweeps can then be created using the same techniques used in traditional design.

4.1.5 Demonstration of Bio-References in Computer Aided Design

The use of bio-references allows for the modeling of customizable products using traditional computer aided design software. Figures 4.5-4.12 show the automatic regeneration of extrusions, revolutions, sweeps, blends, and surfaces in simple examples as datum planes and datum points change. The arrows indicate the plane or point that the geometry is referenced to. These examples demonstrate that the different CAD primitives and sur-
faces can be created using references attached to the body. They also show that as these references are changed, the geometry will automatically regenerate to fit their new locations. With this capability, a designer can now create parametric product models that fit a variety of human surfaces. However, before a product can be designed, one must first consider the mating condition between the human-product interface. This requires that we
look at assembly model techniques and expand this approach to address the needs in bio-interface design.
Figure 4.10  Automatic Regeneration of a Revolution as a Datum Point is moved

Figure 4.11  Automatic Regeneration of a Sweep as a Datum Plane is moved

Figure 4.12  Automatic Regeneration of Sweep as a Reference Point in moved.

Figure 4.13  Automatic Regeneration of Surface as Reference Point Coordinates are changed.
The consideration of human-product interfaces is essential in bio-interface design to ensure the proper form, fit, and/or function of a biomechanical device. Human-product relationships must be identified and defined to create a product that meets customer needs and expectations. Therefore the modeling and design of products with bio-interfaces can be approached using top-down assembly methods, where the human data serves as the base part. The product can then be designed taking into account how the product interacts with the body. This chapter introduces the second strategy discussed in this dissertation: An expanded method of assembly modeling for bio-interface design. This strategy fits into the overall design methodology developed in this dissertation in the areas of system and detailed design. This design methodology is outlined as:

1. Planning

2. Concept Development
   - Geometric Configuration
3. System Level Design

- Liaison Diagram
- **Mating conditions**
- Parametric Strategies
- Feature Structure

4. Detailed Design

- Bio-reference definitions
- Product geometry creation
- Parameterization
- Mass customization

5. Testing and Refinement

6. Production Ramp Up

The bolded steps in the above methodology benefit from the use of the assembly model techniques developed in this theory. In system level design, the mating conditions are identified and specified. This specification helps a designer identify the product interfaces that must be parametric and reconfigure to fit a variety of individuals. Thus, the use of top-down assembly model technique using the human surface as the base part can guide a designer in the development of parametric strategies for complex surfaces.

5.1 Expanded Top-Down Assembly Technique for Bio-Interface Design

As mentioned in Section 2.7, top-down assembly technique begins with the definition of an assembly file, which provides a global reference frame for all parts in the file. In this method, the body serves as the base part of the model. The relationships between the
body and all of the components are well-defined before modeling anything in a CAD program. These relationships between the product and the human body can be represented through assembly constraints. By utilizing this method, parametric relationships can be defined before the parts are created. Figure 5.1 demonstrates the design of one of the components in a top-down assembly process.

The first step is to import the annotated base part (the body scan) into an assembly model in a given CAD system. The next step in the process of a top-down design is to define the interface characteristics and criteria for mating parts. In principle, the mating conditions used in traditional CAD are similar to the mating conditions in biomechanical design. However there are some fundamental differences. Traditional assembly modeling focuses on three types of mating conditions: contact, angular, and distance, as mentioned earlier. However, these traditional mating conditions are specified for prismatic parts and not for interface with the complex surfaces of the human body. New classes of mating conditions must be defined for biomechanical assembly design.
5.2 Biomechanical Additions to Traditional Mating Conditions

In traditional design, there are three classes of mating conditions which were discussed in Section 2.7.1.4. Each class has its own subclasses that are used to further describe the organization of a designed product. However, because of the complex surface geometry of human surfaces, these traditional mating conditions are not sufficient to describe an assembly of a product that contacts the human body, or the interface conditions for the product-to-human interface. Consequently, new mating conditions must be specified to accurately model the product-human interfaces. The same general subclasses for mating conditions, however, will still be used. The additional conditions for biomechanical design will be added to each subclass, when necessary, to address biomechanical modeling needs.

In traditional mechanical design, contact conditions include the mate, align, and tangent mating conditions. Because these conditions address prismatic parts, contact conditions for biomechanical assembly design must also address three additional contact options: surface contacts, curve contacts, and point contacts. In surface contacts, entire complex surface areas contact each other. Since human body surfaces are compliant and will change slightly when force is applied, the surface contact must be prescribed in relation to a force per unit area experienced. The second type of contact mating is the curve contact. In this case, a narrow surface or curve of the geometry contacts the human surface. Finally, point contacts occur when a small surface or a point contacts the human surface.
In traditional design, it is possible to align axes, datums, and surfaces. In biomechanical design, these conditions are valid with respect to datum axes of the human body and the anatomical datum planes of the body. There are no additions needed to the align subclass of contact mating conditions.

The tangent subclass consists of the mating of points or curves along a surface. In biomechanical design, the complex human surfaces may sometimes contact products along a line, curve, or surface. However, because this is similar to the additions in the mate subclass, there is no need to add additional conditions under the tangent subclass.

Angular mating conditions consist of an axis and a rotation. For biomechanical design, this can be done on a datum axis of the human body. Additional conditions for the angular class are not needed.

The final mating condition class is the distance class. In traditional design, this mating condition specifies the distance between two prismatic faces or the distance from a datum. In biomechanical design there are additional distances that need to be specified in order to define the assembly of a product to the human body. These conditions include the following distances:

- Point to point
- Point to curve
- Point to surface
- Curve to curve
- Curve to surface
- Surface to surface

Table 5.1 summarizes current assembly modeling mating conditions as well as the additional mating conditions needed to address biomechanical design. Though the necessary mating conditions for biomechanical design have been defined in this dissertation,
they have not yet been implemented in any CAD system. Assembly files in the CAD system have been created using traditional mating conditions already available in the CAD software.

### 5.3 Assembly Design Techniques for Bio-Interfaces

An important characteristic of assembly models is the appropriate geometric relationships between parts. These relationships include the degree to which the mating conditions are met, such as gaps present between parts in the assembly, the proper alignment of components, and how parts mate together. These geometric relationships must be established to allow the creation and assembly of a product as well as the parameterization of the product through the creation of reusable assembly models.

As mentioned in Section 2.7.1.6, Whitney et al. [74] describe a process for designing assemblies that utilizes geometric relationships and assembly features to achieve kinematic constraints over an entire assembly. These geometric relationships are referred to as
Key Characteristics (KCs) and define important relationships between parts, such as clearances, where failure could result if KC's were not followed. This approach lends itself well to the biomechanical assembly design process. Because of this, this assembly model method will utilize some of these techniques to articulate customizable biomechanical devices. Key characteristics will be defined between the parts of the assembly, where the human scan data is recognized as the base part of the assembly. These KCs and assembly features are used to create a model for biomechanical products that utilize human data as the base part of the assembly.

Whitney et al. made use of liaison diagrams in their research. A liaison diagram is a schematic that illustrates the parts in an assembly and represents the interactions and relationships between the different components of the product. Essential relationships between parts, or key characteristics, are represented by connecting the parts with a double line. Other relationships are represented by connecting parts with a single line. By creating a liaison diagram and representing the key characteristics, mating conditions can be easily and effectively identified and defined.

Assembly modeling technique and the annotation of scan data with bio-references are combined to form a strategy for the planning of parametric biomechanical designs. This strategy and process is discussed in Chapter 7. However, in order to design bio-interfaces we must first address methods and techniques for implementing the creation of bio-interfaces in CAD, namely the constraint equations for these mating conditions.
This dissertation outlines a method to design products that interface with the body through the identification of key interfaces, the classification of mating conditions for these interfaces, and 3D parametric constraints for the product. However, current CAD systems do not support the mating conditions for bio-interface design discussed in Chapter 5. CAD programs allow the specification of mating conditions for prismatic parts, but do not support the mating of complex surfaces, curves, and points. This chapter presents the constraint equations necessary for the implementation of these mating conditions in CAD programs. Because CAD geometry relies on the use of Non-rational B-splines (NURBS), a brief background on computer aided graphics and the mathematics involved is discussed prior to the introduction of the bio-interface constraint equations.

6.1 Overview of Computer-Aided Graphics

NURBS are an industry standard for representing geometry in computer-aided design [91]. In order to discuss NURBS, we must first briefly review Bezier curves and surfaces as well as B-spline curves and surfaces.
6.1.1 Bezier Curves and Surfaces

Bezier Curves were introduced during the 1960’s as a tool to represent complex curves and surfaces [92]. Bezier curves are parametric curves whose shape is specified by a series of control points and are a function of a single parameter. Blending functions in the bezier equation blend the control points together to create a bezier curve. In essence, control points "pull" the curve towards themselves, defining the overall shape of the curve. A bezier curve has \( n + 1 \) control points, where \( n \) is the order of the curve. Figure 6.1 shows several examples of cubic Bezier curves where the control points are represented by the circles.

Figure 6.1 Examples of Cubic Bezier Curves [92]
The blending function for a Bezier curve is represented in Equation (6.1).

\[ B_i^n(t) = \binom{n}{i}(1-t)^{n-i}t^i \]  

(6.1)

Where \( i = 0, 1, \ldots, n \), the binomial coefficient \( \binom{n}{i} \), or "n-choose -i," equals \( \frac{n!}{i!(n-i)!} \), and the parameter \( t \) is in the interval \( t_0 \leq t \leq t_1 \). Generally, the interval for a single Bezier curve is \( 0 \leq t \leq 1 \). As stated previously, this function is used to "blend" the control points, resulting in a geometric curve whose shape is dependent on the location of these control points. Using these equations, the mathematical form of a Bezier curve is:

\[ P(t) = \sum_{i=0}^{n} \binom{n}{i}(1-t)^{n-i}t^i P_i \]  

(6.2)

where \( P(t) \) is the point on the curve at \( t \) and \( P_i \) is control point \( i \). From this equation, one can see that for each value of \( t \), all of the control points are weighted and summed, or blended, to create a point, \( P(t) \), on the curve. Figure 6.2 shows a cubic Bezier curve with the control points labeled.

Bezier curves can also be represented in matrix form by expanding Equation (6.2) into the polynomial form. The coefficients of the polynomial can then be written in matrix form using the polynomial power basis. The conversion from the mathematical form of
the bezier equation and the matrix form for a cubic bezier curve is illustrated in Equation (6.3) through Equation (6.6).

\[
P(t) = \sum_{i=0}^{3} \binom{3}{i}(1-t)^{3-i}t^i P_i
\]  

\[
P(t) = (1-t)^3 P_0 + 3t(1-t)^2 P_1 + 3t^2(1-t) P_2 + t^3 P_3
\]  

\[
P(t) = \begin{bmatrix} (1-t)^3 & 3t(1-t)^2 & 3t^2(1-t) & t^3 \end{bmatrix}
\]  

\[
P(t) = \begin{bmatrix} 1 & t & t^2 & t^3 \end{bmatrix} \begin{bmatrix} 1 & 0 & 0 & 0 \\ -3 & 3 & 0 & 0 \\ 3 & -6 & 3 & 0 \\ 1 & 3 & -3 & 1 \end{bmatrix} \begin{bmatrix} P_0 \\ P_1 \\ P_2 \\ P_3 \end{bmatrix}
\]  

Figure 6.2  Cubic Bezier Curve with labeled Control Points
In more general terms, Equation (6.5) can be represented as:

$$[X] = [B][P]$$  \hspace{1cm} (6.7)

Where $[X]$ represents the matrix of points on the curve, $[B]$ represents the matrix of blending functions, and $[P]$ represents the matrix of control points. With this form, matrix operations can be used to calculate the control points of a curve. Solving for the control points results in Equation (6.8):

$$P = [B^T B]^{-1} B^T X$$  \hspace{1cm} (6.8)

Bezier surfaces, or Bezier surface patches, are an extension of Bezier curves and are created by blending a mesh of control points using blending functions. Just as Bezier curves are a function of a single variable, $t$, and blend a series of control points in one direction, Bezier surface patches are a function of two variables, $u$ and $v$, and blend an array of control points in two directions. Bezier surfaces can be thought of as blending a series of orthogonal Bezier curves [94]. Often a surface patch is referred to as an $m \times n$ surface patch where one direction of the patch is made up of curves or order $n$, while the other direction is composed of curves of order $m$. Figure 6.3 shows a Bezier surface with it’s associated control points.

The equation for a Bezier surface patch is similar to that of a Bezier curve, however, since the surface is a function of two variables in orthogonal directions, the control
points must be blended in both directions. Equation (6.9) is the equation for a bezier surface.

\[
P(u, v) = \sum_{i=0}^{m} \sum_{j=0}^{n} P_{i,j} B^m_i(u) B^n_j(v)
\]

(6.9)

Where \(P(u,v)\) is the point on the surface at parameter \(u\) and \(v\), \(P_{ij}\) are the control points in the control point array, \(m\) is the order of the curves in the \(u\) direction, and \(n\) is the curve order in the \(v\) direction. The blending functions for the Bezier surface are equal to those for a bezier curve, however, they must be calculated along the specified direction \(u\) or \(v\).
Figure 6.6 shows a 3x3 Bezier surface patch demonstrating the directions of Bezier curves as well as the method of specifying control points.

As with Bezier curves, Bezier surfaces can also be expressed in a matrix form by expanding the mathematical definition into the polynomial form and writing the coefficients in matrix form. Equation (6.10) and Equation (6.11) shows the matrix form for a 3x3 Bezier surface.
Where \([P]\) represents the matrix of control points shown in Equation (6.12).

\[
P(u, v) = \begin{bmatrix}
(1 - u)^3 & 3u(1 - u)^2 & 3u^2(1 - u) & u^3
\end{bmatrix}
\begin{bmatrix}
P_0,0 & P_0,1 & P_0,2 & P_0,3 \\
P_1,0 & P_1,1 & P_1,2 & P_1,3 \\
P_2,0 & P_2,1 & P_2,2 & P_2,3 \\
P_3,0 & P_3,1 & P_3,2 & P_3,3
\end{bmatrix} P
\]

\[
P(u, v) = \begin{bmatrix}
1 & 0 & 0 & 0 \\
-3 & 3 & 0 & 0 \\
3 & -6 & 3 & 0 \\
-1 & 3 & -3 & 1
\end{bmatrix}
\begin{bmatrix}
P_0 & P_1 & P_2 & P_3 \\
1 & -3 & 3 & -1 \\
0 & 3 & -6 & 3 \\
0 & 0 & 3 & -3 \\
0 & 0 & 0 & 1
\end{bmatrix} P
\]

Although Bezier curves and surfaces create smooth surfaces whose geometry can be intuitively altered by the moving of control points, most curves and surfaces can not be represented by a single Bezier curve or surface due to their complexity.

### 6.1.2 B-Spline Curves and Surfaces

Because most shapes are too complex to be described by a single Bezier curve, several bezier curves can be connected end to end to create a spline of curves. In connecting a series of curves, the smoothness of the transition from one curve to the next is dependent on whether the curves are connected as well as the matching of tangents and curvatures of the curves at their connection point.
The smoothness of a spline is described by the degree of continuity. There are two types of continuity in describing the smoothness of a curves which include geometric and parametric continuity. Geometric continuity refers the directions of the connecting curves and is represented by $G^n$, where $n$ is the degree of geometric continuity and the connection point of the curves. The main descriptions of Geometric continuity are:

- $G^0$: position matches for both ends of curves at connection point
- $G^1$: tangent directions match for both curves at connection point
- $G^2$: curvature directions match for both curves at connection point

Figure 6.5 demonstrates these degrees of continuity. The second type of continuity, parametric continuity, requires not only the directions to be continuous, as in geometric continuity, but the parametric functions as well. This means that both the direction and magnitude of the derivatives at the connection point must match. Parametric continuity is represented by $C^n$. The main degrees of parametric continuity are:
With geometric continuity, the geometry must be continuous. Parametric continuity requires the parameterization to be continuous as well.

A series of \( n^{th} \) order concatenated Bezier curves that join with a \( C^{n-1} \) continuity is referred to as an \( n^{th} \) order B-spline curve [92]. B-splines specify a series of degree \( n \) Bezier curves that are joined with a \( C^{n-1} \) continuity. If a series of \( m \) Bezier curves of degree \( n \) were concatenated, the set of curves would have \( nm+1 \) control points. However, with the mathematical definition of a B-spline, these curves can be expressed using \( m+n \) B-spline control points [92]. Thus, the control points for the individual Bezier curves are not the same as the B-spline control points. The Bohm algorithm can be used to extract the individual Bezier curves from a B-spline, however, it is not discussed in this dissertation.

In B-spline curves, the domain of the curve is subdivided at the intersection points of the individual bezier curves. These points of subdivision are referred to as knots and have a value that specifies the parameter interval, \( t \), of the next Bezier curve. In addition to the knots that separate the individual curves, two knots exist at both the beginning and end of B-spline and are used to control the end conditions of the curve. The set of these values is referred to as the knot vector. Thus, a B-spline is specified by a series of \( (n+1) \) control
points, a set of \((m+1)\) knots, and a degree \(k\). Unlike Bezier curves where the order of the curve depends on the number of control points, the order of a B-spline curve is an input and not dependent upon to the number of B-spline control points, but dictates which B-spline blending function is used. However, in B-splines, the relationship \(m = n + k + 1\) must be satisfied. The shape of a B-spline can be altered by changing one or two of these variables. Figure 6.6 shows a B-spline curve with the knots and control points of curve.

The mathematical representation of a B-spline curve is:

\[
C(t) = \sum_{i=0}^{n} P_i N_i^k(t)
\]

Where the \(t\) interval value, \(C(t)\) is the curve as a function of \(t\), \(P_i\) is the \(i^{th}\) control point, \(k\) is the order of the B-spline curve, an \(n\) is number of control points plus 1. \(N_i^k(t)\) are the normalized B-spline blending functions for the curve and are equal to
for a degree zero B-spline curve. For higher degree B-spline curves, the recursive formula found in Equation (6.15) is used:

\[
N_j^0(t) = \begin{cases} 
1, & \text{if } (t_i \leq t \leq t_{i+1}) \\
0, & \text{otherwise}
\end{cases}
\] (6.14)

for a degree zero B-spline curve. For higher degree B-spline curves, the recursive formula found in Equation (6.15) is used:

\[
N_j^k(t) = \left( \frac{t-t_j}{t_{j+k}-t_j} \right) N_j^{k-1}(t) + \left( \frac{t_{j+k+1}-t}{t_{j+k+1}-t_{j+1}} \right) N_{j+1}^{k-1}(t)
\] (6.15)

When the knots of the B-spline are equidistant along the curve, the B-spline is uniform. Otherwise, the B-spline is referred to as a non-uniform B-spline. This non-uniformity allows for a greater control of the overall curve because the individual Bezier sections can be lengthened or shortened according the desired shape of the curve. For even greater control, weights can be assigned to the control points in the curve, allowing some of the control points to have a greater influence on the overall shape of the curve. Figure 6.7 demonstrates how weights influence the shape of the curve. When a B-spline is both

Figure 6.7 Two B-spline Curves with the same Control Points and Knot Vector [96]. Different weights on the control points cause the overall shape of the two curves to differ.
non-uniform and uses weights to control the curve shape, it is referred to as a Non-Uniform Rational B-spline, or NURB.

Because of the control that NURBs give designers, NURBs have become an industry standard in computer aided graphics and design. NURBs can represent points, lines, and conic sections. The equation for a NURB curve is:

$$C(t) = \frac{\sum_{i=1}^{n} N_i^k(t)w_i P_i}{\sum_{i=1}^{n} N_i^k(t)w_i} \quad (6.16)$$

Where $w_i$ represents the weight assigned to each control point. Notice that if the weights are all equal to 1, the curve equation reduces to that of a B-spline.

As Bezier surfaces are an extension of Bezier curves, so are B-spline surfaces an extension of B-spline curves. B-spline surfaces use a series or orthogonal B-spline curves and an array of control points to create a surface. Equation (6.17) shows the mathematical representation for a B-spline curve with $n+1$ control points in the $u$ direction, $m+1$ control points in the $v$ direction, $h+1$ knots in the $u$ direction, $g+1$ knots in the $v$ direction.

$$P(u, v) = \sum_{i=0}^{m} \sum_{j=0}^{n} N_i^k(u)N_j^l(v)P_{i,j} \quad (6.17)$$

Where $P(u,v)$ is the value of the point on the B-spline surface at parameter $u$ and $v$, $P_{i,j}$ is a point in the control point array, $k$ is the order of the curves in the $u$ direction and $l$ is the
order of the curves in the \( v \) direction. The fundamental relationship between the number of knots, the order of the B-spline surface, and the number of control points must be satisfied in both the \( u \) and \( v \) directions. These relationships are \( h = n + k + 1 \) and \( g = m + l + 1 \).

For a NURB surface, weights must be assigned to each control points in the control point array, allowing a greater degree of control in the surface geometry. NURB surfaces can be used to model extremely complex geometry. Figure 6.8 shows an example of a surface modeled with a single NURB. The mathematical representation of a NURB is shown in Equation (6.18).

\[
P(u, v) = \sum_{i=0}^{m} \sum_{j=0}^{n} N_i^k(u)N_j^l(v)w_{i,j}P_{i,j}
\]

(6.18)
6.2 Bio-Interface Mating Conditions

To implement bio-interface mating conditions in CAD, constraint equations for bio-interfaces must be developed in a form used in CAD systems. These relationships correlate with interface criteria for comfort where pressures can dictate the distances used in the constraint equation. Although not further developed in this dissertation, the distances between points, curves, and surfaces tie into the mating conditions and constraint equations must follow the method used by CAD systems to calculate geometry of mating parts. This means the constraint equations must use points, lines, planes, and NURBs.

The mating conditions for bio-interface design, discussed in Chapter 5 include:

- Point-to-Point
- Point-to-Curve
- Point-to-Surface
- Curve-to-Curve
- Curve-to-Surface
- Surface-to-Surface

It is important to note that for each mating condition type, the necessary points, curves, and surfaces for the mating condition must be defined parametrically to scan data. This allows the points, curves or surface to adjust and update to fit the new scan data. Although not further developed in this dissertation, methods for allowing this capability include landmarking and template models. With landmarks, points, curves, or surfaces on the scan data can be defined in terms of these landmarks. With a template model, the reference elements are defined in absolute terms where a template model is used to update...
the scan data so that a point on the scan data will have the same number of points at the same location as the template model, but follow the new scan surface.

The following sections define methods for the numeric implementation of the bio-interface mating conditions in a CAD system. To discuss this implementation, the theoretical basis behind the numerical method is also presented. For each mating condition, the description of the constraint, the strategy behind implementation of the constraint, and the numerical constraint implementation in the CAD system is presented.

6.2.1 Point-to-Point Constraint Equation

The point-to-point constraint equation allows a point on the product geometry to interface with a specified point on the human scan data. This interface can be either direct contact, where the distance between points is zero, or a specified distance. Potential applications for a point-to-point constraint in products that interface with the body are:

- knee brace hinge with knee joint
- surgical stereotaxy devices
- elbow brace

6.2.1.1 Theoretical Basis for Point-to-Point Constraint Equation Implementation

In designing a point-to-point mating condition, the parametric relationship between the human surface and the product geometry must first be defined. In the case of a point-to-point mating condition, the parametric relationship is the definition of the dis-
tance between the two points. This distance can be positive, zero, or a negative value if a force is desired at a location on the body.

The constraint equation for a point-to-point mating condition utilizes the equation for the distance between two points, shown in Equation (6.19).

\[ d = \sqrt{(x_2 - x_1)^2 + (y_2 - y_1)^2 + (z_2 - z_1)^2} \]  
(6.19)

Where \( d \) is the distance between points \( P_1 = (x_1, y_1, z_1) \) and \( P_2 = (x_2, y_2, z_2) \).

If the scan data, or human surface, is approximated by a NURB surface, a selected point on the human surface that interfaces with a point on the product geometry can be represented by Equation (6.20).

\[ P_2(x, y, z) = S(u_0, v_0). \]  
(6.20)

Where \( P_2(x, y, z) \) represents a point with \( x, y, \) and \( z \) coordinates at \( u_0, v_0 \) on the human surface \( S(u, v) \). Thus, the distance equation for a point-to-point mating condition would be:

\[ d = \sqrt{((S(u_0, v_0)_x - x_1)^2 + (S(u_0, v_0)_y - y_1)^2 + (S(u_0, v_0)_z - z_1)^2)} \]  
(6.21)

Where \( S(u_0, v_0)_x \) is the \( x \) coordinate, \( S(u_0, v_0)_y \) is the \( y \) coordinate, and \( S(u_0, v_0)_z \) is the \( z \) coordinate at point \( u_0, v_0 \) on the NURB surface \( S(u, v) \).
6.2.1.2 Numeric Implementation of Point-to-Point Constraint Equations

The numeric implementation of the point-to-point constraint in a CAD system requires the system to allow the user to select a point on the human scan data. This point must be fully defined in terms of either anatomical landmarks, bio-references, or in absolute terms to allow for a parametric model. With the definition of the parametric relationship (the distance value) and Equation (6.21), an iterative process, such as Newton Raphson can be used to calculate the point on the product geometry.

Generally, the point on the product geometry will be located on a normal vector from the human data. This normal vector can be either the normal to a curve on the human scan data, or the normal of the human surface. This results in a point-to-curve and the point-to-surface constraint equation. The next sections further develop the theoretical basis and numerical implementation for these constraint equation.

6.2.2 Point-to-Curve Constraint Equation

The point-to-curve constraint equation allows a point on the geometry to interface with a specified curve on the human scan data. Like the point-to-point constraint equation, this interface can either be direct contact or a specified distance. Potential applications of this mating condition in products are:

- Halo Brace
- Foot Orthotic
- Posture Corrector

The next sections describe the strategy and implementation of the point-to-curve constraint equation.
6.2.2.1 Theoretical Basis of Point-to-Curve Constraint Implementation

The point-to-curve constraint equation can be represented using the offset curve equation. If the curve on the human surface is approximated with the NURB $C(t)$ and the point on the NURB curve where the interface is to occur is at $t_0$, the equation for the new point is:

$$ P(x, y, z) = C(t_0) + d\vec{n}_0 $$ (6.22)

Where $P(x, y, z)$ represents the point on the product geometry that interfaces with the curve on the human surface at $t_0$, $d$ is the distance for the point-to-curve interface, and $\vec{n}_0$ is the normal to curve at $C(t_0)$. The equation is referred to as the offset curve equation.

In creating the product geometry, the user will generally know the NURB approximation of the curve on the human surface, $C(t)$ as well as the distance to the point on the product geometry. The steps for creating a point that interfaces with a curve on the scan data is:

1. Define the parametric relationship between the curve on the human surface and the point on the product.
2. Create guide curve on scan data, defined in reference to scan data
3. Specify direction and distance of product point from guide curve
4. Using the distance function, calculate the new point on the geometry the specified point on the guide curve using Equation (6.22).
6.2.2.2 Numerical Implementation of Point-to-Curve Constraint Equations

The Curve-to-curve constraint equation requires that the CAD system allow the user to create a curve on the scan data. This curve must be fully defined in either absolute terms, in reference to bio-reference planes, or with respect to anatomical landmarks. Generally, the curve would be created through a series of points on the scan surface. The steps for numeric implementation are:

1. Create the guide curve through a series of points on the scan surface
2. Specify the distance function for projecting the product point from the guide curve. In general, the scan data will be represented by a polygon. The directional vector can be calculated in terms of the polygon plane
3. At the specified point on the guide curve, calculate the distance function
4. Construct the point on the product.

6.2.3 Point-to-Surface Constraint Equations

The point-to-surface constraint equation allows a point on the geometry to interface with a specified surface on the human scan data. Like the point-to-point and point-to-curve constraint equations, this interface can either be direct contact or a specified distance and utilizes the distance equation between two points. However, in calculating the normal vector from which to project the new point and the specified distance, the normal vector for a surface will be calculated. Potential applications of this mating condition in products are:
Safety glasses frame to side of head
- Orthotic devices
- Radiation therapy masks

6.2.3.1 Theoretical Basis for Point-to-Surface Constraint Equation Implementation

If the human surface is approximated with the NURB surface \( S(u, v) \) and the point on the NURB curve where the interface is to occur is at \( u_0, v_0 \), the equation for the new point is:

\[
P(x, y, z) = S(u_0, v_0) + d\vec{n}_0
\]  \hspace{1cm} (6.23)

Where \( P(x, y, z) \) represents the point that interfaces with \( S(u_0, v_0) \), \( d \) is the distance for the point-to-surface interface, and \( \vec{n}_0 \) is the normal to curve at \( S(u_0, v_0) \).

Generally, the user will know \( S(u_0, v_0) \), the point on the human surface for the interface, and the distance to the point on the product. Therefore the steps for implementation are:

1. Define the parametric relationship between human surface and point on the product.
2. Create guide point on scan data that interfaces with the part. Define point in reference to scan data
3. Specify direction and distance of product point from guide point
4. Using the distance function, calculate the new point from the guide point on the human surface.

6.2.3.2 Numeric Implementation of the Point-to-Surface Constraint Equation

The Point-to-Surface constraint equation requires that the CAD system allow the user to create a reference surface on the scan data. The steps for numeric implementation are:

1. Create the guide surface through a series of points on the scan surface
2. Specify the distance function for projecting the product point from the guide surface. This distance function will be defined by the parametric relationship that defines the type of point-to-surface constraint. This can be in the form of the normal vector or a directional vector. In general, the scan data will be represented by a polygon. The directional vector can be calculated in terms of the polygon plane
3. At the specified point on the guide curve calculate the distance function
4. Construct the relative point of the product.

6.2.4 Curve-to-Curve Constraint Equation

The curve-to-curve mating condition occurs when a curve on the human surface interfaces with a curve on the product geometry. This interface can either be a direct contact mating condition or a distance that must be maintained between the body and the product. Potential applications of this mating condition include:
There are three types of curve-to-curve constraint equations which include:

- Offset Curve-to-Curve
- Projected Offset Curve-to-Curve
- Random Offset

The types of curve-to-curve are a result of the different parametric relationships required between the human body and the designed product. The offset curve-to-curve constraint maintains a constant distance from the curve on the body to the product geometry and results in a constant force. The projected offset curve-to-curve constraint is a scaling of a curve on the body geometry to create the product curve. Finally, in the random offset curve-to-curve constraint, the product curve does not maintain a constant distance from the body curve. This can result in a force on the body. Illustrations of these three curve-to-curve constraint relationships can be found in Figure 6.9.

6.2.4.1 Theoretical Basis for Implementing Curve-to-Curve Constraint Equations

In developing the curve-to-curve constraint equation, the curve on the human surface must be approximated with a NURB curve equation and must be defined in terms of anatomical landmarks and bio-references or in absolute terms. In addition, the parametric relationship, which determines whether the constraint equation is the offset, projected, or
random curve-to-curve must also be defined. The strategy behind these constraint equations utilizes the geometric offset curve equation shown in Equation (6.24).

\[ C_2(t) = C_1(t) + d\mathbf{n} \]  

(6.24)

Where \( C_2(t) \) is the offset curve, \( C_1(t) \) is the original curve, \( d \) is the distance between the curves, and \( n \) is the normal to the curve.

The offset curve-to-curve constraint maintains a constant distance from the curve on the body to the product geometry. This allows the offset curve equation to be used. Points on the product curve can be generated by using Equation (6.24) at different \( t \) values.

Figure 6.9 The Three Types of Curve-to-Curve Constraint Relationships. a) Offset Curve-to-Curve Constraint. b) Projected Offset Curve-to-Curve Constraint c) Random Offset Curve-to-Curve Constraint.
on the curve. Equation (6.25) shows the calculation of a point on the product geometry at $t_0$ for an Offset Curve-to-Curve interface.

$$P(x, y, z) = C(t_0) + d\hat{n}_0$$  \hspace{1cm} (6.25)

Where $P(x,y,z)$ represents the point on the product curve at $t_0$, $C(t_0)$ represents the point on the curve at $t_0$, $d$ is the distance to the product curve, and $\hat{n}_0$ is the normal at $t_0$.

The Projected Offset Curve-to-Curve constraint equation scales the body curve to create the product curve. This equation uses an origin to scale the curve, shown in Equation (6.26).

$$C_2 = C_1 + \|C_1 - origin\|d$$  \hspace{1cm} (6.26)

Where $C_2$ represents the curve on the product geometry, $C_1$ is the curve on the human surface, and $d$ is the distance from the curve on the product geometry and the curve on the human surface.

The random offset curve allows the distance between the product geometry and the human surface to vary, allowing for forces to be exerted on the body. The equation for the random offset curve is shown in Equation (6.27).

$$C_2(t) = C_1(t) + d(t)\hat{n}(t)$$  \hspace{1cm} (6.27)

The construction of this interface requires the definition of a curve on the human surface as well a function specifying the distance from the guide curve to the curve representing on the product geometry. This projection can be done using a ruled surface, which uses a linear blend in one direction, and represents the parametric relationship and dis-
distance function between the curve on human surface and product geometry. The distance function used depends on the type of curve-to-curve constraint, either offset, projected, or random offset. The process of constructing a guide curve projecting the curve using a ruled surface is illustrating in Equation (6.10).

The theoretical process for implementing a curve-to-curve mating condition is summarized in the following steps:

1. Define the parametric relationship between the curve on the human surface and product curve.

2. Create a NURB guide curve on scan data, defined in reference to scan data. Calculate the points on the NURB curve using the NURB equation.

3. Specify direction and distance of product curve from guide curve.

4. Using the distance function, calculate the points on the product geometry from each point on the NURB guide curve.

Figure 6.10 Construction of Ruled Surface for a Curve-to-Curve Mating Condition
5. Interpolate to determine the control points of the curve on product geometry using Equation (6.29).

\[ P = [B^T B]^{-1} B^T X \] (6.28)

With the theoretical basis defined, the numerical implementation of the curve-to-curve interface can be defined.

6.2.4.2 Numerical Implementation for the Curve-to-Curve Constraint Equation

The Curve-to-curve constraint equation requires that the CAD system allow the user to create a curve on the scan data. The steps for numeric implementation are:

1. Create the guide curve through a series of points on the scan surface
2. Specify the distance function for projecting the product curve from the guide curve. This distance function will be defined by the parametric relationship that defines the type of curve-to-curve constraint, either offset, projected, or random offset. This can be in the form of the normal vector or a directional vector. In general, the scan data will be represented by a polygon. The directional vector can be calculated in terms of the polygon plane
3. At each point on the guide curve calculate the distance function
4. Construct the relative points of the product curve.
6.2.5 Curve-to-Surface Constraint Equations

In the curve-to-surface mating constraint, a curve on the designed product is maintained at a specified distance from the surface of the body. This distance can either be a given value or zero, in cases of direct contact between the product and the human surface. Potential applications of this constraint equation are:

- Edge of safety glasses to forehead
- Edge of orthotic to surface of foot
- Edges of prosthetic device to human surface

The implementation of this mating condition relies on the specification of parametric relationships between a curve, representing an edge of the product, and a human surface, represented by scan data. The next sections discuss the theoretical basis of the curve-to-surface implementation and a numerical method for implementing this constraint equation in the CAD system.

6.2.5.1 Theoretical Basis for Curve-to-Surface Constraint Equation Implementation

In developing the Curve-to-Surface constraint equations, parametric relationships between the curve and surface must first be defined. This relationship or interface can be either a direct contact interface, a curve at a normal distance from the surface, or a curve with a distance function from the surface. The surface of the scan data and the curve must be approximated with a NURB surface and NURB curve, respectively.

In the construction of this interface, this application requires a guide curve be defined on the human surface as well a function specifying the distance from this guide
curve to a projected curve representing the edge of the product geometry. This projection can be done using a ruled surface, as in the curve-to-curve constraint equation. The process of constructing a guide curve on a surface and projecting the curve using a ruled surface is illustrating in Figure 6.11. To be parametric, the guide curve must be defined in reference to anatomical landmarks and bio-references through landmarks or absolute terms.

The theoretical process for implementation of the curve-to-surface mating condition is summarized in the following steps:

1. Defined parametric relationship between human surface and product curve.
2. Create a NURB guide curve on scan data, defined in reference to scan data
3. Specify direction and distance of product curve from guide curve
4. Using the distance function, calculate the new points from each point on the guide curve.

5. Interpolate to determine the control points of the product curve using Equation (6.29).

\[ P = \left( B^T B \right)^{-1} B^T X \]  

(6.29)

With the theoretical basis defined, the numerical implementation of the curve-to-surface interface can be defined.

6.2.5.2 Numerical Implementation of Curve-to-Surface Constraint Equation

In the numerical implementation, the ability to define a guide curve on the scan data through a series of points on the scan surface must be provided in the CAD system. The steps for numeric implementation are:

1. Create the guide curve through a series of points on the scan surface

2. Specify the distance function for projecting the product curve from the guide curve. This can be in the form of the normal vector or a directional vector. In general, the scan data will be represented by a polygon. The directional vector can be calculated in terms of the polygon plane

3. At each point on the guide curve calculate the distance function

4. Construct the relative points of the product curve.
As mentioned in the theoretic basis for this constraint equation, the construction of relative points must be defined parametrically to scan data such that when new scan data is used, the curve will be able to adjust and update to fit the new scan data.

6.2.6 Surface-to-Surface Constraint Equation

The surface-to-surface constraint equation exists when a product surface interfaces a human surface. This interface can either be through direct contact or through the specification of a distance that is to be maintained between the surfaces. Potential application of this constraint equation include:

- helmets
- shin guards
- body armor

The next sections discuss the theoretical basis and numerical method for implementation of this constraint.

6.2.6.1 Theoretical Basis for Implementation of Surface-to-Surface Constraint Equations

Because NURB surfaces are an extension of NURB curves, the theoretical basis for implementing a surface-to-surface mating condition is similar to that of the curve-to-surface interface. In developing the curve-to-surface constraint equations, parametric relationships between the product surface and the human surface must first be defined. This relationship or interface can be either a direct contact interface, a product surface at a normal distance from the human surface, or a product surface with a distance function from
the human surface. The surface of the scan data and the product surface must be approximated with a NURB surfaces.

In the construction of the surface-to-surface interface, a guide surface must be defined on the scan surface as well a function specifying the distance from the guide surface to a projected surface, which represents the product geometry. This projection can be done using a ruled solid, which uses a linear blend in the direction of the distance function, and represents the parametric relationship between the human surface and product geometry. This process of constructing a guide surface and projecting the surface using a ruled solid is illustrated in Figure 6.12.

Figure 6.12 Method of Construction for Product Surface in a Surface-to-Surface Interface
As in the curve-to-surface interface, to be parametric the guide surface must be defined in reference to anatomical landmarks and bio-references. This can either be through the definition of landmarks locations on the scan data, or in absolute terms using a template model.

The theoretical process for implementing the surface-to-surface mating condition is summarized in the following steps:

1. Defined the parametric relationship between the human surface and the product curve.
2. Create a guide NURB surface on the scan data, defined in reference to the scan data.
3. Specify the direction and distance of the product surface from the guide surface.
4. Using the distance function, calculate the new points from each corresponding point on the guide surface.
5. Interpolate to determine the control points of the projected NURB surface using Equation (6.29).

\[ P = \left[ B^T B \right]^{-1} B^T X \quad (6.30) \]

With the theoretical basis defined, the numerical implementation of the surface-to-surface interface can be defined.
6.2.6.2 Numerical Implementation of Surface-to-Surface Constraint Equation

In the numerical implementation, the ability to define a guide surface on the scan data through a series of points on the scan surface, specify reference curves, and create a surface from these reference curves must be provided in the CAD system. The steps for numeric implementation are:

1. Create the guide surface by creating several reference curves through a series of points on the scan surface.
2. Specify the distance function for projecting the product surface from the guide surface. This can be in the form of the normal vector or a directional vector. In general, the scan data will be represented by a polygon. The directional vector can be calculated in terms of the polygon plane.
3. At each point on the guide surface calculate the distance function.
4. Construct the relative points of the product surface.

As mentioned in the theoretic basis for this constraint equation, the construction of relative points must be defined parametrically to scan data such that when new scan data is used, the curve will be able to adjust and update to fit the new scan data.

6.3 Bio-interface Constraint Equations

This chapter presents theoretical and numerical methods for the implementation of the bio-interface constraint equations. These methods allow the mating conditions to be implemented in a CAD system.
In the bio-interface design methodology contributed in this dissertation:

1. Planning

2. Concept Development
   - Geometric Configuration

3. System Level Design
   - Liaison Diagram
   - Mating conditions
   - Parametric Strategies
   - Feature Structure

4. Detailed Design
   - Bio-reference definitions
   - Product geometry creation
   - Parameterization
   - Mass customization

5. Testing and Refinement

6. Production Ramp Up

The implementation of the constraint equations in CAD would simplify the creation of these mating conditions using solid modeling operations in the detailed design phase of the methodology. In addition, this implementation would also help in creating parametric models in CAD because the mating interfaces are also the surfaces that must reconfigure during the customization process.

With the development of the geometric references attached to scan data and the expansion of top-down assembly model methods with scan data as the base part, the bio-interface design methodology can now be explained.
CHAPTER 7

A PARAMETRIC BIO-INTERFACE DESIGN METHODOLOGY

The articulation of customizable designs that interface with the human body involves the identification and analysis of product-human interactions, the planning and modeling of complex geometry, and the identification and creation of parametric variables and models. This must be done in addition to the steps in the traditional mechanical design methodologies. By integrating the theories discussed previously, namely the creation of bio-references and assembly modeling techniques, with traditional design methodologies, a methodology for the design of products that interface with the human body was developed.

7.1 Process Overview for Design Methodology for Customizable Bio-Interface Products

The traditional mechanical design method uses a sequence of steps to create a product based on customer inputs. These steps are useful in planning, management, design, quality assurance, and the coordination of the product development process. In order to create a biomechanical process that is familiar to engineers, the steps for biome-
Mechanical design are integrated into the traditional design method described by Ulrich and Eppinger [54]. As mentioned in Section 2.1 steps of this methodology are:

1. Planning
2. Concept Development
3. System Level Design
4. Detailed Design
5. Testing and Refinement
6. Production Ramp Up

Biomechanical assembly modeling techniques need to be integrated into this traditional design method to allow for the creation of reusable models that ultimately allow for the mass customization of products that interface with the human body. In order to allow for this capability, the traditional design methodology is altered to include the following sub-steps that are demonstrated on a ski goggles example. The design strategy for articulating a customizable product that interfaces with the body is as follows:

1. Planning
2. Concept Development
   - Geometric Configuration
3. System Level Design
   - Liaison Diagram
   - Mating conditions
   - Parametric Strategies
   - Feature Structure
4. Detailed Design

- Bio-reference definitions
- Product geometry creation
- Parameterization
- Mass customization

5. Testing and Refinement

6. Production Ramp Up

It is important to note that although this dissertation focuses on designing methods and not on the forces or mechanics in biomechanical design, the appropriate analyses must be performed in the design, which include analyses for comfort, using critical forces and pressures, at the bio-interfaces. In system level design, the two-dimensional analysis for comfort would be done after the identification of mating conditions. This analysis would lead to the approximation of the pressures and forces at the interface. These pressures and forces would then be converted into the appropriate distances for the mating condition. Then, in detailed design, the three-dimensional analysis would finalize these approximations to determine the appropriate distances between the interfaces, whether they be zero for a contact condition, a positive distance, or a negative distance for the application of a force to the bio-surface.

7.1.1 Planning and Concept Development

In the planning and concept development phases, the business strategy, an overall view of technologies in the target market, and the identification of the needs of the target market are identified. The evaluation of the product ideas and a concept selection is made.
In biomechanical design, these steps do not change. A concept would be identified and evaluated. In the assembly model method, the interaction of the concept to the body and to other components of the design is defined. This can be seen for a pair of ski goggles shown in Figure 7.1.

7.1.2 System Level Design

In system level design, the geometric configuration is further developed to specify the Key Characteristics of the assembly. These KCs are represented in a liaison diagram [74], [75]. Following the articulation of the liaison diagram, the diagram is analyzed in order to define the mating conditions, parametric strategies, and the bio-references that will be used to define the feature structure, discussed later in this section.
As stated in [75], the liaison diagram specifies the geometric relationships of the assembly model. Key characteristics are represented with a double line, while assembly features are represented by a single line. In the ski goggles example, the lens must be modeled to fit the human scan data using specific geometric relationships, requiring a KC. In addition, the rubber goggle sealing must properly fit with the ski goggle lens in order fix its position in the assembly and create a seal making a second key characteristic necessary. Where KCs are not essential but parts are still assembled, assembly features exist, such as the relationship between the lens and the strap, the body and the strap, and the sealing and the body. Because the strap and the goggle sealing are flexible and conform to the body, KC’s are not required to define their relationship. Figure 7.2 illustrates the key characteristics and assembly features for the ski goggles example in a liaison diagram.

Following the specification of the liaison diagram and the parts with key characteristic relationships, these key characteristics must be articulated in terms of mating conditions in order to define the parametric strategies for the device. Table 7.1 describes the key characteristics and mating conditions for the ski goggles example.

With the mating conditions defined, the designer can then analyze these mating conditions to determine the parametric strategies for the product. Parametric strategies

![Figure 7.2 A Liaison Diagram for Ski Goggles Design.](image-url)
have been applied to traditional mechanical design to allow for mass customization. Traditional parametric strategies focus on identifying a small set of key parameters upon which all parametric relationships are based [42]. When this strategy is employed, an entire design can be updated as the key parameters are changed. To apply parametric strategies to biomechanical design, anthropometric measurements and datum points based on points on the human surface become the key parameters. As these key parameters are changed to represent a new person, the product design can be updated to accommodate the individual's unique measurements and surfaces. In this research, a template model of human data was used. As mass customization is explored in the future, this template model would be replaced by data from scanned individuals, or changed to fit the surfaces of a scanned individual.

Table 7.2 specifies the parametric strategies for the ski goggles design that are associated with the identified key characteristic. These parametric strategies help dictate the bio-datums necessary for appropriate mating conditions that must be defined for geometry creation. These bio-datums allow for the definition of the feature structure of the device. The Feature Structure decomposes the product into the basic primitives of solid modeling that are used in geometry creation [43]. These features include revolutions,
extrusions, sweeps, and blends. In this method, the key characteristics lead to the definition of the mating conditions and parametric strategies. In turn, these parametric strategies allow the designer to easily determine the bio-geometric references required to satisfy the parametric strategies. With these references defined, the product can then be decomposed into the solid modeling operations and the product feature structure can be defined. In the feature structure, all datum references, sketches, and features are clearly defined in order to easily create the geometry of the device. Figure 7.3 shows a simplified feature structure for the ski goggles design.

After the feature structure is identified and the product design is planned, the designer is now ready to create the appropriate bio-datums on the human scan model in the CAD system and create the geometry for the product in the detailed design phase of the design process.

7.1.3 Detailed Design

The detailed design phase of the design process includes the creation of bio-references, geometry creation, parameterization, and mass customization.

<table>
<thead>
<tr>
<th>KC</th>
<th>Mating Condition</th>
<th>Parametric Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Surface Contact</td>
<td>Lens Extrusion:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Create lens extrusion sketch by referencing datum planes on side of head, browbones, cheekbones, and nose.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Create reference surface for geometry creation by establishing datum points and curves on Human scan data. Extrude lens sketch to the parametric surface to create surface contact.</td>
</tr>
<tr>
<td>2</td>
<td>Contact</td>
<td>Negative Sweep for sealing channel:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Create trajectory for channel that is offset from sketch for lens extrusion. The Channel must maintain offset distance despite changes in frame due to different human scan models. Sweep cross-section referenced to fit sealing.</td>
</tr>
</tbody>
</table>
In bio-interface design, the key characteristics identified in the liaison diagrams are further developed and defined by creating the appropriate bio-datums and references on the scan data within the CAD system. The creation of these references allows for geometry creation and the parameterization of the product model. After the references have been created on the scan data through the use of datum planes, datum axes, and datum points, the product can be modeled using solid and surface modeling techniques. Geometry creation of the ski goggles is illustrated in Figure 7.4.

After the geometry has been created, the product can be parameterized to allow for the mass customization of the designed product. In parameterization, key parametric vari-
variables are specified and related to each other through constraint equations. In biomechanical design, these variables are relationships between the product geometry and the scan data and often take the form of dimensions to the bio-datum planes and references. This will allow the product to change depending on the shape of the human scan data. By entering the new distances between bio-datums, the model regenerates to fit the distances.

Figure 7.4: Geometry Creation for Goggle Lens Frame. a) First, datum points are defined on the surface of the scan data (top) and datum planes are defined in relation to key points (bottom). b) A parametric model is defined utilizing the points and surfaces defined in part a. c) Finished lens extrusion.
Finally, with the parameterization in place, mass customization can be explored. Referencing bio-datums and bio-points allows for key characteristics to be maintained. Scan data for different individuals can be taken and applied to the product model by using the same references identified in the template scan data. With the application of new scan data to the product, the product model can regenerate to fit the references and dimensions of the new person either automatically or manually by entering new reference dimensions.

With the introduction of the bio-interface design methodology, Chapter 8 illustrates the process using three case studies.
This chapter demonstrates the design methodology for bio-interface design in three different case studies and discusses the teaching of the methodology in an introductory Engineering Graphics course. The combination of these case studies incorporates the basic CAD primitives and parametric strategies. The CAD operations of extrusions, sweeps, blends, surfaces, and swept blends are demonstrated along with parametric capabilities for both datum planes and datum points. The case studies include the design of safety glasses, shin guards, and body armor. These case studies were built in the advanced product development laboratory or by students in the mechanical engineering graphics course and step through the design methodology through the parameterization of the product. The mass customization of products that interface with the body is explored in Chapter 9. In the testing of the methodology in an engineering graphics course, the number of students involved as well as the methodology teaching experience is discussed.
8.1 Safety Glasses

The safety glasses example demonstrates extrusions, blends, and sweeps. In addition, because the face has complex curves and surfaces, it demonstrates parametric techniques using key bio-points as well as bio-datum planes.

8.1.1 Safety Glasses: Planning and Concept Development

In the planning and concept development stage, the product is selected and the geometric configuration articulating the interactions between parts is created. In the safety glasses example, the parts include the lens, left pin, right pin, left frame, right frame, right ear hook, and left ear hook. Figure 8.1 shows the product components that interact with each other through the geometric configuration for the safety glasses design.
8.1.2 Safety Glasses: System Level Design

In system level design, the geometric configuration is further developed to specify the Key Characteristics of the assembly. These KCs are then represented in a Liaison Diagram. Following the articulation of the Liaison Diagram, the diagram is analyzed in order to define the mating conditions, parametric strategies, and bio-references used to define the feature structure of the product. In the safety glasses example, the lens frame, frame handles, and ear hooks must all be modeled to fit the human scan data using specific geometric relationships, or KCs. In addition, where KCs are not essential but parts are still assembled, assembly features exist. Figure 8.2 illustrates the Key Characteristics and assembly features for the safety glasses example in the form of a Liaison Diagram.

Following the specification of the Liaison Diagram and the definition of parts with Key Characteristic relationships, how the product interfaces with the body must be
defined through the specification of mating conditions. Table 8.1 shows the Key Characteristics with their associated mating conditions. The type of mating conditions help to define how the model needs to change in order to fit a new set of scan data. This leads to the specification of the parametric strategies, or methods in which the product will change to fit new data. The parametric strategies for each mating condition are illustrated in Table 8.2. The definition of parametric strategies then allows for the creation of a feature structure which decomposes the product into the basic primitives of the solid model used in geometry creation and identifies all datum references, sketches, and features in order to easily create the geometry of the device. Figure 8.3 shows a simplified feature structure for the safety glasses design.

After the feature structure is created and the product design is planned out, the detailed design phase of the design begins.

<table>
<thead>
<tr>
<th>KC</th>
<th>Description</th>
<th>Mating Condition</th>
</tr>
</thead>
</table>
| 1  | Frame to Body  
   a. frame to forehead  
   b. Nose to frame | a. Curve-to-surface distance  
   b. Surface-surface contact |
| 2  | Lens frame to left frame | Distance |
| 3  | Lens frame to Body  
   a. Side of face  
   b. Last half of handle | a. Surface-to-surface Contact  
   b. Point-to-surface Contact |
| 4  | Left Ear | Surface-to-surface with force |
| 5  | Right Ear | Surface-to-surface with force |
| 6  | Lens frame to Body  
   a. Side of face  
   b. Last half of handle | a. Surface-to-surface Contact  
   b. Point-to-surface Contact |
### TABLE 8.2 Mating Conditions and Parametric Strategies for Safety Glasses

<table>
<thead>
<tr>
<th>KC</th>
<th>Mating Condition</th>
<th>Parametric Condition/Strategy</th>
</tr>
</thead>
</table>
| 1  | a. Curve-to-surface distance  
    b. Surface-to-surface contact | a. Create inside curve of lens by referencing points on forehead of scan data. Define normal distance from scan data to sketch of curve of lens  
b. Reference sketch around nose to scan data. Gravity force creates surface-to-surface contact |
| 2  | Distance          | Dimension lens frame so it can open and close without interference |
| 3  | a. Surface-to-surface contact  
    b. Point-to-surface contact | a. reference side of face on scan data for lens creation. Trajectory path of handles created by referencing points on scan data  
Blend cross-sections reference to scan data  
b. Trajectory created that references plane at end of lens geometry |
| 4  | Surface-to-surface with force | Trajectory of sweep referenced to scan data cross-section referenced to fit scan data |
| 5  | Surface-to-surface with force | Trajectory of sweep referenced to scan data cross-section referenced to fit scan data |
| 6  | a. Surface-to-surface contact  
    b. Point-to-surface contact | a. reference side of face on scan data for lens creation. Trajectory path of handles created by referencing points on scan data  
Blend cross-sections reference to scan data  
b. Trajectory created that references plane at end of lens geometry |
| 7  | Distance          | Dimension lens frame so it can open and close without interference |

### 8.1.3 Safety Glasses: Detailed Design

The detailed design phase of the design process includes bio-interface design, geometry creation, parameterization, and mass customization.

In bio-interface design, the critical interfaces identified in the Liaison Diagrams by Key Characteristics are further developed and defined in order to create the appropriate bio-datums and references on the scan data for geometry creation. These Key Characteristics are developed into appropriate mating conditions to allow the product to function
properly with the human body. For example, Key Characteristics were identified for the safety glasses by the Liaison Diagram in Figure 8.2. The references for these Key Characteristics were identified in the feature structure for the safety glasses. In bio-interface design, the Key Characteristics for the sunglasses include the specification of distances between the human face and the lens frame, distances between the human data and the frame handles, and the points of contact on the ear for the ear hooks. These would be considered surface to surface mating conditions for the distance mating conditions. Some of

---

**Figure 8.3** Feature Structure Diagram for Safety Glasses. a) Feature 1: Extrusion of Lens b) Feature 2: Negative Extrusion of Outside Curve c) Feature 3: Negative Extrusion of Inside Curve d) Feature 4: Blend of Frame Handle e) Feature 5: Sweep of Ear Hook
these mating conditions are identified in Figure 8.4. After the mating conditions have been specified, the datum planes can be defined and the geometry can be created. Figure 8.5 shows the sketch of the lens extrusion in the safety glasses. Figure 8.6 shows the extrusion of the lens and the sketch of the negative extrusion for the inside curve. Figure 8.7 demonstrates dimensioning from a key bio-point to maintain a distance from the human surface and the inside curve of the safety glasses and Figure 8.8 shows the negative extrusion of the outside curve.

After the geometry has been created, the product can be parameterized to allow for the mass customization of the designed product. In parameterization, key parametric variables are specified and related to each other through constraint equations.
cal design, these variables are relationships between the product geometry and the scan data and often take the form of dimensions to the bio-datum planes and references. This will allow the product to change depending on the shape of the human scan data. Figure 8.5 Sketch of Lens Extrusion in Safety Glasses Case Study

Figure 8.6 Geometry Creation for Safety Glasses. a) Extrusion of lens sketch in safety glasses study. b) Sketch of negative extrusion of inside curve for safety glasses.

Figure 8.5

Figure 8.6
8.9 demonstrates parameterization of the sunglasses. By entering the new distances between bio-datums, the sunglasses model regenerate to fit the distances.

Finally, with the parameterization in place, mass customization can be explored. Referencing bio-datums and bio-points allows for Key Characteristics to be maintained. Scan data for different individuals can be taken and applied to the product model by using the same references identified in the template scan data. With the application of new scan data to the product, the product model can regenerate to fit the references and dimensions of the new person either automatically or manually by entering new reference dimensions. The mass customization of the safety glasses us discussed in Chapter 9.
8.2 Shin Guard

The second case study is a shin guard example [98]. The majority of the model was created using surface modeling techniques and a revolution/sweep. This study demonstrates the regeneration of a part that uses surface modeling techniques where the surface is constructed referencing key bio-points on the human scan data.
Figure 8.9  Demonstration of Parametric Capabilities in Bio-Interface Design Methodology. a) Safety Glasses with Left and Right Cranial Sagittal Planes 2.75 inches from Median Plane. b) Figure 11: Safety Glasses with Left and Right Cranial Sagittal planes 3.25 inches from Median plane
8.2.1 Shin Guards: Planning and Concept Development

In the shin guard example, the product is construct top guard, front padding, instep guard, instep padding, hack guard, calf padding, and shin-splint prevention band. The interaction of these parts with each other and the body is illustrated in the geometric configuration in Figure 8.10.
8.2.2 Shin Guards: System Level Design

The geometric configuration for the shin guards was further developed to specify the Key Characteristics, mating conditions, parametric strategies, and the feature structure of the assembly. In the assembly, the product comfort is significantly affected by the fit of the top guard, instep guard, shin-splint prevention band, and hack guard. Thus Key Characteristics are needed for these parts. Although there is interaction between the front padding, instep padding, and calf pad, the material is flexible, so a good fit can be created despite small changes in the product model and a Key Characteristic is not necessary. The Liaison Diagram for the shin guard illustrating the Key Characteristics can be found in Figure 8.11.

Following the specification of the Key Characteristics, the mating conditions associated with these Key Characteristics were identified and are shown in Table 8.3. In most cases, a surface-to-surface contact mating condition was required. Following the definition of the mating conditions, the product’s parametric strategies were be developed. Because most of the parts in the shin guard case study have two mating surfaces, the para-

<table>
<thead>
<tr>
<th>KC</th>
<th>Description</th>
<th>Mating Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Instep Guard to Body</td>
<td>Surface-to-surface contact</td>
</tr>
<tr>
<td>2</td>
<td>Top Guard to Body</td>
<td>Surface-to-surface contact</td>
</tr>
<tr>
<td>3</td>
<td>Hack Guard to Body</td>
<td>Surface-to-surface contact</td>
</tr>
<tr>
<td>4</td>
<td>Shin splint prevention band to Hack Guard</td>
<td>Curve-to-surface contact</td>
</tr>
<tr>
<td>5</td>
<td>Shin splint prevention band to Top Guard</td>
<td>Curve-to-surface contact</td>
</tr>
</tbody>
</table>
Parametric strategies rely on referencing the product geometry to key bio-point on the scan data. These parametric strategies are described in Table 8.4.

With the definition of Key Characteristics, mating conditions, and parametric strategies, the feature structure can be created. The feature structure for the shin guard example can be found in Figure 8.12.

After the feature structure is defined with all of the necessary datum planes and sketches for the shin guards, the designer can then begin the detailed design phase of the methodology.
8.2.3 Shin Guards: Detailed Design

In detailed design, the bio-references, product geometry, and parameterization are created and defined in the actual CAD model. Because the majority of the shin guards case study involves surface modeling, most geometry is directly referenced to the scan data, where bio-references take the form of key bio-points. Key bio-points are created on the surface of the scan data and are used to create reference curves and surfaces. These different reference geometries are then used to create an offset surface that fits the scan data during geometry generation. The shin-splint prevention band requires an anatomical datum plane where the trajectory is sketched around the scan data on this plane for the sweep.

After the key bio-points are defined, the shin guard geometry is created. The front padding, top guard, instep padding instep guard, calf padding, and hack guard are all modeled using surface modeling techniques. The key bio-points and reference surfaces are used to create an offset surface that is then thickened create solid model.

<table>
<thead>
<tr>
<th>KC</th>
<th>Mating Condition</th>
<th>Parametric Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Surface-to-surface contact</td>
<td>Reference points on scan data to create curves for surface</td>
</tr>
<tr>
<td>2</td>
<td>Surface-to-surface contact</td>
<td>Reference points on scan data to create curves for surface</td>
</tr>
<tr>
<td>3</td>
<td>Surface-to-surface contact</td>
<td>Reference points on scan data to create curves for surface</td>
</tr>
<tr>
<td>4</td>
<td>Curve-to-surface contact</td>
<td>Reference points on Hack Guard for curve trajectory for sweep</td>
</tr>
<tr>
<td>5</td>
<td>Curve-to-surface contact</td>
<td>Reference points on Top Guard for curve trajectory for sweep</td>
</tr>
</tbody>
</table>
Figure 8.12 Feature Structure for Shin Guard Case Study a) Modeling of Front Padding and Front Guard by the creation and thickening of a reference surface. Front view of Coronal plane with front of leg as reference b) Modeling of Instep padding and Instep guard by the creation and thickening of a reference surface. Front view of median plane with outside of leg as reference. c) Modeling of Calf Padding by the creation and thickening of a reference surface. Back view of median plane with inside of leg as a reference. d) Modeling of Hack Guard Section by the creation and thickening of a reference surface. Front view of Median plane with outside of leg as reference. e) Modeling of shin splint prevention band by a sweep. Trajectory drawn around leg on bio-datum plane offset from transverse plane and through knee. Cross section referenced at a specified distance from leg.
Figure 8.13 shows the front padding with key bio-points and reference curves as well as the creation of solid models in reference to scan data. Figure 8.14 shows the complete shin splint assembly.

The majority of the parameterization of the shin guard case study is based off of key bio-points. As the coordinates of the key bio-points change, the model automatically regenerates to fit the new data. Figure 8.15 demonstrates the parametric capability of the top guard in the shin splint example. In the figure, the position of key bio-points was changed, resulting in the automatic regeneration of the part to fit the new coordinate value.
8.3 Body Armor

The third case study is customizable body armor [99]. This case study is modeled using a swept blend and references key biopoints on the human scan data along with datum planes based off of anatomical features on the body.

8.3.1 Body Armor: Planning and Concept Development

In the Body Armor example, the assembly involves the front and back sections and lining of the body armor. The rigid body armor interacts with both the scan data and the lining. In addition, the body armor sections must fit together and the lining also interacts with the body. The geometric configuration illustrates these interactions and is found in Figure 8.16.
Figure 8.15 Parameterization of Top Guard in Shin Splint Case Study. a) Shin Splint that fits Original Scan Data. b) Shin Splint with Key Bio-Points moved.

Figure 8.16 Geometric Configuration of Body Armor demonstrating Part Interactions.
8.3.2 Body Armor: System Level Design

The geometric configuration is further developed to create Liaison Diagram for the body armor case study. In this case study, the front and back plates of the body armor must be modeled to fit and conform to the body. The lining of the body armor is fabricated from a softer, more flexible material. Because of this, Key Characteristics exist between the front and back of the body armor to the body, while relationships between the lining and body are not as essential. In addition, the front and back of the body armor must fit together properly, so Key Characteristics must be defined between the parts. The Liaison Diagram for the body armor is found in Figure 8.17.

Following the identification of the Key Characteristics for the body armor, the mating conditions and parametric strategies are defined. Because the body armor conforms to the body for the front, back, and lining, the mating conditions for these parts are surface-to-surface. These surface-to-surface mating conditions generally rely on key bio-points in their parametric strategy. Cross-sections of the armor are created referencing key bio-points on the scan data. In order for the two halves of the armor to fit together prop-
erly, a traditional contact mating condition is necessary. Table 8.5 and Table 8.6 define these relationships.

The next step in the design process is the creation of a feature structure of the design. A swept blend was planned in the creation of the body armor requiring several horizontal bio-reference planes to be created at various locations on the torso. On each of these reference planes, the cross-section of the blend was created referencing key bio-points on the scan surface. These cross-sections were then blended together to create a surface for the body armor. This surface was then thickened to create the shape of the body armor. Negative extrusions were used to create the armholes as well as for separating the armor into front and back halves. Figure 8.18 shows the feature structure for the body armor.

8.3.3 Body Armor: Detailed Design

Following the definition of the feature structure, the detailed design of the body armor begins, involving the specification of bio-geometric references, the geometry creation, the parameterization, and eventually the exploration of mass customization.

**TABLE 8.5 Key Characteristics and Mating Conditions for Body Armor Case Study**

<table>
<thead>
<tr>
<th>KC</th>
<th>Description</th>
<th>Mating Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Back armor to body</td>
<td>Surface-to-surface contact</td>
</tr>
<tr>
<td>2</td>
<td>Front armor to body</td>
<td>Surface-to-surface contact</td>
</tr>
<tr>
<td>3</td>
<td>Back to front</td>
<td>Contact (traditional)</td>
</tr>
<tr>
<td>4</td>
<td>Back liner to back</td>
<td>Surface-to-surface contact</td>
</tr>
<tr>
<td>5</td>
<td>Front liner to front</td>
<td>Surface-to-surface contact</td>
</tr>
</tbody>
</table>
The bio-references necessary to create the body of the body armor are a series of datum planes and datum reference points. Key-biopoints were created on the scan data at points where significant changes occur in body geometry, such as the top and bottom of the shoulder blades, the neck, middle of the neck curve, the widest and most narrow part of the chest, the bottom of the sternum, the waist, the hips, and the pectoral muscles. The

<table>
<thead>
<tr>
<th>KC</th>
<th>Mating Condition</th>
<th>Parametric Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Surface-to-surface contact</td>
<td>Create surface by:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. creating curves referenced to key bio-points on scan data surface to make several</td>
</tr>
<tr>
<td></td>
<td></td>
<td>cross-sections.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. create surface through cross-sections using swept blend. As key bio-points change,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>cross sections will adjust to fit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Negative extrusion referenced to coronal plane to cut blend in half for back armor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>section.</td>
</tr>
<tr>
<td>2</td>
<td>Surface-to-surface contact</td>
<td>Create surface by:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. creating curves referenced to key bio-points on scan data surface to make several</td>
</tr>
<tr>
<td></td>
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<td>cross-sections.</td>
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<tr>
<td></td>
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<td>2. create surface through cross-sections using swept blend. As key bio-points change,</td>
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<tr>
<td></td>
<td></td>
<td>cross sections will adjust to fit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Negative extrusion referenced to coronal plane to cut blend in half for front armor</td>
</tr>
<tr>
<td>3</td>
<td>Contact (traditional)</td>
<td>Negative extrusion attached to coronal plane</td>
</tr>
<tr>
<td>4</td>
<td>Surface-to-surface contact</td>
<td>Offset surface from back to ensure parts fit together properly</td>
</tr>
<tr>
<td>5</td>
<td>Surface-to-surface contact</td>
<td>Offset surface from front to ensure parts fit together properly</td>
</tr>
</tbody>
</table>

The bio-references necessary to create the body of the body armor are a series of datum planes and datum reference points. Key-biopoints were created on the scan data at points where significant changes occur in body geometry, such as the top and bottom of the shoulder blades, the neck, middle of the neck curve, the widest and most narrow part of the chest, the bottom of the sternum, the waist, the hips, and the pectoral muscles. The
Figure 8.18 Feature Structure for Body Armor Case study. a) For swept blend, created datum points at locations on scan data where there are significant changes in geometry. b) create datum planes through datum points and parallel to transverse plane. c) Create cross section sketches for body armor on datum planes and referenced to scan data. d) create swept blend through cross sections. e) create negative extrusions for arm holes. For lining, create rectangular negative extrusions. f) Create negative extrusion referenced to coronal plane to remove material on alternating sides of plane for front and back halves.
The creation of these datum planes is shown in Figure 8.19. Datum planes were created at these locations as well as several datum planes in between to allow for accuracy in creating the swept blend. Key-biopoints were also created around the scan data on these datum planes, shown in Figure 8.20.

The geometry creation began with the creation of sketches on the bio-reference planes. The key-biopoints were used to create cross-sections of the body at each of the planes. These cross-sections were then blended to create a surface, which was thickened to
create the solid geometry for the torso, shown in Figure 8.21. Arm-holes referencing bio-points were created using negative extrusions. This can is illustrated in Figure 8.22. Finally, the front and back sections of the armor were created using a negative extrusion referenced to the coronal plane. Each half was removed alternatively to create the front and back parts. Because the geometry is referenced to key bio-points bio-datum planes the
product theoretically should regenerate as the points and datum planes are moved. However, because Pro/E does not allow the movement of points referenced to scan data, we were unable to test the results in this case study. However, because CATIA allows the movement of points referenced to scan data and successfully regenerated in the Shin Guard study, we can assume the body armor would also regenerate due to the method it was constructed.

8.4 Curriculum Development

In order to test this methodology, curriculum was developed and taught to freshman level engineering students in an engineering graphics mechanical engineering course. The students did not have experience with design methodologies or solid modeling prior to the class. In the course, a biomechanical design project that focused on the creation of a solid model was assigned to the students. Several lectures on the design methodology were taught and the students were given a regularized template model of a scan. The initial methodology was developed in Winter 2006. Since then the method was taught to the following number of students:

- Winter 2006: 150 students
- Spring 2006: 20 students
- Fall 2006: 100 students
- Winter 2007: 150 students
- Fall 2007: 105 students
After each semester, the methodology was modified in ways that would allow the students to easily identify mating conditions and strategies to create parametric solid models in CAD. The initial methodology included only a feature structure definition in the system level design phase of the design process. With the addition of the geometric configuration, liaison diagram, mating conditions, and parametric strategies, the students were guided through the process more easily and could identify the human-product interactions as well as create parametric strategies for the device. In detailed design, with the steps followed in the system level design phase, the students were able to model complex product interfaces using traditional mechanical design tools. It became clear that without the specification of a methodology for bio-interfaces that engineering students without prior experience in design would not have been able to model products that interface with the body.

With the demonstration of the bio-interface design methodology in three different case studies and in an introductory to engineering graphics course, we can discuss the exploration of mass customization of products that interface with the body.
Mass customization in biomechanical products involves the personalization of products to fit a specific individual. With the parameterization of a solid model, the use of scanning can now play a key role. Mass customization can be explored by using a scanner to obtain digital 3D models of different individuals. After the scan is taken, the data is then regularized and put in a format that CAD systems can use. Following the regularization, anatomical landmarks can be identified on the human models, either automatically or manually. From these landmarks, individualized sets of bio-datums can be created for each human model and the parametric model for the biomechanical device can be updated to fit the scanned individual's personal Bio-Geometric references. This process is shown in Figure 9.1.

This chapter explores the feasibility of mass customization for products that interface with the body by walking through the mass customization process for the safety glasses case study, discussing issues and concerns in updating models to fit a new set of scan data, and making recommendations to improve mass customization for bio-mechanical products.
9.1 Mass Customization Case Study: Safety Glasses

In the safety glasses case study in Chapter 8, each phase of the bio-interface design process was discussed, resulting in a parametric safety glasses model. This section now takes this parametric model and applies mass customization techniques to update the model to fit four individuals. Each case in this chapter discusses results and issues for the this mass customization process. Due to limitations in the scanner as well as in the CAD system, this model concentrates on fitting the frame of the safety glasses to the head and addresses size of head, distances from the brow bone to the bottom of the orbital cavity, and the fit in the nose area of the safety glasses. For each case, the scan data was used to update the parametric safety glasses model by taking data from the scan data and inputting the data into the model. The scanner used in this example consisted of two cameras. The
cameras faced each other and the individuals scanned were seated in between the cameras, with the front of the face directly facing one camera.

The original solid model of the safety glasses was created and referenced to a regularized template model of scan data. Currently, the CAD systems do not allow access to coordinate values of points for faceted, polygonalized features, therefore the points of the regularized model could not be moved to represent the set of scan data from a person. In the customization process for the safety glasses, feature values and locations of bio-references were extracted from the individual scan data sets and imported into the solid model assembly manually. The values extracted from the individual sets or scan data can be found in Table 9.1.

Following the adjustment of the parametric model, the solid model was exported as an STL file and used to create a prototype. The following sections describe the custom-
ization process for the sunglasses example and discuss issues that should be addressed for future work.

9.1.1 Safety Glasses: Case 1

In the first case, a scan was taken of an individual 1. The scan data was then annotated with the reference planes used as inputs in the parametric safety glasses model, namely datum planes through the center of the eyes, at the sides of the nose, along the forehead, and at the sides of the head. Figure 9.2 shows the front and side views of the scan data and Figure 9.3 shows the annotation of the head with the median and midorbital bio-reference planes.

As shown in Figure 9.2, detail is lost in the scan of the individual. In the side view of Case 1, the detail of the ear is lost entirely. In addition, it appears that the front and back halves of the head scan, one taken by each camera, are not lined up accurately. The back
scan appears shifted to the right, when looking directly at the front of the scan. All of these issues can cause a poor fit in the safety glasses model.

Besides scanning issues, the scan data from Case 1 easily updated the parametric safety glasses model. Measurements were taken from the scan data and manually imported into the parametric model. The model regenerated as expected to create a personalized safety glasses prototype.

9.1.2 Safety Glasses: Case 2

In the second case, a scan was taken of individual 2 and the scan data was annotated with the reference planes used as inputs in the parametric safety glasses model. The front and side views of the scan data is shown in Figure 9.4. Figure 9.5 shows the scan data annotated with the median and midorbital planes.
As in case 1, case 2 also experienced significant loss of detail where the scan halves were joined, namely around the ear. Unlike case 1, however, the front and back scans appear to line up appropriately. In addition to the loss of detail in the scan data, case 2 also demonstrates an example where the median and mid-orbital planes are not perpendicular to each other. In this case the model must be updated to create a model that is visu-
ally symmetric and appealing as well as fit the scan data. This was accomplished by taking the largest measurement in the distance from the midorbital plane to the brow bone for both eyes. The largest measurement between the midorbital plane and the bottom of the orbital cavity for the two eyes was also used to create the frame.

In addition, in Case 2, the model experienced irregularities during regeneration. This was a result of the scan measurements in case 2 exceeding the design space envelope initially created for the parametric model. The regeneration irregularity can be seen in Figure 9.6. The parametric model was altered to include measurements and dimensions required for case 2. After these changes, the safety glasses were successfully regenerated and a prototype was fabricated.
9.1.3 Safety Glasses: Case 3

As in cases 1 and 2, a scan was taken of individual 3 and the scan data was annotated with the reference planes used as inputs in the parametric safety glasses model. Figure 9.7 shows the front and side views of the scan data and Figure 9.8 shows the scan data annotated with the median and midorbital bio-reference planes.

Issues in case three include the loss of detail in interpolating and connecting the scan halves. In working with scan 3, creation of reference planes proved to be difficult.
The points selected to create the reference planes and take measurements were consistently not those intended by the designer. This can be shown in Figure 9.9 where it appears that the center of the eyes were selected to create the midorbital plane, however, on closer evaluation a point in the center of one eye and the back of the head was selected. After several trials, points were successfully selected, the solid model was updated, and the safety glasses were fabricated.

9.1.4 Safety Glasses: Case 4

For case 4, a scan was taken of an individual and the scan data was annotated with the reference planes used as inputs in the parametric safety glasses solid model. The front and side views of the scan data is shown in Figure 9.10. The annotation of the scan data is shown in Figure 9.11.

As in previous examples, there was a loss of detail around the ear area of the scan. However, besides this, reference planes were created and measurements taken easily from
this scan data. All dimensions fit within the design envelope of the parametric model and the model was updated and a prototype created without difficulty.
9.2 Mass Customization Conclusions

In this case study, it was apparent the there are four areas that must be addressed to allow for mass customization in products that interface with the body. These areas include:

- Data Acquisition of the Scan data
- Working with scan data variances
- Scan data point selection
- Design space envelope for product

It is clear from this example, that the quality of the scan data can significantly affect the fit and function of a device. With inaccuracies and the loss of detail in the scan data, it is difficult to ensure that the designed product will properly fit individuals. Therefore, in order to implement mass customization, an scanner that captures the data necessary for the product design is required. In the case of the safety glasses example, a scanner that uses more cameras for data acquisition may be necessary to capture data on the side of the head and ear areas.

In working with scan data where variances exist, such as in case 2 where the midorbital plane and median plane are not perpendicular, the designer must look at the product geometry to create a product that both satisfies form and function. The product must be attractive in appearance as well as provide a good fit for the customer. In cases of these variances, the design will need to be analyzed on a case by case basis and may not be automated as easily.

Scan data point selection must also be addressed to provide ease of use for the designer. The designer must be able to easily select points on the scan data to create a
parametric model and/or change and existing parametric model. This problem can be
solved through the method the scan data is represented in the CAD system.

Finally, the design space envelope for the product must also be acquired before
model design to ensure that the model can regenerate and reconfigure appropriately to fit
different sets of scan data. This involves analyzing a population to determine maximum
and minimum values for anatomical landmarks, feature locations and dimensions, etc. In
addition, designers must plan and analyze the ways in which the CAD model must change
and reconfigure in order to address the needs of a given population and create robust para-
metric models. This reconfiguration space is further explored in Chapter 10.
During the course of researching tools and techniques for the design of products that interface with the human body, it became clear that the design space of these products is bounded by the methods in which the product can be customizable as well as measurement ranges of the anatomical features of a given population. This dissertation discusses the basis of these discoveries, however, the development of this concept is left to future research.

Reconfiguration space is the design space describing the methods and directions of feature reconfiguration in order to adjust product features to fit consumer needs. During the design process, the way the product regenerates to fit different individuals must be defined. This definition affects the overall design space and possible product outcomes of the design. Reconfiguration space can also be thought of as the combination of the product configuration and the customizable envelope.
10.1 Degrees of Freedom in Reconfiguration Space

In mechanics, degrees of freedom describe the independent displacements that are necessary to completely describe the displaced or deformed position of a body or system. As in mechanics, the degrees of freedom in the reconfiguration of a customizable product can also be described in terms of variables. These variables describe how the geometry changes to meet the desired changes in geometry due to differences in the human scan data. The degrees of freedom describe the "virtual motion" the product undergoes as it regenerates to fit new scan data. These degrees of freedom can be categorized similarly to those in mechanics. The types of degrees of freedom in reconfiguration space include:

1. Translation
2. Scaling
3. Rotation

In the translation category, there are three degrees of freedom. These degrees of freedom describe the movement of a point in the geometry in the x, y, or z direction. Translation of a point can cause a changes such as variations in length or a change in an angle.

Scaling involves changing the size of a part based on a scalar value. A part can be scaled in the x, y, and z directions. Generally, when a part is scaled the features maintain the same ratio to each other as the product changes to accommodate different sets of scan data.
Finally, rotation involves rotating a part or feature around a specified axis. There are three possible rotational degrees of freedom which include rotation around the x-axis, y-axis, and z-axis.

10.2 Parametric strategies in Reconfiguration Space

Before parametric strategies are defined, the product has a total of 9 possible degrees of freedom, or 9 independent displacements the product geometry can undergo in order to regenerate to fit a different set of scan data. As parametric strategies are identified and defined, some of these degrees of freedom can be eliminated. In addition, the range of virtual motion for each degree of freedom can be limited according to population characteristics and statistical data, such as bounds in height, length, or width of features on body.

In creating parametric strategies, the designer must look at the range of variation in human characteristics in order to determine how the product should change to fit the data. In doing this, the designer creates a mapping function, illustrated in Figure 10.1, from the parametric model, or product template, to the customized product in the reconfiguration space. This mapping includes how the product features reconfigure for a customized product and the number of degrees of freedom in this reconfiguration. With the planning of

Figure 10.1 Illustration of Mapping Function from Template Space to Reconfiguration Space.
feature reconfiguration, the datums and axes necessary for the parametric model are identified. This method helps to create the parametric strategy for the product as well as identify the feature structure for the product. This also helps reduce inconsistent geometries when the parametric model is updated to fit new scan data.

Steps for creating a mapping between a product template and the reconfiguration space include:

1. Identify features in product assembly that should be adjustable for customization
2. Identify how each feature should be adjusted for customization (identify degrees of freedom for product features)
3. Examine degrees of freedom to determine parametric strategy for geometry
4. Determine datums and axes necessary to create parametric model
5. Create feature structure of product
6. Create geometry following feature structure and parametric strategy

Further development of reconfiguration space will help identify parametric strategies, modeling techniques, and lead to better model planning to allow for robust parametric models that can regenerate to fit numerous sets of scan data.
11.1 Summary and Conclusions

This dissertation has presented a method that addresses the unique problems of implementing mass customization in the design of biomechanical products. The method presented involves first, a consistent method of capturing and representing the human model so that the model can be used with CAx tools and solid modeling techniques. Second, a design methodology based on feature structure planning and assembly modeling is presented that provides a consistent structure to the design process so that it can be reused and parameterized. Third, a strategy for identifying parametric variables that are reference to the human body is introduced.

The tools and techniques developed in this research present a method of design that allows for the articulation of customizable products that interface with the human body. The core of this method is the definition of biomechanical products as an assembly model, where human data is defined as the base part. This research expands on traditional mating conditions in assembly methods by identifying different ways products can interface with the human body. With the identification of these mating conditions, products can
be designed to interact with the body in definable ways through the definition of parametric strategies. This dissertation also presents the necessary theoretical and numerical methods for implementation of these mating conditions in a CAD system.

The following conclusions were made after the testing of the biomechanical design methodology:

Conclusion 1: The structure introduced into the design process by the feature structure planning steps is critical to the success of the method. The procedural aspect of the feature structure planning steps provided a design process and contextual reference for connecting the biomechanical design to the human body. Feature structure sketches were used by the students to document this feature structure planning phase. The bio-interface designs and criteria could then be selected and analyzed as well as parametric strategies defined and evaluated.

Conclusion 2: Annotation of a templatized bio-data model with standardized datum planes facilitates the use of solid modeling techniques for the design of the biomechanical product. This enhances the ease of design of the biomechanical device and improves the parametric possibilities by connecting into volumetric modeling techniques. Without the standardized datum references, it is not possible to use solid modeling techniques that are oriented to the human body.

Conclusion 3: The standardized datum references become the parametric input variables in the mass customization input files. Since all the features in the feature structure are defined in reference to the standardized datum references, the standardized datum references become the independent variables. Individualized scan data must therefore
identify the same set of standardized datum references uniquely determined to the individual scan data.

Conclusion 4: Use of this method results in better biomechanical design as well as parametric models that can be used in mass customization methods. This enables mass customization methods to be applied to biomechanical design. Production of individualized products for the human body is one of the best examples of the value of mass customization.

11.2 Major Contributions

This method significantly contributes to the biomechanical design field through the development of a methodology that allows the use of traditional CAx tools with a greater ease despite the complexity of human surfaces. Because these tools are utilized, parametric strategies and techniques can be applied to biomechanical products, allowing for the mass customization of products with complex human interfaces. Although the initial time investment may be significant, with the ability to create a reusable product model, this method allows for the product-to-consumer cycle time and consumer costs to be significantly reduced.

The methodology is different from conventional parametric and free form surface design because if focuses on mass customization for markets of one. Additionally, because the body is somewhat compliant, it address the design of products that interface with non-rigid surfaces.
11.3 Limitations in CAX Tools

In this research, parts and products were modeled successfully using Pro/Engineer, Catia, Autodesk Inventor, and Nx. However, although these systems can be used to model products that interface with the body, CAD systems have limitations that cause difficulty in modeling.

This research has identified areas of weaknesses in CAD. Two main areas include scan data handling and mating constraint methods. In some of the CAD systems, rendering is difficult because every polygon in the scan data comes in as a different surface/entity. The entities must then be sewn together to create a single surface. In addition, because each polygon is a different entity or scan data is made up of facets, surface operations are not available until vertices are used to create reference surfaces.

11.4 Recommendations for Future Work

This research introduces a methodology for the creation of a parametric products that interface with the human body. Future work in the development the bio-interface design methodology can be pursued in the following areas:

- Application of methodology to products that interface with the body internally
- Development of CAD software tools and operations specific to bio-interface design
- The relationship between forces and pressures in the definition of mating conditions.
- Scan data handling and the creation of a template scan
- Automatic landmarking and annotation of scan data with datum planes and references
- Exploration and development of reconfiguration space

Although this dissertation focuses on the design and modeling of products that interface externally with the human body, this same methodology can be used for the modeling of products that interface internally. Internal imaging technologies exist that allow the acquisition of data for the inside of the body. With this technology, the techniques described in this dissertation can be applied to devices that interface internally, such as knee replacements. This would allow a more customized and a more comfortable fit in these devices.

Software tools and CAD operations specific to bio-interface design is another area for future research. These developments could include operations such as revolutions that around an anatomical axis that follow the human surface, or solids that are extruded to a human surface. These operations would eliminate the tedious creation of complex reference surfaces due to the CAD systems inability to perform modeling operations on a faceted surface.

Research in the development of relationships between mating condition constraints and comfort would allow the designers to select distances between product surfaces and human surfaces. In addition, this would allow the computation of distance functions in variable offset constraints.

The creation of a template scan data that is used to regularize incoming scan data to a specified number of points in similar locations can also be explored. With this capa-
bility, the automatic updating of parametric models to new scan data could be more easily realized.

Much research has already been done in the automatic landmarking of the body. With further development of automatic anatomical landmarking as well as automatic annotation of scan data with bio-references such as datum planes, the creation of parametric models and the mass customization cycle time in products could be significantly reduced.

Finally, the exploration and development of reconfiguration space, involving the planning of a product’s design space, the integration of statistical data to create a feasible reconfiguration space, the further classification of degrees of freedom, and the process of defining a product’s reconfiguration space.
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