MANDIBULAR BONE MECHANICS AND EVALUATION OF TEMPOROMANDIBULAR JOINT DEVICES

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy

By

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ABSTRACT


Knowledge of the mandibular and temporomandibular joint (TMJ) biomechanics is of importance in various clinical scenarios as it helps better understanding of the structure and function necessary to diagnose, prevent, and treat temporomandibular disorder (TMD). The objectives of this dissertation research were to characterize biomechanical behavior of cadaveric human mandible, and to design and analyze patient-specific total TMJ prostheses. We performed a combined experimental-numerical study to validate the finite element (FE) models of 16 cadaveric human mandibles by comparing strain gauge measurements with FE-predicted surface strains. Analysis of experimental data showed that strains at the condylar locations were significantly different from those at other locations on the mandibular cortical surface, and that sex and age of the subject did not have significant correlation with strain. Comparing the FE-predicted strain with the experimental data, we found strong statistical correlation and agreement. This study demonstrated that our methodology of generating subject-specific FE models and performing FE simulations is a valid and accurate non-invasive method to evaluate the complex biomechanical behavior of human mandibles.

Stiffness variation and fatigue microdamage accumulation occur in bone as a result of physiological loading. In this study, stiffness and damage accumulation in cadaveric mandibles were derived from experimental data. Stiffness reduction showed a steep initial decline followed
by a transition into constant stiffness. Analysis of damage accumulation showed an abrupt increase, initially, which transitioned into the region of saturation with nearly no change in damage. Majority of damage accumulation was observed during first few hundreds of loading cycles. Age had negative correlation with maximum load before failure. Age and sex did not have significant effect on fatigue life, change in stiffness, and maximum damage accumulation in the mandibles.

A methodology was developed to design patient-specific total TMJ prostheses based on the patient’s medical images, anatomic condition, and surgeon’s requirements. Our custom-designed TMJ implants offer novel features such as locking mechanism, perforated notches protruding into host bone, customized osteotomy/cutting guides, and custom drill guides. These unique design aspects can maximize the opportunity for accurate adaptation to host anatomy, improved fixation and implant stability for challenging and complex anatomic situations. Stress and strain profiles in patient-specific total TMJ reconstruction were investigated through FE simulations under normal and over-loading conditions. Higher stresses were found in the neck portion of fixation screws, and in areas of host bone surrounding the screws. Peak von Mises stresses were within the limit of safety for the prostheses and host bone. The micro-strains developed in mandibular and fossa bone in the vicinity of fixation screws were well within safe limits. Results indicated that stress development in prosthetic notches could augment bone growth into perforated surface of notches, but the notches may not act as stress-risers in the device. The study demonstrated that our proposed methodology provides viable means for patient-specific design, and improvement of the design and durability of total TMJ prostheses.
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### SYMBOLS, ABBREVIATIONS, AND ACRONYMS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tbody>
<tr>
<td>$\alpha$</td>
<td>Level of significance</td>
</tr>
<tr>
<td>$\mu$</td>
<td>Micro (1 micro unit = $1 \times 10^{-6}$ unit)</td>
</tr>
<tr>
<td>3D</td>
<td>Three-dimensional</td>
</tr>
<tr>
<td>Avg.</td>
<td>Average</td>
</tr>
<tr>
<td>BIN</td>
<td>Bilateral-incisor-normal</td>
</tr>
<tr>
<td>BIO</td>
<td>Bilateral-incisor-overload</td>
</tr>
<tr>
<td>BIS</td>
<td>Bilateral-incisor-spectrum</td>
</tr>
<tr>
<td>BMN</td>
<td>Bilateral-molar-normal</td>
</tr>
<tr>
<td>BMO</td>
<td>Bilateral-molar-overload</td>
</tr>
<tr>
<td>BMS</td>
<td>Bilateral-molar-spectrum</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence interval</td>
</tr>
<tr>
<td>Co-Cr</td>
<td>Cobalt-Cromium</td>
</tr>
<tr>
<td>Co-Cr-Mo</td>
<td>Cobalt-Cromium-Molybdenum</td>
</tr>
<tr>
<td>CT</td>
<td>Computed tomography</td>
</tr>
<tr>
<td>D</td>
<td>Damage</td>
</tr>
<tr>
<td>$D(n)$</td>
<td>Damage at nth cycle</td>
</tr>
<tr>
<td>$D_{max}$</td>
<td>Maximum damage</td>
</tr>
<tr>
<td>E</td>
<td>Enzyme</td>
</tr>
<tr>
<td>ES</td>
<td>Complex</td>
</tr>
<tr>
<td>$F_a$</td>
<td>Axial load/force</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>Abbr.</td>
<td>Description</td>
</tr>
<tr>
<td>-------</td>
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</tr>
<tr>
<td>FE</td>
<td>Finite element</td>
</tr>
<tr>
<td>FEA</td>
<td>Finite element analysis</td>
</tr>
<tr>
<td>FEM</td>
<td>Finite element model/modeling</td>
</tr>
<tr>
<td>FEP</td>
<td>Fossa eminence prosthesis</td>
</tr>
<tr>
<td>$H_0$</td>
<td>Null hypothesis</td>
</tr>
<tr>
<td>Hz</td>
<td>Hertz</td>
</tr>
<tr>
<td>$k$</td>
<td>Axial stiffness</td>
</tr>
<tr>
<td>$K_m$</td>
<td>Michaelis constant</td>
</tr>
<tr>
<td></td>
<td>$= \text{Substrate concentration at which } V = \frac{1}{2} * V_{\text{max}}$</td>
</tr>
<tr>
<td>Or</td>
<td>$= \text{Cycles at } D_{\text{max}} * \frac{1}{2} \ldots \ldots \text{(modified for damage prediction)}$</td>
</tr>
<tr>
<td>kN</td>
<td>Kilo-Newton</td>
</tr>
<tr>
<td>$k_0$</td>
<td>Initial axial stiffness</td>
</tr>
<tr>
<td>L1, L2, L3, L4, L5</td>
<td>Locations of strain gauges attached to cadaveric mandibles</td>
</tr>
<tr>
<td>LD</td>
<td>Linear distance</td>
</tr>
<tr>
<td>LTF</td>
<td>Load-to-failure</td>
</tr>
<tr>
<td>m</td>
<td>Meter</td>
</tr>
<tr>
<td>mm</td>
<td>Millimeter</td>
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<tr>
<td>MRI</td>
<td>Magnetic resonance imaging</td>
</tr>
<tr>
<td>N</td>
<td>Newton</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>$^{\circ}\text{C}$</td>
<td>Degree Celsius</td>
</tr>
</tbody>
</table>
p Probability
P Product
PMMA Polymethylmethacrylate
PPT Pressure pain threshold
PT Proplast/Teflon
PTFE Polytetrafluoroethylene
r Coefficient of correlation
$R^2$ Coefficient of determination
S Substrate
Std. Dev. Standard deviation
Ti-6Al-4V Titanium alloy which contains 6% Aluminum, 4% Vanadium, and nearly 95% Titanium by weight
TMD Temporomandibular disorder
TMJ Temporomandibular joint
UHMWPE Ultra-high molecular weight polyethylene
V Rate of enzymatic reaction
$V_{\text{max}}$ Maximum rate achieved by the system at maximum or saturating substrate concentration
Yrs Years
$\delta_a$ Axial displacement
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DEDICATION

I dedicate this dissertation:

To Aai and Bapu, my loving parents: Words cannot express how grateful I am for the way you raised me up, and your vision and countless sacrifices to ensure a better life for me. There is no greater joy for me than seeing you smile. I strive to bring more smiles.

To my dear siblings, Sharad, Sudarshan, Shalaka: Thank you for always being understanding and supportive. You are the best siblings one could have.

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1. INTRODUCTION

Temporomandibular joint (TMJ), which connects the mandible or lower jaw to the skull and regulates jaw movement, is one of the most complex and highly used joints in a human body.\textsuperscript{2,3,23,24,64} Temporomandibular disorder (TMD) is a set of problems concerning the TMJ and associated components of the masticatory system. 20-25\% of the population is reported to exhibit one or more symptoms of TMD, and approximately one million new TMD patients are diagnosed yearly in USA alone.\textsuperscript{23,24,122} With millions of people affected by TMD of varying form and intensity, it is a problem that should be looked at more fully.\textsuperscript{24,64}

Various non-invasive, minimally invasive, and open surgery options including joint replacement are currently available for TMJ patients. However, since a large fraction of TMD causes are currently unexplained, further knowledge of structure and function of the TMJ components, and etiology of TMD may help in more efficient prevention, diagnosis, and treatment of TMD. The TMJ Bioengineering Conference, held in 2006 and 2009, underlined the importance of collective interdisciplinary research efforts involving tissue engineering, biomechanics, clinical community, and biology.\textsuperscript{24} Advanced technology and knowledge from diverse interdisciplinary and multidisciplinary areas have been utilized to advance the understanding of TMJ components. In recent years, the application of biomechanics to TMJ research has shown promising outcomes. Through this dissertation, we present our TMJ research from biomechanical point of view. This includes biomechanical evaluation of the cadaveric human mandibles tested under different configurations of cyclic fatigue loading; patient-specific three-dimensional (3D) anatomical reconstruction of the mandibles using computed tomography
(CT) images; biomechanical assessment of the mandibles using subject-specific finite element (FE) method, which is validated by our experimental method; and design and analysis of the patient-specific total TMJ prostheses.

Chapter 2 provides background information necessary to perform the proposed study, i.e., biomechanical evaluation of the natural and prosthetic human mandible and TMJ through cadaver experiments and FE analysis. The chapter begins with information about the anatomy and function of the mandible and TMJ, TMD, and treatment options for TMD patients. The chapter then covers the fundamental idea behind the methodology used in this research. Finally, based on the presented background material, the chapter proposes the problem statement and research objectives.

Chapter 3 describes our experimental biomechanical study of the cadaveric human mandibles. We performed mechanical testing of sixteen mandibles divided in four groups, with mandibles in each group subjected to unique cyclic loading configuration. The chapter discusses acquisition of cadaver mandibles and their CT scans, use of strain gauges, mechanical test set-up, and data acquisition. We explored the strain development, stiffness variation, damage accumulation, and failure modes in the mandibles. The chapter also describes statistical distribution of age, maximum load before failure, cycles until failure, overall change in stiffness, and maximum damage accumulation across the mandibles from all loading groups. Analysis of experimental strain data, and its use in validating the numerical strain predictions through FE simulations are discussed in the subsequent chapter.

Chapter 4 focuses on our methodology for subject-specific 3D anatomical reconstruction of the mandibles using CT images, creation of FE volume mesh models, and FE simulations
accurately replicating the experimental technique. We discuss statistical aspects of the experimentally acquired surface strains in cadaveric human mandibles under different configurations of cyclic compressive loads. Analysis of experimental data showed that strain measured at the condylar locations were significantly different from those at other locations on the mandible, and that sex and age of the subject did not have significant correlation with the strain. Strain patterns of each mandible were derived from the FEA paralleling the experimental setup, and matched with the experimental data. Comparison of the FE numerical predictions of mandibular strain with the experimental data showed a good statistical correlation and statistical agreement between in-vitro measurements and FE results. Chapter 4 demonstrates that our methodology of generating subject-specific FE models and performing FE simulations is a valid and accurate non-invasive method to evaluate the complex biomechanical behavior of cadaveric human mandibles. Such validated FE models which adequately reproduce mechanical behavior of the mandibles can be used further to study the TMJ, and to design and pre-clinically evaluate implants for the mandible and TMJ.

Chapter 5 explains our approach to developing novel patient-specific total TMJ prosthesis. Our unique patient-fitted designs based on medical images of the patient’s TMJ offer accurate anatomical fit, and better fixation to the host bone. The special features of our prostheses promise an improved osseo-integration and durability of the TMJ devices. Our design process is based on surgeon’s requirements, feedback, and pre-surgical planning to ensure anatomically accurate and clinically viable device design. We use our validated methodology of subject-specific FE modeling and simulations to evaluate the design and performance of TMJ prostheses.
Pre-clinical performance evaluation of our prosthetic system is performed through FE analysis under loading scenarios which reflect the patient’s normal and or worst-case TMJ loading.

Chapter 6 ties together the results of Chapters 3, 4 and 5, and presents a summary of the key findings of this research. The chapter provides a discussion of the findings in light of the broader picture of the structural and biomechanical aspects of the mandible and our TMJ implant design, highlights the significance of the findings from clinical and product development viewpoints, and provides recommendations for future research.
2. BACKGROUND

2.1 Overview

Temporomandibular joint (TMJ) connects the mandible or lower jaw to the skull and regulates movement of the jaw (see Figure 1.1). TMJ is one of the most complex as well as most used joints in a human body. The most important functions of TMJ are mastication and speech. Temporomandibular disorder (TMD) is a generic term used for any problem concerning the jaw and TMJ. Injury to the jaw, the TMJ, or muscles of the head and neck can cause TMD. Other possible causes include grinding or clenching the teeth; dislocation of the disc; presence of osteoarthritis or rheumatoid arthritis in the TMJ; stress, which can cause a person to tighten facial and jaw muscles or clench the teeth; aging. The most common TMJ disorders are pain dysfunction syndrome, internal derangement, arthritis, and trauma. TMD is seen most commonly in people between the ages of 20 and 40 years, and occurs more often in women than in men. In 1996, the National Institutes of Health (NIH) estimated that 10 million Americans had painful TMJ dysfunction, and more women were affected by it than men. Some surveys have reported that 20-25% of the population exhibit symptoms of TMD, with approximately one million new patients diagnosed yearly. We have previously published a comprehensive, state-of-the-art review about the structure, function, dysfunction, treatment options, and biomechanics of the TMJ.
2.2 TMJ Anatomy and Function

TMJ is a bi-condylar joint in which the condyles, located at two ends of the mandible, function at the same time. The movable round upper end of the lower jaw is called the condyle and the socket is called the articular fossa (see Figure 1.1). Between the condyle and the fossa is a disc made of fibrocartilage that acts as a cushion to absorb stress and allows the condyle to move easily when the mouth opens and closes. The bony structure consists of the articular fossa; the articular eminence, which is an anterior protuberance continuous with the fossa; and the condylar process of the mandible that rests within the fossa. The articular surfaces of condyle and fossa are covered with cartilage. The disc divides the joint cavity into two compartments - superior and inferior. The two compartments of the joint are filled with synovial fluid which provides lubrication and nutrition to the joint structures. The disc distributes joint stresses over broader area thereby reducing chances of concentration of the contact stresses at one point in the joint. The presence of disc in the joint capsule prevents the bone-on-bone contact and possible higher wear of the condylar head and articular fossa. The bones are held together with ligaments. These ligaments completely surround the TMJ forming the joint capsule.

Strong muscles control movement of the jaw and the TMJ. The temporalis muscle which attaches to the temporal bone elevates the mandible. The masseter muscle closes the mouth and is the main muscle used in mastication (see Figure 1.2). Movement is guided by the shape of the bones, muscles, ligaments, and occlusion of the teeth. TMJ undergoes hinge and gliding motion. The TMJ movements are very complex as the joint has three degrees of freedom, with each of the degrees of freedom associated with a separate axis of rotation. Rotation and anterior
translation are the two primary movements. Posterior translation and medio-lateral translation are the other two possible movements of TMJ.\textsuperscript{29}

\textbf{Figure 2. 1.} Anatomical structure of the temporomandibular joint (TMJ).\textsuperscript{3}
Figure 2.2. Normal anatomy of the jaw and the TMJ. The lateral view of the skull (Panel A) shows the normal position of the mandible in relation to the maxilla, the TMJ capsule, and the masticatory muscles – temporalis, masseter, mylohyoid, anterior and posterior digastrics, hyoglossus, and stylohyoid. Also shown (Panels B and C) are the deep muscles associated with jaw function and the TMJ intra-articular disc. Source: Scrivani, et al.119
2.3 Temporomandibular Disorder (TMD)

TMD is a generic term used for any problem concerning the jaw joint. The most common TMJ disorders are pain dysfunction syndrome, internal derangement, arthritis, and traumas.\(^{16, 22-24}\) TMD is seen most commonly in people between the ages of 20 and 40 years, and occurs more often in women than in men.\(^{16, 22-24, 140, 147}\) Some surveys have reported that 20-25% of the population exhibit symptoms of TMD while it is estimated that 30 million Americans suffer from it, with approximately one million new patients diagnosed yearly.\(^{23, 42, 122, 153}\) The majority of TMJ patients is female, aged between 20–40 years.\(^{23, 140, 147}\) The female to male patient prevalence is reported to be varying from 3:1 to 8:1.\(^{15, 23, 24, 44, 122}\)

Disc displacement is the most common TMJ arthropathy and is defined as an abnormal relationship between the articular disc and condyle.\(^{31, 129}\) As the disc is forced out of the correct position there is often bone on bone contact which creates additional wear and tear on the joint, and often causes the TMD to worsen.\(^{31, 129}\) Almost 70% of TMD patients have disc displacement.\(^{23, 31}\) Different types of functional malocclusion have been shown to be partly responsible for signs and symptoms of TMD. The functional unilateral posterior cross-bite, habitual body posture during sleep, juvenile chronic arthritis – a chronic arthritis in childhood with an onset before the age of 16 years and a duration of more than three months – are also reported as TMD risk factors.\(^{6, 54, 100}\)
2.4 Treatment Options for TMD

Treatments for the various TMJ disorders range from physical therapy and nonsurgical treatments to various surgical procedures. Usually the treatment begins with conservative, nonsurgical therapies first, with surgery left as the last option. The majority of TMD patients can be successfully treated by non-surgical therapies, and surgical interventions may be required for only a small part of the patient population. The initial treatment does not always work and, therefore, more intense treatments such as joint replacement may be a future option.

The non-surgical treatment options include medication; self-care; physical therapy, to keep the synovial joint lubricated and to maintain full range of the jaw motion; wearing splints, the plastic mouthpieces that fit over the upper and lower teeth to prevent the upper and lower teeth from coming together, lessening the effects of clenching or grinding the teeth. Splints are used to help control bruxism – a TMD risk factor in some cases. However, the long-term effectiveness of this therapy has been widely debated, and remains controversial.

Surgery can play an important role in the management of TMD. Conditions that are always treated surgically involve problems of overdevelopment or underdevelopment of the mandible resulting from alterations of condylar growth, mandibular ankylosis, and tumors of the TMJ. The surgical treatments include arthrocentesis, arthroscopy, discectomy, and joint replacement. Arthrocentesis is the simplest form of surgical intervention into the TMJ performed under general anesthesia for sudden-onset, closed lock cases in patients with no significant prior history of TMJ problems. It involves inserting needles inside the affected joint and washing out the joint with sterile fluids. Arthroscopy is a surgery performed to put the displaced articular disc back into place. However, if the ligament and retrodiscal tissue was previously
stretched beyond its elastic range, then just popping the disc back into place is only a temporary fix as the joint still would not work as well as usual. Therefore, an anchor – Mitek mini anchor – and artificial ligaments have been used for several years to stabilize the articular disc to the posterior aspect of the condyle.\textsuperscript{32} Discectomy is a surgical treatment, which is often performed on individuals with severe TMD, to remove the damaged and very often dislocating articular disc without going to a more extreme treatment such as a joint prosthesis. However, removal of the painful pathologic disc causes the TMJ reduced absorbency and increased loading during articulation.\textsuperscript{128, 132}

2.4.1 Alloplastic Replacement of TMJ

While more conservative treatments are preferred when possible, in severe cases or after multiple operations, the current end stage treatment is joint replacement.\textsuperscript{128, 132} Before a joint replacement option is ever considered for a patient, all non-surgical, conservative treatment options must be exhausted; and all conservative surgical methodologies should be employed.\textsuperscript{107, 108} Joint replacement is a surgical procedure in which the severely damaged part of TMJ is removed and replaced with a prosthetic device. TMJ replacement is performed in certain circumstances such as bony ankylosis, recurrent fibrous ankylosis, severe degenerative joint disease, aseptic necrosis of the condyle, advanced rheumatoid arthritis, two or more previous TMJ surgeries, absence of the TMJ structure due to pathology, tumors involving the condyle and mandibular ramus area, and loss of the condyle from trauma or pathology.\textsuperscript{86, 107, 108, 151} The success of joint replacement surgeries significantly depends on the number of prior surgeries with better outcomes for patients with fewer previous TMJ surgeries.\textsuperscript{107, 152} Long-term follow-up
studies now available in the literature support the safety and efficacy of joint replacement under appropriate circumstances.\textsuperscript{84, 86, 107, 108, 151}

2.4.2 TMJ Implants

TMJ devices are used as endosseous implants for articular disc replacements, condylar replacements, fossa replacements, and as total joint prostheses. To be a successful treatment option, a TMJ implant must have biocompatible materials; functionally compatible materials; low wear, and fatigue; adaptability to anatomical structures; rigidly stabilized components; and corrosion resistant and non-toxic nature.\textsuperscript{152} van Loon, et al.\textsuperscript{140} stipulated the life expectancy of TMJ implant as one of the most critical requirements. To reduce the frequency of painful and expensive revision surgery, a TMJ device should have an expected lifetime of more than 20 years.

A total TMJ prosthesis was not described until 1974.\textsuperscript{71} Till then, surgeons had concentrated on implanting either a fossa or a condylar head, but not both.\textsuperscript{123} Although alloplastic TMJ prostheses were in use since early 1960s; those became popular in 1980s with the introduction of the Vitek-Kent prosthesis. Many other alloplastic TMJ devices were introduced later.\textsuperscript{151} However, many of the alloplastic devices failed in delivering the intended results due to their vulnerability to the repeated mechanical stresses encountered in the TMJ with functional movements of the jaw. The predicted in-vivo service life of such devices was one to three years.\textsuperscript{91} The United States Food and Drug Administration (FDA), in 1993, halted the manufacture of the TMJ implants – except for Christensen and Morgan implants which were on
the market prior to the enactment of the medical device law in 1976 – due to lack of safety and efficacy information to support the indicated use.\textsuperscript{138, 151} In 1993, TMJ implants were reclassified into Class III - the highest risk category.\textsuperscript{138, 139} Since December 30, 1998, only following four TMJ implants (from three manufacturers) are approved by the US FDA to date: (1) Christensen/TMJ Implants, Inc., total joint implant, (2) Christensen/TMJ Implants, Inc., partial joint implant, (3) TMJ Concepts implant, and (4) Walter Lorenz/Biomet implant.\textsuperscript{138, 139, 151}

The Christensen TMJ implant system was introduced in early 1960s.\textsuperscript{42, 123} Later, in 1995, it was described as a total joint replacement system for the TMJ.\textsuperscript{123} The Christensen prosthesis system includes either a partial or total TMJ prosthesis available as a stock device. The Christensen fossa eminence prosthesis (FEP) is fabricated entirely of Cobalt-Chrome (Co-Cr) alloy and is approximately 20 mm to 35 mm across and 0.5 mm thick with a polished articulating surface.\textsuperscript{42, 108} This device can support either unilateral or bilateral partial joint reconstruction. The Christensen condylar prosthesis has a Co-Cr alloy frame work with a molded Polymethylmethacrylate (PMMA) head and is available in three lengths of 45, 50, and 55 mm. Co-Cr bone screws and drill bits sized to the screws are used to fix the FEP to the base of the skull and condylar device to the ramus.\textsuperscript{42, 108}

Techmedica, Inc. developed the joint prosthesis in 1989 as a custom-made device. After FDA’s halting of the manufacture of any TMJ devices developed after 1976, Techmedica’s (now known as TMJ Concepts, Inc.) implant was re-approved by the FDA in 1997 based on the outcomes of a 5-year follow-up study on 36 patients with 65 TMJs presented by Wolford, et al.\textsuperscript{150-153} The TMJ Concepts total joint prosthesis uses materials that are well proven in orthopedic joint reconstruction for hip and knee replacements.\textsuperscript{150, 151} The fossa component of this
device is made from commercially pure titanium mesh (ASTM F67 & F1341) with an articular surface made of ultra-high-molecular-weight polyethylene (UHMWPE ASTM F68).  

The body of condylar component is made from medical grade titanium alloy (ASTM F136) with a condylar head of cobalt-chromium-molybdenum alloy (ASTM F1537). Both the fossa and condylar components are secured with titanium alloy (Ti-6Al-4V) screws.  

Compared to the “off-the-shelf” implant devices, a patient-fitted TMJ Concepts prosthesis is reported to have provided a better fit and stabilization of its components to the host bone thereby mitigating any micro-movement leading to loosening of the components and maximizing the opportunity for osseointegration of components and fixation screws. Osseointegration can contribute to improved patient function and decreased micro-movement, which limits overall prosthesis wear and stress. Wolford, et al. performed direct clinical comparison of pre-implantation and post-implantation subjective and objective data from two similar groups of patients who underwent reconstruction with two different TMJ reconstruction systems. These studies evaluated 23 patients treated with Christensen prostheses (followed for a mean of 20.8 months) along with 22 patients implanted with TMJ Concepts prostheses (followed for a mean of 33 months). The investigators reported statistically significant improved outcomes relative to post-surgical incisal opening, pain, jaw function, and diet for the TMJ Concepts prosthesis group compared to the Christensen prosthesis group.  

Biomet’s Walter Lorenz TMJ implant is a “ball and socket” type prosthetic joint similar to a knee or hip implant. The condylar component of this prosthesis is manufactured from Cobalt-Chromium-Molybdenum (Co-Cr-Mo, ASTM F799) alloy with a roughened titanium porous coating on the host bone side of the ramal plate.
available in lengths of 45 mm, 50 mm, and 55 mm. The fossa component is manufactured from a specific grade of ultra-high molecular weight polyethylene (UHMWPE) called ArCom which has shown a 24% reduction in wear compared to traditional UHMWPE.\textsuperscript{107, 108} The swan neck curvature on the medial surface of condylar neck avoids the inherent fitting problems of the right angle design found in most metallic condylar prosthesis.\textsuperscript{107, 108} The fossa is available in three sizes with predrilled holes for the screws. It also has an exaggerated circumferential lipping to protect the condyle from possible heterotopic bone formation and to avoid condylar dislocation.\textsuperscript{107, 108} Both the condyle and fossa implants are attached to bone using self-retaining, self-tapping bone screws made of titanium alloy (Ti-6Al-4V).\textsuperscript{107, 108}

After three year follow-up of 50 patients (69 joints; 31 unilateral and 19 bilateral) reconstructed with Lorenz/Biomet prosthesis, Quinn\textsuperscript{107, 108} reported significant improvement in pain intensity, mouth opening, and functional diet capability. According to 2007 FDA documentation, a total of 268 joints (92 unilateral and 88 bilateral) were reconstructed with W. Lorenz/Biomet total TMJ replacement system after appropriate non-surgical treatment and/or previous implant failure.\textsuperscript{139} The average patient follow-up for 19.6 months demonstrated improvement in patients’ condition through decrease in pain, increase of function, increase in maximal incisal opening, and satisfaction with the treatment outcome. Barbick, et al.\textsuperscript{7} demonstrated that the Lorenz/Biomet prosthesis fits satisfactorily in the majority of patients undergoing surgical TMJ Concepts custom joint replacement with minimal anatomical reduction. The safety and effectiveness of revision surgery using a second set of W. Lorenz/Biomet total TMJ replacement system implants is not known. Long-term follow-up studies of this device are not available.
2.4.2.1 Alloplastic Materials for TMJ Implants

Alloplastic materials used as medical devices have traditionally been viewed as biologically inert substances that can be designed to achieve desirable mechanical properties. Silicone rubber and Proplast/Teflon (PT) were widely used materials in alloplastic TMJ implants from mid 1970s to late 1980s. Implants composed primarily of carbon fiber and polytetrafluoroethylene (PTFE/Teflon or PT) were introduced in the mid 1970s to reconstruct the TMJ after discectomy. Early reported successes with the use of these materials included greater implant stability, and soft-tissue ingrowth into the more porous PT implants.

In many TMJ patients, alloplast materials initially provided pain relief and improved function of the joint. However, in most patients, silicone rubber and PT implants were found to gradually break down as they could not sufficiently withstand the contact stresses generated during functional movements of the jaw. The structural failure of the implants resulted in formation of microparticulate implant debris which elicited a foreign-body response characterized by the presence of multinucleated giant cells. The breakdown particles provoked the foreign body giant cell reactions resulting in severe pain, headaches, inflammation, fibrosis, malocclusion, progressive bone and soft-tissue destruction, and severely limited joint function often requiring further surgery.

2.5 Bone – Material and Mechanical Properties

Mandibular and temporal bones play an important role in the form, function and dysfunction of the TMJ. Understanding the structural aspects and biomechanical behavior of these bony
components is an essential part of the TMJ research. At the whole-bone level, the entire bone is considered as a single structure, which incorporates the macroscopic geometric and material properties of bone.\textsuperscript{19} The outer layer of bone is covered by a dense layer of calcified tissue called cortical bone. The trabecular bone presents itself as a meshwork of needlelike structures. The cortical and trabecular bone have the same material composition, but they differ in structure and function. Quantitatively, 80 to 90 percent by mass of the cortical compartment is bone, whereas only 15 to 25 percent of the trabecular compartment is bone and the rest marrow.\textsuperscript{19} This structural arrangement makes cortical bone more rigid and less flexible compared to trabecular bone. Young’s modulus and Poisson’s ratio are the two main parameters that describe the mechanical properties of the bone material.\textsuperscript{4} Bone is an anisotropic material in which a variation in mechanical properties depends on the orientation of the load acting on the bone.\textsuperscript{143} It has been recorded that both cortical and trabecular bone are stronger in the longitudinal direction than in the transverse direction.\textsuperscript{21} However, for simplicity, bone is often assumed materially isotropic during structural assessments.\textsuperscript{143} Due to viscoelastic behavior of bone, the stress depends not only on the magnitude but also the rate of strain.\textsuperscript{4} However, at low strain rates cortical and trabecular bones may be considered elastic.\textsuperscript{4} Bone displays non-linearity in its response to load after the yield strength of bone is crossed.\textsuperscript{4, 19} However, prior to yield strength the response of both cortical and trabecular bone to load is linear. Therefore, in cases where post-yield characteristics of bone are not critical, both cortical and trabecular bone may be assumed to have a linear response to varying loads.\textsuperscript{143}
2.5.1 Bone Stiffness and Microdamage

Strain is the deformation or change in dimensions and/or shape caused by a load on any structure or structural material. Strain can include stretching, shortening, twisting, and/or bending. Special gauges (i.e., strain gauges) can measure bone strain in the laboratory and in-vivo. Stiffness is the resistance of the bone to its deformation or straining under a load. Stiff bones deform or strain less than less stiff (more “compliant”) ones under the same load. Repeated strains in the bone cause microscopic fatigue damage in bone.\textsuperscript{36} Bone microdamage begins at the ultramicroscopic level, and then progresses to microcracks and delamination which is accompanied by the decrease in stiffness of the affected bone.\textsuperscript{36,98} Such damage degrades the physical integrity of the bone tissue.\textsuperscript{36,40} It weakens bone without affecting its size, shape, content of material, or appearance.\textsuperscript{36} The decrease in stiffness and accumulation of microdamage can lead to complete fracture, also known as stress fracture, of the affected bone. Larger and/or more numerous strains can reduce bone strength below 20\% of normal.\textsuperscript{36}

Normally bones detect their microdamage, and then repair it by removing and replacing the damaged bone with new bone. Under this condition, bone modeling and remodeling can normally repair the small amounts of microdamage indefinitely as long as the microdamage caused by the strain remains below the intrinsic modeling threshold of the bone.\textsuperscript{36,66} However, dead bone cannot detect and repair microdamage. Due to the inherent adaptability of the living bone, it needs only enough strength to keep strains below the level that could cause larger amounts of microdamage. Bone can carry loads that cause smaller strains indefinitely. Frost\textsuperscript{34,36} formulated this relation as expressed below:
Remodeling Threshold < Peak Strains from Voluntary Actions < Modeling Threshold << Microdamage Threshold <<< Fracture Strain …………………………… Equation (2.1)

This relationship is reported to exist in the bones, cartilage, collagenous tissue, joints, tendons, and ligaments.\textsuperscript{34,36} If the damage accumulation rate exceeds the bone’s inherent capacity to repair, stress fractures take place. These fractures occur commonly in high intensity and repetitive activities. If, on the other hand, damage accumulates at ‘normal’ rates but the bone’s repair mechanism is deficient, fragility fractures result, which occurs commonly in ageing bone.\textsuperscript{98} Excessive microdamage causes all spontaneous fractures; so they are not really spontaneous.\textsuperscript{36} Complete fractures of trabecular bone are suggested to stem from fatigue failures rather than from single loads above ultimate strength of the trabeculae.\textsuperscript{36} Normal mechanical usage of osteopenic bones (which are characterized by decreased calcification, density or mass) could increase their microdamage and their fragility enough to cause spontaneous fractures and/or bone pain. This osteoporosis of osteopenic bones is less common, and it affects women more than men or children.\textsuperscript{36} It needs to be investigated if the high prevalence of true osteoporosis in women has any correlation with the gender paradox of TMJ patient population.

2.5.2 In-Vitro Biomechanical Analysis of Bone

Mechanical tests are widely acceptable method of directly assessing the geometric and material properties of cadaver bones.\textsuperscript{19} However, the results of these tests can be affected by specimen preparation (size, shape, aspect ratio, method of specimen extraction, etc.), test
methods (direct tests such as tensile tests, compressive tests, torsion tests and bending tests or indirect tests such as nano-indentation methods, optical methods, etc.) and environmental conditions (loading-rate, deformation-rate, specimen-hydration, specimen-gripping techniques, etc.).\textsuperscript{143} For standard engineering structures, the protocols for testing have been well established. However, in the case of bone, such standard testing methods cannot always be utilized due to restrictions imposed by the complex geometry, material anisotropy and finite size of the bone specimens, difficulties in gripping the specimens, and in some cases the need to use relatively low loads to study bone response.\textsuperscript{143}

The only way to directly assess material integrity of the bone is using strain analysis. Stress cannot be directly measured using a sensor but only be estimated using mathematical formulas, which are based on Young’s modulus and bone geometry. Strain, on the other hand, can be directly assessed using strain gauges. The primary limitations of the strain gauge technique are that the test sites are limited to the area covered by the strain gauge, and the varying bone topography prevents easy attachment of the gauges at many locations.\textsuperscript{19}

FE models which are similar, materially and geometrically, to the actual bone can be used to perform stress and strain analyses on an element by element basis to study the role of 3D geometric and material properties of bone. Since strain is an independent parameter that can be assessed using strain gauges attached to bone under mechanical loading, such strain measurements can be used to determine the accuracy of FE models simulating identical mechanical loading.\textsuperscript{142} In FE analysis, a complex geometry is discretized into simple, finite, geometric shapes called elements. Each element is given a material property and a governing inter-element relationship (i.e., linear or non-linear) to form the required model. Accurate
assignment of material properties to different components (such as cortical layer, cancellous section, teeth) of the FE model of bone is necessary to obtain precise replication of the bone’s biomechanical behavior in the results of FE simulations.

Different approaches have been used by researchers to assign the material properties to FE models of the bone reconstructed from patient’s medical images. Varghese, et al.\textsuperscript{142} adopted consistent bone-material properties based on a parameter optimization study. They held constant the Young’s modulus value of the cortex volume between periosteal and endocortical boundaries, and used an inhomogeneous isotropic material model for the trabecular volume of FE models of long bones. An optimized Poisson’s ratio was adopted for both cortical and trabecular bone. A mask representing the endosteal region of the bone model was eroded twice to obtain material information without influence of partial-volume effect for the trabecular region near the endosteal boundary. The authors dilated the grayscale twice to re-grow the volume to original size, which replicated the grayscale values of the eroded periphery to the re-grown region as previously described by Wu, et al.\textsuperscript{154} The resultant volume contained partial-volume corrected density values along the endosteal boundary. The density values were assigned using a method previously published by Hangartner.\textsuperscript{47} Gröning, et al.\textsuperscript{45} reconstructed the mandibular anatomy from CT data of a human mandible, and created a FE volume mesh. They assigned a same set of material properties to the entire bone and teeth components of the FE mesh by defining Young’s modulus and Poisson’s ratio. We performed anatomical reconstruction of the cadaveric mandibles from their CT scans as described in Chapter 4. FE volume mesh was generated for each of the mandibular model. Material properties to cortical component,
cancellous component, and teeth of each mandibular FE mesh from their respective masks in Mimics using the in-built ‘mask method’ of the software as described in Chapter 4.

Once the user defines the nature of the FE problem, i.e., structural or non-structural, nodal coordinates, inter-nodal relationships, geometry of elements, loading condition with constraints and type of analysis desired, the computer constructs the governing equations and solves them to provide the required analysis results. Accurate FE models of human bones are in demand in the clinical environment; to determine the mechanical stress/strains that physiological activities induce in bones. This information is of great importance in the field of patient rehabilitation, especially in patients recovering from orthopedic procedures.19, 143

### 2.6 Biomechanics of the Mandible and TMJ

Mandibular motions result in static and dynamic loading in the TMJ. During natural loading of the joint, combinations of compressive, tensile, and shear loading occur on the articulating surfaces.132 The analysis of mandibular biomechanics helps us understand the interaction of form and function, mechanism of TMDs; and aids in the improvement of the design and the behavior of prosthetic devices, thus increasing their treatment efficiency 48, 64, 77

#### 2.6.1 In-Vivo Assessment

Very few studies about in-vivo biomechanical assessment of the TMJ can be found in the literature. In contrast to some earlier studies which reported the TMJ to be a force-free joint,
Hylander\textsuperscript{60} demonstrated that considerable forces were exerted on the TMJ during occlusion as well as mastication. In face of these contrary reports, Breul, et al.\textsuperscript{14} showed that the TMJ was subjected to pressure forces during occlusion as well as during mastication and it was slightly eccentrically loaded in all positions of occlusion.

Korioth and Hannam\textsuperscript{76} indicated that the differential static loading of the human mandibular condyle during tooth clenching was task dependent, and both the medial and lateral condylar thirds were heavily loaded. Huddleston-Slater, et al.\textsuperscript{58} suggested that when the condylar movement traces coincide during chewing, there is compression in the TMJ during the closing stroke. However, when the traces do not coincide, the TMJ is not or only slightly compressed during chewing. Naeije and Hofman\textsuperscript{95} used these observations to study the loading of the TMJ during chewing and chopping tasks. Their analysis showed that the distances traveled by the condylar kinematic centers were shorter on the ipsilateral side than on the contralateral; and the kinematic centers of all contralateral joints showed a coincident movement pattern during chewing and chopping. The indication that the ipsilateral joint is less heavily loaded during chewing than the contralateral joint may explain why patients with joint pain occasionally report less pain while chewing on the painful side.\textsuperscript{64, 95}

Hansdottir and Bakke\textsuperscript{48} evaluated the effect of TMJ arthralgia on mandibular mobility, chewing, and bite force in TMD patients (categorized as disc derangements, osteoarthritis, and inflammatory disorders) compared to healthy control subjects. The pressure pain threshold (PPT), maximum jaw opening, and bite force were significantly lower in the patients as compared to that in controls. The patients were also found to have longer duration of chewing cycles. The bite force and jaw opening in patients were significantly correlated with PPT. The
most severe TMJ tenderness (i.e., lowest PPT) and the most impeded jaw function with respect to jaw opening and bite force were found to be more severe in the patients with inflammatory disorders than the patients with disc derangement or osteroarthritis.\textsuperscript{48}

### 2.6.2 In-Vitro Assessment

As the TMJ components are difficult to reach, and as the applications of experimental devices inside the TMJ cause damage to its tissue, the direct methods are not used often. Indirect techniques utilized to evaluate mandibular biomechanics have had limited success due to their ability to evaluate only the surface stress of the model but not its mechanical properties.\textsuperscript{64} Mechanical testing and finite element method (FEM) have been progressively used by TMJ researchers.

Excessive shear strain can cause degradation of the TMJ articular cartilage and collagen damage eventually resulting in joint destruction.\textsuperscript{136} Tanaka, et al.\textsuperscript{136} attempted to characterize the dynamic shear properties of the articular cartilage by studying shear response of cartilage of 10 porcine mandibular condyles using an automatic dynamic viscoelastometer. The results showed that the shear behavior of the condylar cartilage is dependent on the frequency and amplitude of applied shear strain suggesting a significant role of shear strain on the interstitial fluid flow within the cartilage. Beek, et al.\textsuperscript{9} performed sinusoidal indentation experiments and reported that the dynamic mechanical behavior of disc was nonlinear and time-dependent.

FE modeling has been used widely in biomechanical studies due to its ability to simulate the geometry, forces, stresses and mechanical behavior of the TMJ components and implants during
simulated function.\textsuperscript{10, 16, 74, 75, 102, 104, 112, 134} Chen, et al.\textsuperscript{16} performed stress analysis of human TMJ using a two-dimensional FE model developed from magnetic resonance imaging (MRI). Due to convex nature of the condyle, the compressive stresses were dominant in the condylar region whereas the tensile stresses were dominant in the fossa-eminence complex owing to its concave nature. Beek, et al.\textsuperscript{10} developed a 3D linear FE model and analyzed the biomechanical reactions in the mandible and in the TMJ during clenching under various restraint conditions. Nagahara, et al.\textsuperscript{96} developed a 3D linear FE model and analyzed the biomechanical reactions in the mandible and in the TMJ during clenching under various restraint conditions. All these FE simulations considered symmetrical movements of mandible, and the models developed only considered one side of the joint. Hart, et al.\textsuperscript{49} generated 3D FE models of a partially edentulated human mandible to calculate the mechanical response to simulated isometric biting and mastication loads. Vollmer, et al.\textsuperscript{146} conducted experimental and FE study of human mandible to investigate its complex biomechanical behavior. Tanaka, et al.\textsuperscript{130, 135} developed a 3D model to investigate the stress distribution in the TMJ during jaw opening, analyzing the differences in the stress distribution of the disc between subjects with and without internal derangement. Tanaka, et al.\textsuperscript{133} suggested, from the results of FE model of the TMJ based on magnetic resonance images, that increase of the frictional coefficient between articular surfaces may be a major cause for the onset of disc displacement.

In 2006, Koolstra and van Eijden\textsuperscript{74} performed a FE study to evaluate the load-bearing and maintenance capacity of the TMJ using a combination of rigid-body model with a FE model of both discs and the articulating cartilaginous surfaces to simulate the opening movement of the jaw. The results indicated that the
construction of the TMJ permitted its cartilaginous structures to regulate their mechanical properties effectively by imbibitions, exudation and redistribution of fluid. Perez-Palomar and Doblare\textsuperscript{104} used more realistic FE models of both TMJs and soft components to study clenching of mandible. The FE model included both discs, ligaments, and the three body contact between all elements of the joints, and was used to analyze biomechanical behavior of the soft components during a nonsymmetrical lateral excursion of the mandible to investigate possible consequences of bruxism. This study suggested that a continuous lateral movement of the jaw may lead to perforations in the lateral part of both discs, conforming to the indications by Tanaka, et al.\textsuperscript{130, 135} Later, Perez-Palomar and Doblare\textsuperscript{103} suggested that unilateral internal derangement is a predisposing factor for alterations in the unaffected TMJ side. However, it would be necessary to perform an exhaustive analysis of bruxism with the inclusion of contact forces between upper and lower teeth during grinding. Whiplash injury is considered as a significant TMD risk factor and has been proposed to produce internal derangements of the TMJ.\textsuperscript{68, 102} However, this topic is still subject to debate.\textsuperscript{24}

A theoretical model developed by Gallo, et al.\textsuperscript{39} for estimating the mechanical work produced by mediolateral stress-field translation in the TMJ disc during jaw opening/closing suggested that long-term exposure of the TMJ disc to high work may result in fatigue failure of the disc. Gallo, et al.\textsuperscript{38} studied the effect of mandibular activity on mechanical work in the TMJ, which produces fatigue that may influence the pathomechanics of degenerative disease of the TMJ. Nickel, et al.\textsuperscript{97} validated numerical model predictions of TMJ eminence morphology and muscle forces, and demonstrated that the mechanics of the craniomandibular system are affected by the combined orthodontic and orthognathic surgical treatments. Using this validated
numerical model to calculate ipsilateral and contralateral TMJ loads for a range of biting positions and angles, Iwasaki, et al.\textsuperscript{65} demonstrated that TMJ loads during static biting are larger in subjects with TMJ disc displacement compared to subjects with normal disc position.

\section*{2.6.3 Post-surgery Assessment}

TMJ reconstruction using the partial or total TMJ prosthetics, in most cases, improves range of motion and mouth opening in the TMJ patients. However, loss of translational movements of the mandible on the operated side has been often observed, especially in anterior direction, owing to various factors such as loss of pterygoid muscle function, scarring of the joint region and muscles of mastication.\textsuperscript{155} Komistek, et al.\textsuperscript{72} assessed in-vivo kinematics and kinetics of the normal, partially replaced, and totally replaced TMJs. Less translation was reported in the partial (fossa) replacement and total TMJ reconstruction cases than in the normal joints. The study suggests that total TMJ implants only rotate and do not translate; and the muscles do not apply similar forces at the joint when the subject has a total TMJ implant, compared to a subject who has a normal, healthy TMJ.

In the post TMJ replacement follow-up studies, Mercuri, et al.\textsuperscript{89} obtained the measures of mandibular interincisal opening and lateral excursions. The assessment showed a 24\% and a 30\% improvement in mouth opening after 2 years and 10 years, respectively. On the other hand, at 2 years post-implantation, there was a 14\% decrease in left lateral excursion and a 25\% decrease in right lateral excursion from the pre-implantation data. As the loss of lateral jaw movement is a great disadvantage to total TMJ prosthesis replacement, a future prosthesis must allow some
lateral translation as well as the anterior movement of mandible on the operated side when the mouth is opened.\textsuperscript{141} Yoon, et al.\textsuperscript{155} followed a kinematic method that tracked the condylar as well as incisors path of the TMJ motion. An electromagnetic tracking device and accompanying software were used to record the kinematics of the mandible relative to temporal bone during opening-closing, protrusive, and lateral movements.\textsuperscript{155} Mean linear distance (LD) of incisors during maximal mouth opening for the surgical patient group was 18\% less than the normal subjects. Mean LD for mandibular right and left condyles was symmetrical in the normal group; however, in the surgical patient group, measurements for operated condyle and unoperated condyle were asymmetric and reduced as compared with normal subjects by 57\% and 36\%, respectively.\textsuperscript{155} In protrusive movements, operated and unoperated condyles of surgical patients traveled less and significantly differently as compared with condyles of normal subjects, which moved almost identically. For the surgical patient group, the mean incisor LD away from the operated side and toward the operated side as compared with the normal group incisors were reduced by 67\% and 32\%, respectively.\textsuperscript{155}

### 2.7 Problem Statement and Research Objectives

With a large fraction of human population suffering from problems concerning the jaw and the TMJ, a comprehensive understanding of the associated structures is essential. Relations between muscle tensions, jaw motions, bite and joint force, and craniofacial morphology are not fully understood. A large fraction of TMD causes are currently unexplained. There is a great need and demand for relatively less expensive and more efficient treatment modalities including durable patient-fitted TMJ implants. Hence, better understanding of the etiology of TMDs is
necessary to prevent not only occurrence of TMDs but also failure of an implanted joint in the same way as the joint it replaced.

The goal of the proposed research is to aid better understanding of the form and function of the mandible and TMJ. This research will make contributions to furthering our knowledge of the biomechanical behavior of the mandible and TMJ by achieving the following goals:

1. Perform patient-specific three-dimensional (3D) anatomical reconstruction of the mandible and TMJ to gain insight about structural aspects of the anatomy.
2. Study variation in stiffness of human cadaver mandibles during cyclic fatigue tests simulating the physiological loading scenarios.
3. Study microdamage accumulation in human cadaver mandibles during cyclic fatigue tests simulating the physiological loading.
4. Study strain profile at different locations on the surface of cadaver mandibles during fatigue tests.
5. Develop specimen-specific finite element (FE) models of human cadaveric mandibles, and perform FE simulations imitating experimental tests.
6. Validate the FE methodology of mandibular assessment by comparing with experimental measurements.
7. Present a methodology to design a novel patient-fitted total TMJ implant system. Propose design features capable of offering better fixation and durability for such implants.
8. Evaluate biomechanical performance of the designed TMJ implants.
3. EXPERIMENTAL BIOMECHANICAL EVALUATION OF CADAVERIC HUMAN MANDIBLES

3.1 Introduction

Mandible is the most frequently fractured facial bone because of its prominence as it occupies a central and vulnerable position in the face. Functional overloading, malocclusion, and injury or fractures of the mandible are some of the factors that either co-exist with or may cause the temporomandibular disorders (TMD) of varying degree of complications. As millions of people suffer from problems concerning the mandible, knowledge of mandibular biomechanics during different loading conditions can provide valuable information useful to understand the mechanism of fracture. Biomechanical analysis is a useful tool to understand the normal function, predict changes due to alteration, and propose methods of artificial intervention for the treatment of diseases associated with the mandible, TMJ, and the masticatory system. As mandible and associated components of the masticatory system are difficult to reach, and as the applications of experimental devices may cause damage to the masticatory tissue in living persons, the direct methods of biomechanical investigation are not used often. Indirect techniques such as in-vitro mechanical testing of cadaveric specimens, and FE modeling and analysis offer practical alternative.

Cyclic loading of bone results in degradation of mechanical properties such as strength and stiffness, ultimately leading to fatigue failures, also known as stress fractures, at loads well below the fracture strength of the bone. Repeated strains in the bone cause microscopic fatigue damage in bone. Bone microdamage begins at the ultramicroscopic level, and then progresses
to microcracks accompanied by the decrease in stiffness of the affected bone.$^{36,98}$ Such damage degrades the physical integrity of the bone tissue.$^{36,40}$ The decrease in stiffness and accumulation of microdamage can lead to complete fracture, also known as stress fracture, of the affected bone.

Information about fatigue failure mechanisms is necessary to identify the critical loading component and damage mechanism that cause fatigue failures under physiological conditions involving superimposition of tensile, compressive, and torsional loading.$^{40}$ It is noteworthy that, despite some individual studies focused on biomechanical assessment of the mandible, limited information is available about stiffness, damage accumulation, and fracture modes in mandibular bone under cyclic fatigue loading. In view of this paucity of experimental knowledge, the key objective of our study is to identify the damage mechanism in the mandible characterized by stiffness variation, microdamage accumulation, fatigue life (i.e., number of loading cycles before failure), and fracture locations when subjected to cyclic compressive loading which closely resembles the physiological loading during repeated jaw closing or clenching activity.

Fractures occur when the load on a bone exceeds the ability of the bone to carry that load.$^{13,137}$ Bone characteristics under load in-vitro depend on type, rate, and direction of applied load.$^{78}$ Anatomical regions of mandible are reported to have different biomechanical behavior depending on the direction of load.$^{78,137,137}$ To analyze material properties, bone can be represented by a fiber-reinforced composite model based on the rule of mixtures.$^{46,55}$ The haversian osteons, which are composed of collagen and minerals, act as the load-bearing fibers. Fatigue damage in bone is characterized by a three stage model (see Figure 3.1) for axial loading similar to that used for fiber-reinforced composite.$^{46,55}$ In stage I, initiation of micro-cracks
begins in the interstitial bone tissue. This is where a significant amount of stiffness reduction can be seen. Stiffness reduction slows into a linear progress as the material is weakened in stage II. By stage III, the osteons are debonded and stiffness drops leading to crack growth. These stages of crack growth have been utilized in many studies of fatigue damage in bone.25, 41, 99, 144, 145

Figure 3.1. Schematic showing stages of damage progress in cortical bone versus fatigue cycles. Source: Varvani-Farahani and Najmi144
Frost\textsuperscript{35} investigated Wolff’s concept of relationship between biomechanics and morphology of bony tissue, and proved the relationship between the amount of strain in the bony microenvironment and the biological reaction.\textsuperscript{35,146} Although it is nearly impossible to standardize the real functional and para-functional behavior of the masticatory system in living persons, the biomechanical properties of the human mandible can be determined experimentally using models to simulate standardized normal physiological and non-physiological loads. The biomechanical behavior of the mandible is important in various clinical situations, and has been studied by different approaches. Indirect methods such as mechanical testing and FE analysis have been widely used for in-vitro assessment of anatomical structures. Direct biomechanical testing of bone provides useful information about mechanical integrity. We investigated in-vitro the biomechanical behavior of mandible under four different configurations of cyclic compressive loading.

The schematic in Figure 3.2 depicts the outline of the experimental-numerical study assessing biomechanical aspects of the cadaveric mandibles. Mechanical testing of the cadaveric mandibles is performed under different loading conditions, specimen-specific 3D anatomical models are reconstructed from computed tomography (CT) images of the mandibles, numerical analysis paralleling experimental set-up is performed through finite element method, and the FE results are validated by comparing the numerical strain values with the experimental strain data collected during mechanical testing. Chapter 3 discusses the experimental aspects of the study, and Chapter 4 focuses on analysis of the experimental strain data, 3D reconstruction, and FE analysis of the mandibles. The aim of the experimental investigation covered in this chapter is to
examine the stiffness reduction, damage accumulation, and failure of the cadaveric human mandibles. The following questions are examined:

1. Can a difference be stated for cadaveric mandibles tested under different fatigue loading conditions with respect to fatigue life (i.e., number of cycles until failure), maximum load before failure, stiffness, damage accumulation, and failure location?
2. Do age and sex have significant effect on number of cycles until failure, maximum load before failure, stiffness, damage accumulation, and failure location of the mandible?
3. Does incisor loading of the mandible result in a lower number of cycles until failure compared with molar loading?
4. Does dental status of the mandible have a significant effect on number of cycles until failure, maximum load before failure, stiffness, damage accumulation, and failure location when subjected to cyclic fatigue loads?
Figure 3.2: Schematic showing steps involved in the experimental-numerical biomechanical analysis of human cadaver mandible. Mechanical testing of the cadaveric mandibles is performed under different loading conditions, specimen-specific 3D anatomical models are
reconstructed from CT images of these mandibles, numerical analysis paralleling experimental set-up is performed through finite element (FE) method, and the FE results are validated by comparing the numerical strain values with the experimental strain data collected during mechanical testing.

### 3.2 Materials and Methods

Sixteen fresh-frozen human cadaveric mandibles with no visible structural bone defects or fracture fixation devices were collected from adult human cadavers (nine females, seven males, aged 61 years to 98 years) (see Table 3.1). All of the cadavers were obtained through Wright State University Anatomical Gift Program with the necessary consent, protocol, and Wright State University IRB approval. On arrival of the cadavers, the bones were harvested, cleaned of soft tissue and wrapped in cloth soaked with saline prior to sealing them in a plastic bag and freezing them at –20 °C. 24 hours prior to the experiment date, the mandibles were moved from –20 °C freezer to a 4 °C refrigerator and then thawed at room temperature for at least 3 hours. Once the mandibles were thawed, any remaining soft tissue attached to the bone surface was removed using scalpel.
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</tbody>
</table>

ǂMandible Dental Status: E – edentulous (no teeth); M - mixed dental status (with one or more teeth missing)

**Table 3.1.** Demographics of the cadaveric mandible specimens.

### 3.2.1 Image Acquisition

Prior to mechanical testing, CT scans of all specimens were performed for 3D anatomical reconstruction to be done later. The cleaned mandibles were immersed, one at a time, into a cylindrical water tank, and trans-axial CT scans of entire specimen were obtained using a 16-slice GE Light speed scanner (General Electric Health Care, Milwaukee, WI, USA). The
scanning parameters are as following: 80 kVp, 200 mAs, 512 x 512 matrix and an isotropic voxel size of 0.625 x 0.625 x 0.625 mm$^3$.

### 3.2.2 Strain Gauge Attachment

Uniaxial strain gauges (KFG-1-120-C1-11 L3M3R, Kyowa Electronics, Tokoyo, Japan) were used to measure surface strain. Five strain gauges were attached at exactly defined five locations on the cortical surface of the mandibular bone after the attachment sites were cleaned and degreased using standard protocol (see Figures 3.3 and 3.6).\textsuperscript{11, 18, 127, 142} The positions of the strain gauges were selected based on the literature,\textsuperscript{28, 110} and results of our prior FE simulation of a mandible specimen. The attachment sites for strain gauges were defined as following: one strain gauge (L1) placed fronto-laterally at left mental protuberance, below alveolar process; one buccally on left mandibular body, caudal to first and second molars, anterior to oblique line (L2); another at the dorsal region of the left condylar process (L3); one buccally on right mandibular body, caudal to first and second molars, anterior to oblique line (L4); and another at the dorsal region of the right condylar process (L5) as shown by the schematic in Figure 3.3. Strain gauges are simple to use, although care must be taken in selection and implementation to minimize error.\textsuperscript{18, 110} The deformation of the bone surface leads to a corresponding change in the length of the strain gauge wire which is proportional to its electrical resistance.\textsuperscript{17, 28} The parameter used to describe this deformation process is $\mu \text{strain} \text{(}\mu \text{m/m)}$. 

38
**Figure 3.** Schematic of strain gauge attachment at five exactly defined locations on the cortical surface of the mandible. Panel-A shows the left lateral view, and Panel-B shows the right lateral view of a mandibular 3D model depicting positions of the strain gauges. The strain gauges were named according to their site of attachment as following –

L1: fronto-laterally at left mental protuberance, below alveolar process;

L2: buccally on left mandibular body, caudal to first and second molars, anterior to oblique line;

L3: at the dorsal region of the left condylar process;

L4: buccally on right mandibular body, caudal to first and second molars, anterior to oblique line;

L5: at the dorsal region of the right condylar process.

Each strain gauge was connected through a quarter-bridge wiring configuration of Wheatstone bridge circuit to the instruNet Data Acquisition System (Omega, Stamford, CT, USA), which was linked to a computer to record the data using instruNet World PLUS (iW+) software (Omega, Stamford, CT, USA). During cyclic loading of each specimen, strain at the
gauge attachment sites was continuously measured and recorded throughout the experiment at a sampling rate of 2 Hz. To identify the site of attachment for each strain gauge, images of the specimens were taken with a digital camera from approximately 400 mm before, during, and after mechanical testing. This helped in accurately defining the strain acquisition sites and boundary conditions during the FE simulations discussed in Chapter 4.

3.2.3 Mechanical Testing

Tests were conducted in axial compression mode. The cyclic load was applied at 2 Hz using an EnduraTEC materials testing machine (ElectroForce Systems Group, Bose Corporation, Eden Prairie, MN, USA) that allowed a controlled application of force simulating bite forces. Similar to previous studies by Schupp, et al.\textsuperscript{117} and Gröning, et al.\textsuperscript{45}, custom-designed fixtures were used to set-up the mandible upside down in the machine so that it rested on the two condyles and either molars or incisors as required for a given loading configuration. The mandibles were placed in a reverse position for practical reasons (see Figures 3.5 and 3.6). Cyclic, axial, compressive loads were applied to the mandibular angles on both sides of the mandible.

3.2.3.1 Loading configurations

The mandibles were divided in four groups to undergo cyclic loading of four different configurations. Groups 1 and 2 consisted of six mandibles each, and Groups 3 and 4 consisted of two mandibles each. In Group-1, the mandibles were loaded bilaterally with support at the molar
region (see Figure 3.6-A). During the bilateral-molar-normal (BMN) loading phase, the load varied between 140N and 200N for 30,000 cycles. The BMN phase was immediately followed by bilateral-molar-overload (BMO) phase during which the load varied between 280N and 400N for another 30,000 cycles (see Figure 3.4-A). Group-2 specimens underwent bilateral loading through support at the incisor region (see Figure 3.6-B). During the bilateral-incisor-normal (BIN) loading phase, the mandibles underwent load varying between 105 N and 150 N for 30,000 cycles. The BIN phase was immediately followed by a bilateral-incisor-overload (BIO) phase of cyclic compressive load varying between 210 N and 300 N for another 30,000 cycles (see Figure 3.4-B). The chosen magnitudes of load are reflective of bite forces under functional and parafunctional loading of the mandible. These forces are comparable to those previously reported in the literature.1, 5, 6, 12, 101, 121

The load configuration of Groups 3 and 4 consisted of spectrum of load blocks (see Figure 3.4-C). In Group-3, the mandibles were loaded bilaterally at the molar region. This bilateral-molar-spectrum (BMS) loading configuration consisted of cyclic, axial, compressive load varying between 50 N and the upper limit for a given load block for 3,000 cycles in each block. BMS configuration included 20 load blocks with the upper limit of 100 N for the first block and 1050 N for the last block. The upper load limit for each block exceeded that of the previous block by 50 N. Mandibles in Group-4 were loaded bilaterally at the incisor region. This bilateral-incisor-spectrum (BIS) loading configuration consisted of cyclic, axial, compressive load varying between 50 N and the upper limit for a given load block for 3,000 cycles in each block. Similar to Group-3 loading configuration, the BIS configuration of Group-4 included 20 load blocks with
the upper limit of 100 N for the first block and 1050 N for the last block. The upper load limit for each block exceeded that of the previous block by 50 N.
Figure 3.4. Schematic representation of load variation during mechanical testing of mandibles. Panel-A shows molar load configuration of Group-1 in which applied axial load varies between
140 N and 200 N during bilateral molar normal (BMN) loading phase, and between 280 N and 400 N during bilateral molar over-load (BMO) phase. Panel-B depicts incisor load configuration of Group-2 in which applied load varies between 105 N and 150 N during 30000 cycles of bilateral incisor normal (BIN) loading, and between 210 N and 300 N during next 3000 cycles or bilateral incisor over-load (BIO) phase. Panel-C shows the spectrum loading configuration which is of similar form for molar (BMS) and incisor (BIS) loading of mandibles in Group-3 and Group-4, respectively. Note: The frequency of load variation in the visuals is not representative of actual experiment.

**Figure 3.5.** Loading set-up of EnduraTEC materials testing machine using custom-designed fixture for mandibles.
Figure 3.6. Loading set-up of EnduraTEC materials testing machine with custom-designed fixture for mandibles. Fixture arrangement for the molar loading of mandibles in Groups 1 and 3 (Panel-A), and the incisor loading in Groups 2 and 4 (Panel-B) are shown.

In all loading groups, any specimen without failure during the cyclic testing was subjected to a load-to-failure (LTF) test at the displacement rate of 2mm/min. Visible fracture was considered a failure of the mandible. Axial position and load data were collected every 10 second using an axial displacement transducer and an EnduraTEC 2.2 kN axial/torsion bi-axial load cell (Model No. 1215CEW-250), respectively. At the same time, strain at the gauge attachment sites was continuously measured at a sampling rate of 2 Hz using the inStruNet Data Acquisition System and a personal computer. The strain data from all strain gauges attached to one specimen (EH) from loading Group-1 could not be recorded due to an unforeseen problem with the computer system recording strain data. The experimental strain data, its statistical analyses, and comparison with numerical strain predictions from FE analysis are discussed in Chapter 4.
3.3 Damage Development

The axial stiffness (k) and damage (D) of each specimen were determined from the data collected for each of the mandibles. Stiffness is determined from the axial compressive load \(F_a\) applied to the mandible and the axial displacement \(\delta_a\) of the mandible determined from change in axial position (see Equation 3.1).\(^8\)

\[
k = \frac{F_a}{\delta_a} \quad \text{-------- Equation (3.1)}
\]

Damage is determined as a resultant of the axial stiffness \((k)\) and the initial axial stiffness \((k_o)\) (see Equation 3.2).

\[
D = \frac{k}{k_o} \quad \text{-------- Equation (3.2)}
\]

3.4 Results

Table 3.2 summarizes the demographics and observations for mandibles in all loading groups. Due to the practical constraints associated with a typical cadaveric experiment, such as the limited number of cadavers obtained during a given time span through an academic institute’s anatomical gift program, our study includes only sixteen cadaveric mandibles. Due to the small sample size, we would like to present this study as a unique and novel exploratory experiment. The inferences from the statistical analysis of the study data are a by-product of the novel exploration. During mechanical testing, the cadaveric mandibles in Group-1 and Group-2
undergo similar loading pattern with only difference in location and magnitude of loads. Due to this similarity in loading configurations, Group-1 and Group-2 are comparable with each other. Similarly, Group-3 and Group-4 are comparable with each other.

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<td>966.6</td>
<td>60,000</td>
<td>47.3497</td>
<td>97.7837</td>
<td>36.6076</td>
</tr>
<tr>
<td>8</td>
<td>HK</td>
<td></td>
<td>671</td>
<td>60,000</td>
<td>41.6044</td>
<td>123.2044</td>
<td>77.0342</td>
</tr>
<tr>
<td>9</td>
<td>AM</td>
<td></td>
<td>281</td>
<td>30,025</td>
<td>25.0099</td>
<td>176.0829</td>
<td>145.4035</td>
</tr>
<tr>
<td>10</td>
<td>BS</td>
<td></td>
<td>1001.6</td>
<td>60,000</td>
<td>78.0178</td>
<td>125.5732</td>
<td>46.9500</td>
</tr>
<tr>
<td>11</td>
<td>PO</td>
<td></td>
<td>299.8</td>
<td>30,674</td>
<td>33.2355</td>
<td>148.3740</td>
<td>114.8405</td>
</tr>
<tr>
<td>12</td>
<td>FH</td>
<td>Group-3</td>
<td>501.4</td>
<td>60,000</td>
<td>69.6915</td>
<td>115.8779</td>
<td>44.4932</td>
</tr>
<tr>
<td>13</td>
<td>FK</td>
<td></td>
<td>2449.4</td>
<td>60,000</td>
<td>44.4012</td>
<td>144.2950</td>
<td>91.6651</td>
</tr>
<tr>
<td>14</td>
<td>VV</td>
<td>Group-4</td>
<td>1984.9</td>
<td>60,000</td>
<td>91.7637</td>
<td>671.2330</td>
<td>561.0770</td>
</tr>
<tr>
<td>15</td>
<td>OM</td>
<td></td>
<td>352.4</td>
<td>16,851</td>
<td>7.9775</td>
<td>211.9790</td>
<td>203.9810</td>
</tr>
<tr>
<td>16</td>
<td>ES</td>
<td></td>
<td>312.4</td>
<td>34182</td>
<td>37.5582</td>
<td>358.1150</td>
<td>320.4420</td>
</tr>
</tbody>
</table>

*Failure during cyclic loading or load-to-failure test
#If cycles = 60000, the specimen did not fail during cyclic loading, and later underwent load-to-failure test
*Failure location: A - mandibular angle; B – mandibular body; C – symphysis or parasymphysis; D – condylar neck; E - condylar head

Table 3.2. Patient demographics, loading type, and observations for mandibles tested under cyclic compressive loading.
3.4.1 Statistical Analysis

Table 3.3 shows the statistical analyses of data for mandibles in loading groups 1 and 2. The Mann-Whitney Test was used to evaluate significance of maximum load before failure, number of cycles to failure, stiffness, and damage accumulation at 5% significance level (i.e., $\alpha = 0.05$). Another non-parametric test, Spearman’s Correlation Test, was used to analyze significance of age for $\alpha = 0.05$.

The distribution of age ($p = 0.31$), maximum load before failure ($p = 0.39$), cycles until failure ($p = 1.0$), change in stiffness ($p = 0.589$), and maximum damage accumulation ($p = 0.49$) were not significantly different across cyclic molar loading (Group 1) and cyclic incisor loading (Group 2). Age had weak negative correlation with maximum load before failure ($r = -0.51$), cycles until failure ($r = -0.01$), overall change in stiffness ($r = -0.12$), and maximum damage accumulation ($r = -0.11$). The correlation between age and maximum load before failure of the mandibles in this study is comparable to the reports by Craig, et al.\textsuperscript{20} who studied biomechanical response of the human mandible to impacts of the chin. Age was not found to have significant effect on cycles until failure ($p = 0.48$), overall change in stiffness ($p = 0.76$), and maximum damage accumulation ($p = 0.50$). Sex did not have significant effect on cycles until failure ($p = 0.27$), overall change in stiffness ($p = 0.64$), and maximum damage accumulation ($p = 0.76$) in the mandibles from both loading groups. Correlation between failure location and age, and that between failure location and sex could not be statistically determined due to small sample size and more groups of failure locations.
The mandibles in groups 3 and 4 were subjected to spectrum loading at molars and incisors, respectively. In our knowledge, this is the only study to date which explores mandibular biomechanics under spectrum of cyclic fatigue loads. Our unique molar and incisor spectral loading groups consisted of two specimens each. Statistical analysis was not performed due to small sample size. The experimental results of this novel exploration are reported in Table 3.2.

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Null Hypothesis (H0)</th>
<th>Significance (p-value)</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The distribution of maximum load before failure is the same across categories of groups 1 and 2</td>
<td>0.31</td>
<td>Retain H0</td>
</tr>
<tr>
<td>2</td>
<td>The distribution of cycles until failure is the same across categories of groups 1 and 2</td>
<td>1.0</td>
<td>Retain H0</td>
</tr>
<tr>
<td>3</td>
<td>The distribution of minimum stiffness is the same across categories of groups 1 and 2</td>
<td>0.39</td>
<td>Retain H0</td>
</tr>
<tr>
<td>4</td>
<td>The distribution of maximum stiffness is the same across categories of groups 1 and 2</td>
<td>0.49</td>
<td>Retain H0</td>
</tr>
<tr>
<td>5</td>
<td>The distribution of overall change in stiffness is the same across categories of groups 1 and 2</td>
<td>0.59</td>
<td>Retain H0</td>
</tr>
<tr>
<td>6</td>
<td>The distribution of maximum damage accumulation is the same across categories of groups 1 and 2</td>
<td>0.49</td>
<td>Retain H0</td>
</tr>
<tr>
<td>7</td>
<td>The distribution of maximum load before failure is the same across categories of sex</td>
<td>0.07</td>
<td>Retain H0</td>
</tr>
<tr>
<td>8</td>
<td>The distribution of cycles until failure is the same across categories of sex</td>
<td>0.27</td>
<td>Retain H0</td>
</tr>
<tr>
<td>9</td>
<td>The distribution of minimum stiffness is the same across categories of sex</td>
<td>0.53</td>
<td>Retain H0</td>
</tr>
<tr>
<td>10</td>
<td>The distribution of maximum stiffness is the same across categories of sex</td>
<td>0.76</td>
<td>Retain H0</td>
</tr>
<tr>
<td>11</td>
<td>The distribution of overall change in stiffness is the same across categories of sex</td>
<td>0.64</td>
<td>Retain H0</td>
</tr>
<tr>
<td>12</td>
<td>The distribution of maximum damage accumulation is the same across categories of sex</td>
<td>0.76</td>
<td>Retain H0</td>
</tr>
</tbody>
</table>

Table 3.3. Statistical analyses using non-parametric Mann-Whitney Test for specimens in Groups 1 and 2. For α = 0.05, no significant difference was found within and between Groups 1 and 2 for maximum load before failure, cycles until failure, overall change in stiffness,
maximum damage accumulation. Also, sex was not found to have significant effect on these parameters.

3.4.2 Mandible Fracture

A visible fracture of the mandible was regarded as its failure during the mechanical testing. Figure 3.7 shows pictures of some of the specimens failed with fractures at different locations. As seen from Table 3.2, more of the mandibles from molar loading configuration (Groups 1 and 3) were seen to fail in the mandibular body region. Out of the combined total of eight mandibles in these two groups of molar loading, six failed in mandibular body, and one each failed at mandibular angle and condylar neck/head region. Thus, for molar loading of the cadaveric mandibles in this study, the fracture at mandibular body was a prominent mode of failure. For the incisor loading configuration (Groups 1 and 3) of the mandibles, out of the combined total of eight mandibles in these two groups, each mandible failed in either condylar neck or head region. In addition, three out of eight specimens also failed at the mandibular angle, and one failed at the symphysis and parasymphysis. Thus, for incisor loading of the cadaveric mandibles in this study, the fracture in the mandibular condyle region was a prominent mode of failure. Per the general categorization of the mandibular fractures reported in the literature, higher percentage of fractures occurs in the symphyseal/parasymphyseal region. However, these reported numbers are the generalization of fractures under nearly all of the possible loading scenarios in real world. The loading configurations in our experiment represent only a small subset of the actual functional and para-functional loading of the mandible. Hence, in contrast with the generalized fracture occurrences of the mandible, we observed more prominent fractures at the mandibular
body during molar loading and at the condylar region during the incisor loading of the mandibles in our experimental set-up.

**Figure 3.7.** Failure of the mandibles at different locations. Visuals show fractures at left condyle (Panels A, B, D), mandibular angle (Panels C, D), and molar region of mandibular body (Panel C).
3.4.3 Effect of Dental Status

Table 3.1 summarizes the dental status of each cadaveric mandible harvested for this study. None of the mandibles had all teeth intact. Some of the specimens had no teeth, and others had one or more teeth missing. Based on their dental status, we categorized the mandibles as edentulous (i.e., without any teeth) and mixed denture. Statistical analysis was performed to explore whether the dental status of the cadaveric mandibles had a significant effect on number of cycles until failure, maximum load before failure, stiffness, damage accumulation, and failure location for the mandibles in all loading groups. The t-test statistics demonstrated that, $\alpha = 0.05$, the distribution of cycles until failure, maximum load before failure, stiffness, and damage accumulation in all of the tested mandibles was same across the two categories of the dental status. Fisher’s Exact Test showed that the patient’s sex did not have a significant effect on the dental status of the mandibles. Due to small sample size and large number of failure locations of the mandible, no reliable statistical analysis can be performed to evaluate the effect of dental status on failure location of the mandibles.

3.4.4 Stiffness Reduction

Stiffness is a measure of the resistance of an elastic body to deflection when an external force is applied. Since it is a structural property, stiffness varies both by the specimen tested and applied load. Displacement of the specimen under a specific load measures the stiffness of the specimen. Smaller displacement or deformation at a given load produces higher stiffness values. Figures 3.8, 3.9, 3.10 and 3.11 show the stiffness of the mandibles plotted against number of
cycles for all specimens in loading groups 1, 2, 3, and 4; respectively. Also shown in these visuals are the plots of average stiffness for each loading group plotted against number of cycles, determined until none of the specimens in the given group failed.

As seen from each of the plots, stiffness undergoes a steep initial decline which transitions over the time into a region of nearly constant stiffness. Similar trend of stiffness reduction was observed in mandibles from all loading groups. At the transition of applied axial load from one loading phase to the next (i.e., at the end of 30,000 cycles for groups 1 and 2; after every 3000 cycles for groups 3 and 4), there is a sudden and significant change in the load. This variation in the applied load is reflected in stiffness values as fluctuations of higher magnitude which transition into nearly constant stiffness after few hundred cycles.

Figure 3.8. Axial stiffness reduction during cyclic compressive loading of mandibles in Group 1.
Figure 3. 9. Axial stiffness reduction during cyclic compressive loading of mandibles in Group 2.

Figure 3. 10. Axial stiffness reduction during cyclic compressive loading of mandibles in Group 3.
Figure 3.11. Axial stiffness reduction during cyclic compressive loading of mandibles in Group 4.

3.4.5 Damage Accumulation

Figures 3.12, 3.13, 3.14 and 3.15 show the damage accumulation plotted against number of cycles for loading groups 1, 2, 3 and 4; respectively. The average of damage accumulation in all specimens of each group (derived for the number of cycles during which no specimen failed) is also plotted. Damage accumulation undergoes a steep increase which transitions into a region of saturation with nearly no change in damage. Same trend of damage accumulation was observed among specimens in all loading groups. As seen from these plots, at the transition of the applied load from one loading phase to the next, a sudden and significant change in accumulated damage is observed in all specimens due to fluctuations in axial stiffness values in that region. After a few hundred loading cycles, the damage accumulation transitions into the region of nearly
constant damage. The mandible bone damage observed in both loading configurations in this study follows the trends of Stage I and Stage II bone damage similar to previously reported in the literature.\textsuperscript{41, 144, 145}

\textbf{Figure 3.12.} Damage accumulation in the mandibles from Group-1 during cyclic compressive molar loading.
**Figure 3.13.** Damage accumulation in the mandibles from Group-2 during cyclic compressive incisor loading.
Figure 3.14. Damage accumulation in the mandibles from Group-3 during cyclic compressive molar spectrum loading.

Figure 3.15. Damage accumulation in the mandibles from Group-4 during cyclic compressive incisor spectrum loading.
3.4.5.1 Damage Prediction

Numerical/probabilistic models capable of predicting damage accumulation in the bone based on experimental and/or clinical data can provide valuable information of clinical relevance. Ability to accurately predict bone damage can be of significance in understanding disease mechanism; diagnosing and preventing bone deterioration and fracture; and developing and improving treatment methods, including bone fracture fixation devices. Different models of bone damage assessment are reported in the literature.\textsuperscript{41,144,145} We attempted to develop a predictive damage model for mandibular bone from the experimental data. Linear summation approach has been used by researchers to predict damage accumulation in metals.\textsuperscript{93} However, we could not use this approach for mandibular bone damage prediction due to lack of sufficient information needed for this method. Hence, we used Michaelis-Menten equation for this purpose.

Michaelis–Menten kinetics is a best-known model of enzyme kinetics. This model describes the rate of enzymatic reactions by relating reaction rate to the concentration of substrate as following:

\[ E + S \xrightarrow{K_{cat}} E + P \quad \text{-------- Equation (3.3)} \]

Where,

\begin{align*}
E &= \text{Enzyme} \\
S &= \text{Substrate} \\
ES &= \text{Complex}
\end{align*}
P = Product

\[ V = \frac{d[P]}{dt} = \frac{V_{\text{max}} \cdot [S]}{K_{m} + [S]} \]  \hspace{1cm} \text{Equation (3.4)}

Where,

\[ V = \text{Rate of enzymatic reaction} \]

\[ V_{\text{max}} = \text{Maximum rate achieved by the system at maximum or saturating substrate concentration} \]

\[ K_{m} = \text{Michaelis constant} \]

= Substrate concentration at which \( V = \frac{1}{2} \cdot V_{\text{max}} \)

We modified the Michaelis-Menten equation to predict damage accumulation in cadaveric mandibular bone based on experimental data as following:

\[ D(n) = \frac{D_{\text{max}} \cdot \text{Cycles (n)}}{K_{m} + \text{Cycles (n)}} \]  \hspace{1cm} \text{Equation (3.5)}

Where,

\[ D(n) = \text{Damage at nth cycle} \]
\[ D_{\text{max}} = \text{Maximum damage} \]

\[ K_{m} = \text{Cycles at } D_{\text{max}}/2 \]

We modeled the mandibular bone damage using non-linear regression to the Michaelis-Menten equation. Similar approach was used previously by George-Whitney and Goswami for predicting damage accumulation in femur. They found strong correspondence between experimentally derived damage in femur and the damage predicted by Michaelis-Menten model. Figure 3.16 shows experimentally derived average damage and predicted damage plotted against number of fatigue load cycles for mandibles in loading Group-1. As seen from this figure, the predicted damage has extravagant peaks and valleys in the beginning of first loading phase (BMN) as well as at the time instance when applied load changes from first phase (BMN) to the second (BMO). Apart from the initial excursions and some outliers in the region of saturated damage, the predicted damage closely follows the damage pattern of the experimentally derived damage during first loading phase (BMN). However, at the loading phase transition and during the second loading phase (BMO), the prediction model produced more erroneous damage magnitude as seen in Figure 3.16. Nearly similar trend of damage prediction was seen for mandibles in loading Groups 2, 3, and 4 as shown in Figures 3.17, 3.18, and 3.19, respectively.
Figure 3.16. Damage prediction for Group-1 specimens. Figure shows a plot each for the average of experimentally derived damage and predicted damage plotted against number of loading cycles for all mandibles in the group.
Figure 3.17. Damage prediction for Group-2 specimens. Figure shows a plot each for the average of experimentally derived damage and predicted damage plotted against number of loading cycles for all mandibles in the group.
Figure 3.18. Damage prediction for Group-3 specimens. Figure shows a plot each for the average of experimentally derived damage and predicted damage plotted against number of loading cycles for all mandibles in the group.
Figure 3. 19. Damage prediction for Group-4 specimens. Figure shows a plot each for the average of experimentally derived damage and predicted damage plotted against number of loading cycles for all mandibles in the group.

George-Whitney and Goswami\textsuperscript{41} have modeled the damage accumulation in femur bone using the Michaelis-Menten equation. Strong correspondence was found between the experimental and damage predicted in that study. Their study included only one phase of applied load during mechanical testing. However, the current study where cadaveric mandibles underwent two loading phases each for Group- 1 (BMN-BMO) and Group 2 (BIN-BIO), and 20 loading phases for the spectrum loading configuration of Groups 3 and 4. A more comprehensive
exploration is required to predict damage accumulation in bone more accurately under different loading scenarios.

### 3.5 Discussion

We investigated in-vitro the biomechanical behavior of mandible under four different configurations of cyclic compressive loads applied at molars (Groups 1 and 3) and incisors (Group 2 and 4). The loading conditions utilized in this study are representative of bite forces under functional and parafunctional loading of the mandible. This study intends to provide meaningful information to the clinicians and medical device designers about biomechanical behavior of the mandible under cyclic fatigue loading at the molars and incisors. The data provide insights about stiffness, damage accumulation, failure modes, and correlation between failure load and age of the patient.

The correlation between age and maximum load before failure of the mandibles in this study is comparable to the reports by Craig, et al.\textsuperscript{20} who studied biomechanical response of the human mandible to impacts of the chin. Our study indicates that the older mandibles tend to fail at lower magnitudes of cyclic compressive load when compared with the mandibles of younger patients. Swasty, et al.\textsuperscript{126} reported that the human mandible continued to mature through 40 to 49 years of age, and then the thickness of mandibular cortical bone decreased after this age. This may explain why we saw the negative correlation between the age and maximum load before failure of the mandibles. Age and sex were not found to have significant effect on cycles until failure,
overall change in stiffness, and maximum damage accumulation in the mandibles from both loading groups.

Larger and/or more numerous strains can reduce bone strength below 20% of normal.\textsuperscript{36} This can cause significant decrease in stiffness, and accumulation of microdamage, thereby, leading to stress fracture.\textsuperscript{36} Normally bones detect and repair such microdamage through modeling and remodeling provided the microdamage remains below the intrinsic modeling threshold of the bone.\textsuperscript{36, 66} However, dead bone cannot detect and repair microdamage. Therefore, further exploration is needed to extrapolate findings of this cadaveric study for their application to the real-world clinical scenarios involving living mandible or grafts.

The stiffness of mandibles was derived from test data, and the damage accumulation was determined from the stiffness. In this process, the effect of variations in the cross-section, modulus of elasticity and viscoelastic properties of the mandibular bone was considered negligible for the purpose of calculations. Published test results have shown that such effect is small and can be neglected with sufficient accuracy.\textsuperscript{8} In all loading groups, the stiffness of mandibles underwent a steep initial decline in each of the loading phases followed by a saturation region of nearly constant stiffness (see Figures 3.8 – 3.11).

The damage accumulated in the cadaveric mandibles showed a steep increase during first few hundred loading cycles followed by a region of saturation with nearly no change in the magnitude of damage. The mandible bone damage observed in all loading configurations in this study followed the trends of Stage I and Stage II of the bone damage model similar to the previously reported studies.\textsuperscript{41, 144, 145} Similar to the stage I of the bone damage models reported in the literature,\textsuperscript{46, 55} a significant amount of stiffness reduction occurs during initial loading.
cycles. This stiffness reduction then slows into a nearly constant linear pattern in stage II.

Normal mechanical usage of osteopenic bones is suggested to increase their microdamage and their fragility enough to cause spontaneous fractures and/or bone pain.\textsuperscript{36} The osteoporosis of osteopenic bones is reported to affect women more than men or children.\textsuperscript{36} Since skeletal pathology of subjects in the present study is not known, we cannot make any observations regarding the osteoporosis and mandibular fracture. A comprehensive investigation is required to explore a possible correlation between high prevalence of true osteoporosis in women and the gender paradox of TMD population (which is significantly dominated by female patients).

We considered the visible fracture as failure of the specimen under fatigue loading. In molar loading configuration (Groups 1 and 3), the mandibles failed at either one or more of the following sites: mandibular angle, molar region, condylar neck, condylar head (see Table 1). The molar region of mandibular body was a prominent failure location with four out of six mandibles in Group-1 failing at this site. In incisor loading configuration (Groups 2 and 4), the mandibles failed at either one or more of the following sites: mandibular angle, incisor region, condylar neck, condylar head. The condyles appeared to be the most susceptible failure location since each of the six mandibles in Group-2 failed at either condylar head or condylar neck or both. However, due to small sample size and large number of failure locations, the correlation of the failure location with age, sex, and dental status could not be statistically determined. Though mandible is reported to fracture more frequently in the symphyseal or parasymphyseal region in real-world scenarios, this form of fracture mode occurred in only one specimen (in incisor loading group) in the present study. We observed more fractures at the molar region of the mandibular body during molar loading, and at the condylar region during incisor loading of the
mandibles in our experimental set-up. One possible explanation for this deviation in fracture modes can be that our experimental loading set-up represents only a small subset of the real-world functional and para-functional loading of the mandible.

Our experimental study has some notable limitations. As in case of a typical cadaver study, the sample size of our specimens is small. Also, the subjects included in our study are of older age (between 61 years and 98 years) as we did not have control on the age of acquired cadavers. Another limitation of our study is due to the type of loading used. Our experimental study offers limited insight into the fatigue behavior of mandible as it is restricted to only compressive loading. This study did not incorporate the tensile and shear loading.

In summary, we investigated biomechanical behavior of cadaveric mandibles under four configurations of cyclic compressive loads. Since injury and fracture of the mandible are reported to co-exist with, and potentially contribute to the deterioration/progress of the TMD, we studied stiffness reduction and fatigue damage accumulation in mandibles. Our analysis of stiffness variation showed steep initial decline in each of the loading phases followed by a saturation region of nearly constant stiffness, and the damage accumulation during cyclic compression showed a steep initial increase which transitioned into a region of saturation with nearly no change in damage. Also, the older mandibles showed a tendency to fracture at lower magnitudes of cyclic compressive fatigue load. Within the limitations of this study, it can be concluded that the majority of the damage accumulation in the mandible under cyclic compressive loads at incisors or molars occurs during first few hundred of the fatigue cycles.
4. THREE-DIMENSIONAL ANATOMICAL AND FINITE ELEMENT MODELING AND ANALYSIS OF CADAVERIC MANDIBLES

4.1 Introduction

Biomechanical behavior of the mandible is important in various clinical situations. Several researchers have attempted to explore the biomechanical behavior of mandible and associated components of masticatory system. Analysis of mandibular biomechanics helps us understand the interaction of form and function, and mechanism of associated disorders. It also aids in improving of the design and performance of the prosthetic devices, thus increasing their treatment efficiency.\textsuperscript{64, 77}

Frost\textsuperscript{35} investigated Wolff’s concept of relationship between biomechanics and morphology of bony tissue, and demonstrated the relationship between the amount of strain in bony microenvironment and the biological reaction.\textsuperscript{35, 146} Although it is nearly impossible to standardize the real functional and para-functional behavior of the masticatory system in living persons, the biomechanical properties of human mandible can be determined experimentally using models to simulate normal physiological and non-physiological loads. Indirect methods such as mechanical testing and finite element analysis (FEA) have been widely used for in-vitro assessment of anatomical structures.

Though FEA is a powerful modeling tool useful in predicting mechanical behavior of complex structures, crucial to its application is the knowledge of how well finite element (FE) results replicate reality.\textsuperscript{79, 111} To be confident in the results of FE models of complex biological structures such as bones, experimental validation is required.\textsuperscript{45, 63, 64, 79, 116} Knowledge of the
biomechanical behavior of mandible gained from experimental studies can be used to validate the analytical/numerical models such as FEA. Such validated FE models can be useful in further exploration of the biomechanical aspects of mandible and TMJ necessary to improve the treatment modalities including enhancement of the designs of prosthetic devices by predicting their performance.\textsuperscript{24, 64, 120} For experimental validation of FE bone models, several studies have used strain in the bone measured either with strain gauges\textsuperscript{11, 28, 111, 116, 127, 142, 146} or interferometry.\textsuperscript{45} The results of these studies confirm the reliability and practicality of using strain gauges for validation purpose. Most of the literature, though, deals with the measurement of surface strains on long bones such as femur and tibia to respond to a clinical question. Fewer numerical and experimental studies are available for mandible, especially concerning the correlation of experimental and FE results.\textsuperscript{64, 110, 116} FE modeling and analysis requires precise knowledge of the material parameters as well as the geometry of the mandible under investigation.\textsuperscript{110} Morphological data of the specimen can be obtained by non-invasive means through medical images such as three-dimensional (3D) computed tomography (CT). The CT data can be used to accurately reconstruct anatomical components of interest, and material properties can be defined using Young’s modulus based either on bone density values from the CT data or on data acquired from experiments or literature. Use of this CT-based FEM methodology provides both subject-specific geometric parameters and material properties at the same time.

This chapter describes the experimental evaluation of strains/deformation of human cadaver mandibles under in-vitro loading conditions and numerical evaluation using FEA, based on 3D reconstruction from CT data, performed on the same mandibles paralleling the experimental
setup. Comparison between experimental and numerical data is performed to evaluate validity of the FE models and methodology. The objective is to establish a non-invasive methodology to accurately predict biomechanical behavior of the mandibles under mechanical loading. We investigated in-vitro the biomechanical behavior of mandible under four different configurations of cyclic compressive loading as described in Chapter 3. The strain profiles were examined at five different locations on the cortical surface of mandible under these loading conditions through experimental and analytical (FE) methods. The experimental part of the study is discussed in Chapter 3. Results of experimental and numerical methods were compared to evaluate statistical correlation and agreement between experimental/measured strain data and FE-predicted strains. Following questions were examined:

1. Can a difference be stated in strain magnitudes measured at condylar surface locations (L3, L5) with respect to other locations of strain acquisition (L1, L2, L4) for the experimental strain data of four loading groups?
2. Does ‘Age of Patient’ have a significant effect on magnitude of experimental strain?
3. Does ‘Sex of Patient’ have a significant effect on magnitude of experimental strain?
4. What degree of statistical correlation and statistical agreement do experimental/measured strain data have with analytical (FE) strain for mandibles in all loading groups?
4.2 Materials and Methods

Sixteen fresh-frozen human cadaveric mandibles with no visible bone defects or fixation devices were collected from adult human cadavers, and harvested, cleaned of soft tissue and preserved as discussed in Chapter 3. Prior to mechanical testing, CT scans of all specimens were performed for 3D anatomical reconstruction to be done for creating specimen-specific FE models.

4.2.1 Experimental Strain Measurement

During mechanical testing, uniaxial strain gauges (KFG-1-120-C1-11 L3M3R, Kyowa Electronics, Tokoyo, Japan) were used to measure surface strain. Five strain gauges were attached at exactly defined five locations (L1, L2, L3, L4, L5) on the cortical surface of each mandibular bone after the attachment sites were cleaned and degreased using standard protocol as explained in Chapter 3. The positions of strain gauges were selected based on literature and results of our prior FE simulation of a mandible specimen.\textsuperscript{28,110} Each strain gauge was connected through a quarter-bridge wiring configuration of Wheatstone bridge circuit to the instruNet Data Acquisition System (Omega, Stamford, CT, USA), which was linked to a computer to record the data using instruNet World PLUS (iW+) software (Omega, Stamford, CT, USA). During cyclic loading of each specimen, strain at the gauge attachment sites was measured and recorded throughout the experiment at a sampling rate of 2 Hz. Deformation of the bone surface leads to a corresponding change in length of the attached strain gauge wire which is proportional to its electrical resistance.\textsuperscript{17,28} Change in electrical resistance of the strain gauge, which acts as one
arm of Wheatstone bridge, results in the unbalancing of the bridge circuit. Resultant output voltage of Wheatstone bridge circuit is proportional to the magnitude of deformation of the bone surface to which strain gauge is attached, and the voltage is measured by the instruNet data acquisition system. The parameter used to describe this deformation process is $\mu$strain ($\mu$m/m).

To identify the site of attachment for each strain gauge, images of the specimens were taken with a digital camera from approximately 400 mm before, during, and after mechanical testing. This helped in accurately defining the strain acquisition sites and boundary conditions during FE simulations.

Tests were conducted in axial compression mode. The cyclic load was applied at 2 Hz using an EnduraTEC materials testing machine (ElectroForce Systems Group, Bose Corporation, Eden Prairie, MN, USA) that allowed a controlled application of force simulating bite forces. As discussed in Chapter 3, in each of the four loading groups of mandibles, forces were applied at mandibular angles on both sides of the specimens which were set up upside down in the test machine using custom-designed fixtures. Strain data from all strain gauges attached to one specimen (EH) from loading Group-1 could not be recorded due to an unforeseen problem with the computer system recording strain data. Due to loss of this experimental data, we did not include FE strain data of this specimen in this study as it could not have been validated against measured strains.
4.2.2 Subject-Specific FE Model Creation

Subject-specific 3D anatomical reconstruction of each mandible specimen was performed using commercial software Mimics 14.12 (Materialise, Plymouth, MI, USA) from computed tomography (CT) scans. Independent masks were created each for the cortical bone, cancellous bone and teeth using inbuilt threshold values followed by manual editing and morphological and Boolean operations on the masks (see Figure 4.1). Surface models of cortical bone, cancellous bone and teeth were constructed, and volume bound within each surface was meshed. The volume mesh was generated with ten-node quadratic tetrahedral elements of type C3D10 (see Figure 4.2).
Figure 4. 3D reconstruction of mandible in Mimics software. Mimics enables users to perform segmentation of medical images in three different views – axial, coronal, and sagittal. From CT scan of the mandible, individual masks were created for cortical bone, cancellous bone, and teeth as indicated by yellow, purple, and red color respectively. 3D equivalent of the mandible was reconstructed by combining all masks. After forming 3D volume mesh, material properties were assigned to each component of the mesh based on the masks.
Figure 4.2. Subject-specific anatomical reconstruction of the mandible. Figure shows the right-lateral, axial and coronal intersections of the surface model with triangular elements (panel-A) of a 3D reconstructed mandible. The surface mesh was later converted into a 3D finite element volume mesh (panel-B) with ten-node quadratic tetrahedral elements of type C3D10.

A convergence study was performed comparing maximum principal strain in three mandibular FE models with different element sizes (maximum element lengths: 1.0, 1.5, 2.0 and 2.5 mm). Based on the outcomes of this study, maximum element size of 2 mm was considered optimal. The computational time for the 2 mm element size on a 2.53 GHz processor was 8–10 hours, which was about 3 times faster compared to that for the 1 mm element size, and the results were within 3–6% of those from the 1 mm elements.

Homogeneous, elastic, isotropic material properties were assigned to the specimen-specific FE models using corresponding masks in Mimics. Following material properties,
which are values that lie within the range of published values for human mandibles, were used in this study – Young’s modulus: 14.7 GPa for cortical bone, 0.49 GPa for cancellous bone, 17.6 GPa for teeth; Poisson’s ratio: 0.3 for cortical and cancellous bone, 0.25 for teeth.\textsuperscript{45, 61, 112, 118}

The mandibular 3D volume mesh was then exported to a commercially available FEA software ABAQUS 6.10 (SIMULIA, Providence, RI, USA) to perform FE simulations paralleling our experimental setup and testing.

### 4.2.3 Finite Element Analysis

Boundary and loading conditions were carefully applied to the FE models using ABAQUS software to accurately reproduce the conditions used in mechanical tests of the cadaveric mandibles. To simulate the experimental loading conditions, the nodes at tips of condyles of FE model that coincided with the position of the supports in mechanical test were constrained in all of their translational degrees of freedom and free in all their rotational degree of freedom. Additionally, similar constraints were applied to nodes at the tips of molar region on both sides for models in the molar loading Groups 1 and 3, and to nodes at tips of the central incisor region for the models in the incisor loading Groups 2 and 4 (see Figure 4.3). Vertical compressive forces were applied to nodes in the region of mandibular angle on each ramus which coincided with the position of loading bar in experimental setup.
Figure 4.3. A Mandibular FE model, and illustration of loading and boundary conditions. Panel-A shows schematic of molar loading simulation (Groups 1 and 3), and Panel-B depicts incisor loading configuration (Groups 2 and 4). The arrows point at nodes of the region where vertical compressive forces were applied. The asterisks indicate the regions of constrained nodes at the condylar heads during all loading configurations, molars for Group-1 and Group-3 simulations (Panel-A), and incisors for Group-2 and Group-4 simulations (Panel-B).

The material properties associated to FE model were assumed to be homogeneous, isotropic and with linear elastic behavior in accordance with other studies.\textsuperscript{45, 79, 110, 111, 124} Load data similar to that of mechanical testing were used to perform FE simulations. Linear static FE analysis was performed. The maximum principal strain at the nodes of FE models that matched the position of strain gauges on the surface of mandible was recorded. Three runs/repetitions of FE simulation of each specimen were performed. These repetitions were carried out to account for any user-induced error due to variations such as deviations in accurately selecting the exact nodes for applying load and boundary conditions on the FE model. The FE-predicted strain data reported
in Table 4.1 are average of three simulations performed for each FE model. Figure 4.4 shows the visualization of FE strain profile for one of the specimens.

**Figure 4.4.** Maximum principal strain distribution in one of the mandible FE models. Strains of higher magnitude are seen in the condylar region and the region of load application compared to rest of the model.
4.2.4 Data Analysis

The measured strain data and the FE-predicted maximum principal strain data were reduced to acquire a reading every tenth second for each of the five selected locations on the mandible. The mean and standard deviation were calculated for experimental and FE strain values for each location, and this information was used for statistical analyses. Figures 4.5, 4.6, 4.7 and 4.8 show the measured/experimental strains and FE-predicted maximum principal strains for the mandibles in loading Groups 1, 2, 3 and 4; respectively; plotted against the measurement locations on the surface of the specimen. As seen from these plots, the strains at the condylar locations (L3 and L5) are higher than those measured at other locations on the same mandible. Also, the plots illustrate that the FE-predicted strains closely follow the profiles of experimental strains measured at the corresponding locations on the same mandible surface. Figures 4.9, 4.10, 4.11, 4.12 and 4.13 show the average experimental strain data for strain gauge locations L1, L2, L3, L4 and L5, respectively, plotted for all specimens.

According to Markert,\textsuperscript{83} when comparing measurements of the same parameter (e.g., strain) by two different methods (e.g., mechanical testing and FEA), to analyze the correspondence between the data from two methods more reliably, it is necessary to evaluate the statistical correlation as well as the statistical agreement between the two data sets. During statistical analysis, we used Wilcoxon Signed Ranks Test (to check distribution of strain at condylar locations and other sites), Spearman’s Correlation Test (for effect of age on experimental strain), t-Test (for effect of sex), Pearson’s Correlation Test (for correlation between experimental and FE strain), and Intra-class Correlation Test (for statistical ‘agreement’ between experimental and FE strain).
### 4.3 Results

Table 4.1 summarizes the demographics and observations for mandibles in both loading groups. The experimental strains measured at the condylar locations (L3, L5) were compared with those measured by the strain gauges attached to the mandible surface at other locations (L1, L2, L4). Due to small sample size, Wilcoxon Signed Rank Test was used to evaluate the distribution of experimental strains measured at different locations. The distribution of strains measured at each of the condylar locations (L3, L5) were found to be significantly different from the strains measured at each of other three locations (L1, L2, L4) on the mandible bone surface \((p \geq 0.001 \text{ at } \alpha = 0.001)\) (see Table 4.2). Per Spearman’s Correlation Test, no significant correlation was found between age of patient and experimental strain measured at five locations \((p > 0.05 \text{ for } \alpha = 0.05)\), with an exception of location L3 \((p = 0.042 \text{ for } \alpha = 0.05)\). t-Test statistics showed no significant correlation between sex of patient and experimental strain at measure at five locations \((p > 0.05 \text{ for } \alpha = 0.05)\) (see Table 4.3).
<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Load Type</th>
<th>Patient Code</th>
<th>Sex</th>
<th>Age (yrs)</th>
<th>Maximum Load before Failure (N)</th>
<th>Cycles Until Failure</th>
<th>Failure Location*</th>
<th>Strain Data</th>
<th>Experimental Strain (µm/m)</th>
<th>FE Strain (µm/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group-1 (BMN-BMO)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>L1</td>
<td>L2</td>
</tr>
<tr>
<td>1</td>
<td>EH</td>
<td>F</td>
<td>98</td>
<td>398.9</td>
<td>59074</td>
<td>A</td>
<td>Avg.</td>
<td></td>
<td>-0.3248</td>
<td>-0.4935</td>
</tr>
<tr>
<td>2</td>
<td>MD</td>
<td>F</td>
<td>84</td>
<td>1009.9</td>
<td>60000</td>
<td>B</td>
<td>Avg.</td>
<td></td>
<td>-0.2290</td>
<td>-0.5187</td>
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<tr>
<td>3</td>
<td>HL</td>
<td>M</td>
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<td>60000</td>
<td>B</td>
<td>Avg.</td>
<td></td>
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<td>0.0039</td>
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<tr>
<td>4</td>
<td>PS</td>
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<td>396.1</td>
<td>42700</td>
<td>B</td>
<td>Avg.</td>
<td></td>
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<td>-0.4870</td>
</tr>
<tr>
<td>5</td>
<td>LV</td>
<td>M</td>
<td>61</td>
<td>1429.2</td>
<td>60000</td>
<td>B</td>
<td>Avg.</td>
<td></td>
<td>-0.3393</td>
<td>-0.5123</td>
</tr>
<tr>
<td>6</td>
<td>CE</td>
<td>M</td>
<td>71</td>
<td>399.1</td>
<td>54490</td>
<td>D, E</td>
<td>Avg.</td>
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<td>7</td>
<td>JL</td>
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<td>Avg.</td>
<td></td>
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<tr>
<td>8</td>
<td>HK</td>
<td>M</td>
<td>87</td>
<td>671</td>
<td>60000</td>
<td>A, E</td>
<td>Avg.</td>
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<tr>
<td>9</td>
<td>Group-2 (BIN-BIO)</td>
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<td></td>
<td>-0.3142</td>
<td>-0.6870</td>
</tr>
<tr>
<td>10</td>
<td>AM</td>
<td>F</td>
<td>83</td>
<td>281</td>
<td>30025</td>
<td>C, E</td>
<td>Avg.</td>
<td></td>
<td>-0.0002</td>
<td>0.0002</td>
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<tr>
<td>11</td>
<td>BS</td>
<td>M</td>
<td>91</td>
<td>1001.6</td>
<td>60000</td>
<td>D</td>
<td>Avg.</td>
<td></td>
<td>-0.3029</td>
<td>-0.4937</td>
</tr>
<tr>
<td>12</td>
<td>PO</td>
<td>F</td>
<td>82</td>
<td>299.8</td>
<td>30674</td>
<td>A, D, E</td>
<td>Avg.</td>
<td></td>
<td>-0.3217</td>
<td>-0.4846</td>
</tr>
<tr>
<td>13</td>
<td>FK</td>
<td>M</td>
<td>85</td>
<td>2449.4</td>
<td>60000</td>
<td>B</td>
<td>Avg.</td>
<td></td>
<td>-0.3250</td>
<td>-0.4953</td>
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<tr>
<td>14</td>
<td>VV</td>
<td>F</td>
<td>62</td>
<td>1984.9</td>
<td>60000</td>
<td>B</td>
<td>Avg.</td>
<td></td>
<td>-0.3032</td>
<td>-0.6877</td>
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<tr>
<td>15</td>
<td>Group-4 (Molar Spectrum)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-0.0002</td>
<td>0.0001</td>
</tr>
<tr>
<td>16</td>
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<td>M</td>
<td>90</td>
<td>352.4</td>
<td>16851</td>
<td>A, D</td>
<td>Avg.</td>
<td></td>
<td>-0.5676</td>
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<tr>
<td>17</td>
<td>ES</td>
<td>F</td>
<td>65</td>
<td>312.4</td>
<td>34182</td>
<td>D</td>
<td>Avg.</td>
<td></td>
<td>-0.3743</td>
<td>-0.4931</td>
</tr>
</tbody>
</table>

M: Male, F: Female.
*Failure during cyclic loading or load-to-failure test.
If cycles = 60000, the specimen did not fail during cyclic loading, and later underwent load-to-failure test.

*Failure location: A - mandibular angle, B – mandibular body, C – symphysis and parasympysis, D - condylar neck, E - condylar head.

Avg.: Average; Std. Dev.: Standard Deviation.

Strain gauge nomenclature: L1 – fronto-laterally at left mental protuberance, below alveolar process; L2 – buccally on left mandibular body, caudal to first and second molars, anterior to oblique line; L3 – at the dorsal region of the left condylar process; L4 – buccally on right mandibular body, caudal to first and second molars, anterior to oblique line; L5 – at the dorsal region of the right condylar process.

**Table 4.1.** Patient demographics, load type, and observations about mechanical testing and finite element analysis (FEA) of mandibles subjected to cyclic compressive loading.
Figure 4.5. Plot of experimental/measured strain and FE predicted maximum principal strain (µm/m) (average ± standard deviation) for mandibles in loading Group-1.

Note 1 – Read legend as: XX = experimental strain for the specimen XX, XX FE = FE predicted strain for the specimen XX. E.g., MD = experimental strain for the specimen MD, MD FE = FE predicted strain for the specimen MD.

Note 2 – Data for one specimen (EH) from this group are not included due to loss of information during experimental strain acquisition.
Figure 4.6. Plot of experimental/measured strain and FE predicted maximum principal strain (μm/m) (average ± standard deviation) for mandibles in loading Group-2.

Note – Read legend as: XX = experimental strain for the specimen XX, XX FE = FE predicted strain for the specimen XX. E.g., JL = experimental strain for the specimen JL, JL FE = FE predicted strain for the specimen JL.
Figure 4.7. Plot of experimental/measured strain and FE predicted maximum principal strain (µm/m) (average ± standard deviation) for mandibles in loading Group-3.

Note – Read legend as: XX = experimental strain for the specimen XX, XX FE = FE predicted strain for the specimen XX. E.g., FK = experimental strain for the specimen FK, FK FE = FE predicted strain for the specimen FK.
Figure 4.8. Plot of experimental/measured strain and FE predicted maximum principal strain (μm/m) (average ± standard deviation) for mandibles in loading Group-4.

Note – Read legend as: XX = experimental strain for the specimen XX, XX FE = FE predicted strain for the specimen XX. E.g., OM = experimental strain for the specimen OM, OM FE = FE predicted strain for the specimen OM.
Figure 4.9. Plot of experimental strain (µm/m) (average ± standard deviation) measured with strain gauge at location L1 on mandibles in all loading groups.
Figure 4.10. Plot of experimental strain (µm/m) (average ± standard deviation) measured with strain gauge at location L2 on mandibles in all loading groups.
Figure 4.11. Plot of experimental strain (µm/m) (average ± standard deviation) measured with strain gauge at location L3 on mandibles in all loading groups.
Figure 4.12. Plot of experimental strain (μm/m) (average ± standard deviation) measured with strain gauge at location L4 on mandibles in all loading groups.
Figure 4.13. Plot of experimental strain (µm/m) (average ± standard deviation) measured with strain gauge at location L5 on mandibles in all loading groups.
<table>
<thead>
<tr>
<th>Location of strain measurement</th>
<th>Wilcoxon Signed Ranks Test Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condylar</td>
<td>Non-condylar</td>
</tr>
<tr>
<td>L3</td>
<td>L1</td>
</tr>
<tr>
<td></td>
<td>L2</td>
</tr>
<tr>
<td></td>
<td>L4</td>
</tr>
<tr>
<td>L5</td>
<td>L1</td>
</tr>
<tr>
<td></td>
<td>L2</td>
</tr>
<tr>
<td></td>
<td>L4</td>
</tr>
</tbody>
</table>

<sup>b</sup>. Based on negative ranks
<sup>c</sup>. Based on positive ranks
<sup>˅</sup>. Significance at p ≥ 0.001

**Table 4.2.** Statistical analyses using Wilcoxon Signed Ranks Test (to analyze distribution of strain at condylar locations and other sites of strain measurement). For $\alpha = 0.001$, strains measured at the condylar locations (L3, L5) are significantly different from those measured at other locations (L1, L2, L4) on the surface of the mandible bone.
<table>
<thead>
<tr>
<th>Location of strain measurement</th>
<th>Correspondence between 'age' and 'experimental strain'</th>
<th>Correspondence between 'sex' and 'experimental strain'</th>
<th>Statistical correlation between 'experimental strain' and 'FE strain'</th>
<th>Statistical agreement between 'experimental strain' and 'FE strain'</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Spearman's Rho - Significance (2-tailed)§</td>
<td>t-test Significance (2-tailed)±</td>
<td>Pearson Correlation</td>
<td>95% CI</td>
</tr>
<tr>
<td>L1</td>
<td>0.815</td>
<td>0.494</td>
<td>0.984</td>
<td>0.951 to 0.995</td>
</tr>
<tr>
<td>L2</td>
<td>0.22</td>
<td>0.24</td>
<td>0.964</td>
<td>0.892 to 0.988</td>
</tr>
<tr>
<td>L3</td>
<td>0.042</td>
<td>0.298</td>
<td>0.999</td>
<td>0.997 to 1.00</td>
</tr>
<tr>
<td>L4</td>
<td>0.064</td>
<td>0.867</td>
<td>0.569</td>
<td>0.08 to 0.837</td>
</tr>
<tr>
<td>L5</td>
<td>0.795</td>
<td>0.47</td>
<td>0.997</td>
<td>0.991 to 0.999</td>
</tr>
</tbody>
</table>

§ Correlation is significant at the 0.05 level (2-tailed)
± Correlation is significant at the 0.05 level (2-tailed)

**Table 4.3.** Statistical analyses using Spearman’s Correlation Test (to analyze effect of age on experimental strain), t-test (to evaluate effect of sex on experimental strain), Pearson’s Correlation Test (to evaluate statistical correlation between experimental strain and FE strain, and Intra-class Correlation Test (to analyze ‘statistical agreement’ between experimental strain and FE strain). For $\alpha = 0.05$, sex does not have significant effect on the experimental strains at any of the five locations, and no significant correlation is found between age of patient and experimental strain (with an exception of location L3). Strong correlation is found between the measured and FE strain data for locations L1, L2, L3 and L5 ($0.964 < R^2 < 0.999$) with narrow confidence interval. The strain measurement location L4 shows a moderate correlation ($R^2 = 0.569$) between the experimental and FEA results with a wider confidence interval (0.08 to 0.837). Strong statistical agreement is seen between the experimental and FE strain data for locations L1, L2, L3 and L5 ($0.936 < $Intraclass Correlation Coefficient$ < 0.999$) with narrow confidence intervals. A moderate statistical agreement ($Intraclass Correlation Coefficient = 0.659$) with wider confidence interval ($CI = -0.17$ to 0.885) is found for location L4.
Pearson’s Correlation Test was used to analyze the concordance between experimental and FEA strain. Strong correlation was found between the measured and FE strain data for locations L1, L2, L3 and L5 ($0.964 < R^2 < 0.999$) with narrow confidence interval (see Table 4.3). Location L4 showed a moderate correlation ($R^2 = 0.569$) between the experimental and FEA results with a wider confidence interval (0.08 to 0.837). We used the ‘Intraclass Correlation Test’ to analyze statistical agreement between experimental and FEA strain. Strong agreement was found between the experimental and FE strain data for locations L1, L2, L3 and L5 ($0.936 < \text{Intraclass Correlation Coefficient} < 0.999$) with narrow confidence interval (see Table 4.3). However, a moderate statistical agreement ($\text{Intraclass Correlation Coefficient} = 0.659$) with wide confidence interval (CI = -0.17 to 0.885) was found between the experimental and FE strain values for location L4. Overall, FE and mean experimental strains showed close correspondence for all load configurations and measurement locations. Apart from some local deviations at location L4, FE and mean measured strain corresponded well for all load cases and for all strain gauges.

4.4 Discussion

Indirect techniques such as in-vitro mechanical testing of cadaveric specimens, and FE modeling and analysis offer practical alternative to the direct methods of investigating biomechanical behavior of the mandible and associated structures. FE modeling has been used widely in biomechanical studies due to its ability to simulate the geometry, forces, strains, stresses and mechanical behavior of complex anatomical components and implants during
simulated function. It is important to note that the experimental strains recorded in our study are from in-vitro rather than in-vivo loading of cadaveric specimens. The key advantage of in-vitro loading is that, although it does not replicate behavioral loads, the experimental loading and constraints can be easily characterized, controlled, and further reproduced during FEA. The patient-specific computerized anatomical and FE models can be used to estimate non-measurable loads, strains and stresses to understand the underlying mechanism of the diseases. However, experimental or clinical validation of theoretical predictions of FEA should be performed to be confident in the numerical results.

Strain distribution in mandible is extremely complex in nature, and its knowledge has an important impact in different clinical situations. From a biological view, strains determine the functional behavior of bone cells to a great extent. Knowledge of strain may permit assessment of the regenerative capacity of bone, and stress evaluation in different anatomical positions can be used to investigate potential fracture sites under artificial loading. The combined assessment of strains and stresses can be helpful in improving the designs of fracture fixation and joint replacement devices for mandible and TMJ. Our study suggests that the validated FE models and analyses provide a reliable approach to evaluate in-vitro biomechanical behavior of the mandible.

Most studies found in literature concerning experimental validation of FE models of bone report comparison of measured and analytical data in terms of statistical correlation. However, as suggested by Markert, to be statistically more confident in the correspondence of experimental data and FE predictions, we evaluated statistical correlation and statistical agreement between strain data obtained from the two methods. In our study, FE results in terms
of strain magnitude accorded well with experimental data. Moderate to strong statistical correlation and agreement between the experimental and FE predicted strain data was achieved in this study establishing confidence in the validity of the computed results.

Although our methodology somewhat differs from other published studies, our results are comparable to studies by Gröning, et al.\textsuperscript{45} who compared strain profiles in cadaveric mandible using digital speckle pattern interferometry and FEA; Ramos, et al.\textsuperscript{110} who demonstrated that FE models of the mandible can correctly reproduce experimental strains under different loading configurations; and Vollmer, et al.\textsuperscript{146} who confirmed that the experimental validation of FEA can provide precise insight into the complex mechanical behavior of mandibles affected by mechanical loading which is difficult to assess otherwise. Ichim, et al.\textsuperscript{61} obtained the equivalent strains, Ramos, et al.\textsuperscript{110} assessed maximal and minimal strains, and we evaluated the maximal principal strain through FEA. Even then, the behavior of the strains reported in these studies is qualitatively in conformance with the one obtained in our study. The magnitudes of strain differ due to use of muscle forces as opposed to forces applied at the mandibular angle in our loading cases. In our study, significantly different strain magnitudes were generated at the condylar locations (L3, L5) compared to other locations on the mandible. These findings coincide with the results of experimental and numerical investigations described by Hylander\textsuperscript{59}; Hart, et al.\textsuperscript{49}; and Vollmer, et al.\textsuperscript{146} who reported significant changes in stress distribution and magnitude near condyles.

We used fresh-frozen cadaveric mandibles for our experiments whereas some other studies employed either dry cadaveric mandibles\textsuperscript{45} or synthetic mandibles.\textsuperscript{110} We performed relatively more accurate 3D anatomical reconstruction and more refined FE mesh compared to some
models in studies by Vollmer, et al.\textsuperscript{146} and Gröning, et al.\textsuperscript{45} These aspects of our study methodology provide closer approximation to the actual size, shape and biological behavior of the living human mandible. Overall, when the experimental and FEA strain results are compared, a very good statistical correlation and statistical agreement is found. This high degree of correspondence is notable, since homogeneous and isotropic elastic properties were assumed in FE models of the mandibles, although the elastic properties of fresh and dry human mandibles are reported to be heterogeneous and orthotropic.\textsuperscript{45,118} Similar to other reports in literature,\textsuperscript{45,79,111,124} results of our study indicate that homogeneous and isotropic elastic properties are sufficient, at least in our experimental setup, to accurately predict the strain magnitudes.

Different approaches have been used by researchers to assign the material properties to FE models of the bone reconstructed from patient’s medical images. As previously discussed in Chapter 2, Varghese, et al.\textsuperscript{142} adopted consistent bone-material properties based on a parameter optimization study. They held constant the Young’s modulus value of the cortex volume between periosteal and endocortical boundaries, and used an inhomogeneous isotropic material model for the trabecular volume of the FE models of long bones. An optimized Poisson’s ratio was adopted for both cortical and trabecular bone. A mask representing the endosteal region of the bone model was eroded twice to obtain material information without influence of partial-volume effect for the trabecular region near the endosteal boundary. The authors dilated the grayscale twice to re-grow the volume to original size, which replicated the grayscale values of the eroded periphery to the re-grown region as previously described by Wu, et al.\textsuperscript{154} The resultant volume contained partial-volume corrected density values along the endosteal boundary. The density values were assigned using a method previously published by Hangartner.\textsuperscript{47} Gröning, et al.\textsuperscript{45}
reconstructed the mandibular anatomy from CT data of a human mandible, and created a FE volume mesh. They assigned a same set of material properties to the entire bone and teeth components of the FE mesh by defining Young’s modulus and Poisson’s ratio. We performed anatomical reconstruction of the cadaveric mandibles from their CT scans as described in Chapter 4. FE volume mesh was generated for each of the mandibular model. Material properties to cortical component, cancellous component, and teeth of each mandibular FE mesh from their respective masks in Mimics using the in-built ‘mask method’ of the software as described in Chapter 4. By using the material assignment from mask, one can use the segmentation in created for anatomical reconstruction to assign materials to mesh elements. For each used mask, one material is created. For each element one of the materials is assigned based on the volume of intersection of that element with each mask. If an element has the same intersection volume with several masks, the first mask in the list is used for assigning a material to that element. Though the present study used different approach than Varghese, et al.\textsuperscript{142} and Gröning, et al.\textsuperscript{45} to assign material properties to the FE models, the close correspondence between FE results and experimental data in all these studies call for a study exploring the comparative accuracy and efficiency of these approaches using same set of FE models.

A prominent limitation of our study is the inability to experimentally measure strains at locations within the specimen because strain gauges can measure only the surface strain. Hence, our biomechanical assessment of the mandible has been limited to surface deformations, and neither stresses nor dislocations in the specimen can be measured. However, the accuracy of FEA describing the biomechanical behavior of bony specimens has been shown by different authors.\textsuperscript{49, 77, 111, 127, 142, 146} Given the high degree of congruence between the experimental and
numerical results of this study, various data within the specimen can be visualized using the FE calculations.\textsuperscript{18}

The magnitudes of measured strain show that the locations of strain gauges selected in this study were not at the regions where specimen fractures occurred. Although a better estimation of gauge locations can be obtained through FE simulations prior to design of experiments, the topography of mandibular surfaces often presents hurdles in attaching a strain gauge at every/any location of choice. This leaves us with limited choices of locations for experimental measurement of strain. However, a validated FE method provides an alternate solution to this limitation.

More detailed FE models incorporating and varying cortical, cancellous, and cartilage material properties, and different element types would allow further exploration of the correlation between experimental and numerical methods. Our future studies will use this validated FE methodology to evaluate otherwise difficult to assess parameters such as stress and strain in different components of the mandible and TMJ under different functional and para-functional loading configurations.\textsuperscript{63} This promises to aid in developing and improving the methods to prevent, diagnose, and treat TMD. Also, design of the durable and efficient prostheses for mandible and TMJ is challenging due to complex geometry and function of associated anatomical components. Our future work will extend the discussed methodology of subject-specific anatomical modeling and FEA to design and analyze patient-specific implants for mandible and TMJ. In summary, our combined numerical-experimental study demonstrated that mandibular FE models accurately replicating the geometry, material properties, and constraints can predict strain profiles in strong correspondence with the experimental results.
Such validated FE models which adequately reproduce mechanical behavior of mandible can be used further to study the TMJ, and to design and pre-clinically evaluate implants for mandible and TMJ.
5. DESIGN AND FINITE ELEMENT ANALYSIS OF PATIENT-SPECIFIC TOTAL TEMPOROMANDIBULAR JOINT IMPLANTS

In this chapter we discuss our approach to developing novel patient-specific total TMJ prostheses. Our unique patient-fitted designs based on medical images of the patient’s TMJ offer accurate anatomical fit, and better fixation to host bone. Special features of the prostheses have potential to offer improved osseo-integration and durability of the devices. The design process is based on surgeon’s requirements, feedback, and pre-surgical planning to ensure anatomically accurate and clinically viable device design. We use the validated methodology of FE modeling and analysis to evaluate the device design by investigating stress and strain profiles under functional/normal and para-functional/worst-case TMJ loading scenarios.

5.1. Introduction

In treating the TMJ dysfunction, all nonsurgical approaches should be exhausted. In some select patients, the end-stage TMJ pathology resulting in distortion of anatomical architectural form and physiological dysfunction dictates the need for total joint replacement (TJR). The goal of TMJ TJR is the restoration of mandibular function and form; any pain relief attained is considered of secondary benefit. The TMD patients with serious osteoarthritis, rheumatoid arthritis, psoriatic arthritis, and ankylosis might be good candidates for receiving TMJ prosthesis.

TMJ resections have been carried out for about 150 years. Before 1945, the technique of alloplastic reconstruction of TMJ was mainly limited to replacement of condyle.
Interposition of alloplastic implants, resection dressings and prostheses were the dominant techniques. Sterilization, biocompatibility and fixation of the alloplastic implants were main concerns in early days. No evidence-based data on outcomes are available from that time. By 1945 reconstruction of the TMJ involved the close cooperation of surgeons and dentists. In view of the rare application of TMJ prostheses, their relatively wide variety described over past six decades emphasizes that alloplastic TMJ reconstruction is still evolving.

TMJ implants can be differentiated into fossa-eminence prostheses, ramus prostheses and condylar reconstruction plates, and total joint prostheses. Although singular replacement of the fossa or condyle is preferred as a temporary solution, the partial TMJ reconstruction finds comparatively declining usage by surgeons for clinical reasons. Total TMJ implants are recommended when the glenoid fossa is exposed due to excessive stress in conditions such as degenerative disorders, arthritis ankylosis, and multiply operated pain patients. Table 5.1 lists indications for alloplastic reconstruction of the TMJ.
<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Indications for alloplastic TMJ reconstruction</th>
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<tbody>
<tr>
<td>1.</td>
<td>Ankylosis or reankylosis, degeneration, or resorption of joints with severe anatomic abnormalities.</td>
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<tr>
<td>2.</td>
<td>Failed autogenous grafts in multiply operated patients.</td>
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<tr>
<td>3.</td>
<td>Destruction of autogenous graft tissue by pathology.</td>
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<tr>
<td>4.</td>
<td>Failed Proplast-Teflon that results in severe anatomic joint mutilation.</td>
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<tr>
<td>5.</td>
<td>Failed Vitek-Kent total or partial joint reconstruction.</td>
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<tr>
<td>6.</td>
<td>Severe inflammatory joint disease, such as rheumatoid arthritis which results in anatomic mutilation of the joint components and functional disability.</td>
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**Table 5.1.** Indications for the alloplastic reconstruction of the temporomandibular joint (TMJ).

Relative contraindications to the use of alloplasts in reconstruction of the TMJ are age of the patient, mental status of the patient, uncontrolled systemic disease such as diabetes mellitus or myelodysplasia, active or chronic infection at the implantation site, and allergy to materials that are used in the devices to be implanted. The perceived potential disadvantages of the alloplastic TMJ TJR are cost of the device, need for two-stage procedure in ankylosis cases, material wear debris with associated pathologic responses, failure of the prostheses secondary to loosening of the screw fixation or fracture from metal fatigue, lack of long-term stability, inability of alloplastic implant to follow physical growth of the younger patients, and unpredictable need for revision surgery. Long-term studies...
comparing functional and aesthetic results of various TMJ prostheses are not available (with an exception of one study by Mercuri, et al.\textsuperscript{84} with up to 14-year follow-up), which leaves the choice of prosthesis to surgeon’s personal experience.

We performed a comprehensive review\textsuperscript{64} of published literature regarding TMJ reconstruction, and based our TMJ prostheses design approach on the knowledge gained from clinical, biomechanical and scientific reports about the history, designs, efficacy, and clinical outcomes of TMJ prostheses. There are two categories of the TMJ TJR devices approved for implantation by the United States Food and Drug Administration (FDA) – the stock or off-the-shelf devices, and the custom or patient-fitted devices. At the time of implantation, the surgeon has to ‘make fit’ the stock (off-the-shelf) device. In contrast, the custom (patient-fitted) devices are ‘made to fit’ each specific case. To date, there is only one study, by Wolford, et al.\textsuperscript{150}, reported in the literature that compares a stock and a custom TMJ TJR system. This study concluded that patients implanted with the custom TMJ TJR system had statistically significant better outcomes in both subjective and objective domains than did those implanted with the stock system devices studied.\textsuperscript{150}

The history of alloplastic TMJ reconstruction has, unfortunately, been characterized by multiple highly publicized failures based on inappropriate design, lack of attention to biomechanical principles, and ignorance of what already had been documented in the orthopedic literature.\textsuperscript{64, 107, 108, 141} In addition, because TMJ is the only ginglymoarthrodial joint in human body, and because its function is intimately related to occlusal harmony, a prosthetic TMJ necessitates characteristics not considered in orthopedic implant design.\textsuperscript{108} The use of inappropriate materials and designs has resulted in success rate of many TMJ implants being
lower than those for total hip and knee prostheses.\textsuperscript{141} Most of the published literature regarding TMJ implants has been clinical and case reports, with much less studies investigating the design and biomechanics of the TMJ implants. In view of paucity of this information, and need for more efficient and durable total TMJ implants, we undertook a study aimed at designing and evaluating customized total TMJ prostheses.

### 5.1.1 Design Requirements for Total TMJ Prosthesis

van Loon, et al.\textsuperscript{140} indicated that there are three major requirements in TMJ TJR – (i) to imitate the functional movement, (ii) to realize a close fit to the skull, and (iii) to achieve a long lifetime. Table 5.2 lists summary of requirements for successful total reconstruction of the TMJ. Stability of alloplastic joint replacements depends not only on fixation, but also on adaptation of the implant to the bone to which it is to be fixed.\textsuperscript{84, 86, 87} The orthopedic experience with implantation of alloplastic joints has shown that better adaptation of the device to the host bone results in more stability and functional longevity of the implant.\textsuperscript{86, 87, 105, 125} Stability of TMJ prosthesis at the time of implantation is equally important for its success. Motion of the implanted prosthesis under a load can cause the surrounding bone to degenerate, leading to further device loosening and consequent failure.\textsuperscript{86} Currently, screw fixation of TMJ implants is the most predictable and stable form of stabilization developed.\textsuperscript{86} Screws may loosen with time and function, requiring replacement. To assure long-term success of the TMJ implants, primary stability of prosthetic components must be ensured by biointegration of the screws.\textsuperscript{87}
<table>
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<tr>
<th>Sr. No.</th>
<th>Requirements/criteria for success of alloplastic total joint replacement devices</th>
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<tr>
<td>1.</td>
<td>The materials from which the devices are made must be biocompatible.(^{86, 87, 105, 140})</td>
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<tr>
<td>2.</td>
<td>The devices must be designed with sufficient mechanical strength to withstand the loads delivered over the full range of function of the joint.(^{86, 87, 105, 140})</td>
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<tr>
<td>3.</td>
<td>The devices must be stable in-situ.(^{86, 87, 105, 140})</td>
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<tr>
<td>4.</td>
<td>The surgery to implant the prosthesis must be performed for the proper indications, and it must be performed aseptically.(^{86, 87, 105})</td>
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<td>5.</td>
<td>The prostheses should imitate the condylar translation during mouth opening, and without restricting movements of non-replaced TMJ.(^{140})</td>
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<tr>
<td>6.</td>
<td>The prostheses should be fitted correctly to the mandible and the skull.(^{140})</td>
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<tr>
<td>7.</td>
<td>Expected lifetime of more than 20 years.(^{140})</td>
</tr>
<tr>
<td>8.</td>
<td>Low wear rate; and wear particles must be tolerated by the body.(^{140})</td>
</tr>
<tr>
<td>9.</td>
<td>Simple and reliable implantation procedures.(^{140})</td>
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**Table 5.2.** Criteria for the successful alloplastic total reconstruction of the TMJ.

Most patients requiring TMJ replacement have deformed local bony anatomy. During implantation of the stock TMJ prosthesis, the surgeon confronts with a difficult challenge of making ‘off-the-shelf’ components fit and remain stable, and often the precious host bone needs to be sacrificed to make the stock TMJ components to create stable component-to-host-bone contact.\(^{87}\) Surgeon’s attempt to make stock devices fit by bending or shimming may lead to component or shim material fatigue and/or overload fostering early failure under repeated cyclic
functional loading. Potential micromotion of any altered or shimmed component adversely affects the screw fixation biointegration. Micromotion leads to the formation of a fibrous connective tissue interface between the altered component and the host bone, and can cause early loosening of the screws leading to device failure. Our patient-specific TMJ implants are designed to accurately fit each patient’s specific anatomical condition. They conform to any unique or complex anatomical host bone condition. These designs do not require any alteration or shimming of either the device or the host bone to achieve initial fixation and stability. The screws secure implant components intimately to the host bone mitigating possibility of micromotion and maximizing the opportunity for biointegration.

5.2 Materials and Methods

In this section, we discuss the methodology of designing condylar and fossa components of the custom-designed total TMJ prostheses. Also discussed are unique design features such as accurate fit of the prosthetic surface to the host bone in contact, perforated notches of implant which protrude and fit into the custom-cut slots in native bone, customized surgical guides, and screws with locking mechanism.

5.2.1 Design of Patient-specific Total TMJ Prosthesis

The schematic in Figure 5.1 outlines our approach to developing a novel patient-specific total TMJ implant system. Our unique patient-fitted designs based on computed tomography (CT)
images of the patient’s TMJ and associated anatomic structures offer accurate anatomical fit and better fixation to the host bone. The novel/unique features of the prostheses promise an improved osseo-integration and durability. Our design process is based on surgeon’s requirements, feedback, and pre-surgical planning to ensure anatomically accurate and clinically viable device design. Pre-planning of the surgery is an integral part of the proposed design and development methodology, and is intended to reduce intra-operative adjustments of the device components, complexity of the already challenging operating procedure, and the overall time spent in the operating room.

Subject-specific 3D anatomical reconstruction of the patient’s mandible and skull/fossa/articular eminence is performed using commercial software Mimics v14.12 (Materialise, Plymouth, MI, USA) from computed tomography (CT) scans (see Figure 5.2). Upon importing the patient’s CT images in Mimics, anatomical model comprising of the patient’s mandible and fossa eminence is developed from the CT scan by performing a series of operations such as image processing, segmentation, region growing, mask formation for the anatomic region of interest (i.e., bone and teeth), and calculation of 3D equivalent similar to the 3D reconstruction method described in Chapter 4. The prostheses and accessories are designed using commercial software packages 3-matic v6.0 (Materialise, Plymouth, MI, USA) and SolidWorks v2010 (SIMULIA, Providence, RI, USA) as discussed in following sections of this chapter.
Figure 5.1. Methodology followed for design and preliminary analysis of the patient-specific total temporomandibular joint (TMJ) prostheses.
5.2.1.1 Surgical Pre-planning and Surgeon Input

Close collaboration between device designer and surgeon (treating the given TMJ patient) is an important aspect of the proposed design and development approach. Mutual sharing of knowledge and expertise, clinical and design requirements and constraints is vital in ensuring the optimal design and performance of TMJ devices. We utilize the computerized anatomical model and its 3D printed equivalent to acquire surgeon’s design requirements such as location of the facial nerve (to keep it from any damage or injury during surgery), location of the condylar osteotomy (i.e., removal of the degenerated or damaged condylar bone), outline of shape for the planned condylar and fossa prostheses, location of screws to secure the condylar and fossa components to host bone, number and dimension of screws, etc.

To help the surgeon accurately remove the damaged part of condylar neck/head, a surgical guide is custom designed for each reconstruction case as shown in Figure 5.3. During surgery, after putting the patient in intermaxillary fixation (IMF) and gaining access to TMJ capsule, the...
surgical guide can be fixated to mandible using screws located superior and inferior to the line of osteotomy/condylectomy. In other words, the surgical guide is secured using screws at the condylar head and condylar neck/ramus depending on osteotomy location and surgeon’s preference. After completing the osteotomy, surgical guide is detached from the bone by removing the screws. The location of condylectomy guide screw hole inferior to the anterio-posterior excision line can be selected (and custom designed) such that the same screw hole can also be used later by one of the screws used to secure condylar/ramus implant to the host mandible.

**Figure 5.3.** Custom-designed surgical guide for condylectomy (i.e., removal of damaged part of the condylar bone). Panel-A and B show the medial and lateral view, respectively, of surgical guide placed at the location on mandible where osteotomy is to be performed. Panels C and D show medial and lateral-anterior view, respectively, of the surgical guide alone. The visuals
demonstrate that custom-design of the device enables it to accurately adapt to the native bone. This methodology allows the designer to control size and shape of the device, and location of its fixation screws as prescribed by the surgeon.

Our design approach and pre-surgical planning enables appropriate design of screws and pre-drilled screw holes in implants to avoid unintentional injury to facial nerve, soft tissue, and other delicate structures in the vicinity of the complex surgical site. Following the similar design approach used for osteotomy guide, the screw-drill-guide is custom designed each for the condylar/ramus component and the fossa-eminence part of the TMJ prostheses. These drill guides are intended to create a hole of preferred dimension (diameter and depth) at the accurate location and orientation for each screw as prescribed by the surgeon. For a given screw, a drill of smaller diameter than that of the particular screw is selected so ensure less bone damage, optimal purchase, and rigid interface between the screw and host bone during and after implantation.

Based on surgeon’s initial design requirements, the prostheses, drill guides, osteotomy guide, and templates are designed. In response to surgeon’s feedback about the initial designs, suggested changes are incorporated to improve the device design. This feedback loop is kept open, and the designs are fine-tuned, till the surgeon approves the designs. In-vitro biomechanical assessment of patient’s host bone and TMJ prostheses is incorporated in the design validation and improvement loop as described later in this chapter. After sufficiently improving the designs, the prostheses graduate to the next stage where finished implants and accessories are ready for prototyping and pre-surgical simulation of the operating procedure.
using anatomical models and finished prototypes. In real-world scenario, before applying our methodology to actual clinical application, it has to be verified and validated through cadaver studies.

5.2.1.2 Design of Condylar Prosthesis

Anatomically accurate fit of TMJ prosthesis to the host bone is essential for stable fixation leading to efficacy and longevity of the device. Our custom-designed condylar components follow the anatomical geometry and contours on the lateral surface of ramus and condylar part of host anatomy to which the prosthesis is to be fixated. Custom shape of the prosthesis maximizes the possibility of precise fit and secure fixation. Different shapes of the condylar and ramal parts can be designed per surgeon’s recommendations to conform to the patient’s unique/complex anatomical situation. Figures 5.4 to 5.12 show various such shapes of the condylar component of our TMJ prostheses. Since these components are custom designed to meet the unique requirements of each individual patient’s situation, the characteristic length, width, and thickness of condylar component; the number and locations of screws; and dimensions of condylar neck and head vary from patient to patient. The minimal level of the condylar thickness, width, head diameter, and number and location of screws are maintained (based on orthopaedic experience listed in the literature, surgeon’s prescription, and pre-clinical biomechanical evaluation of the device designs) to ensure that the device provides sufficient mechanical strength and stability during functional and para-functional loading after implantation.
Figure 5.4. Shape outline of a custom-designed condylar/ramus prosthesis. Panels A and B show medial-anterior view and lateral-anterior view, respectively, of the prosthesis accurately adapting to the host bone. Panel-C shows medial-inferior view of the prosthesis shape outline.

Figure 5.5. Shape outline of a custom-designed condylar/ramus prosthesis for the replacement of right TMJ of a patient. Panels A and B show lateral-anterior view and lateral-posterior view, respectively, of the prosthesis accurately conforming to geometric shape of patient’s mandible.
Figure 5. 6. Shape outline of a custom-designed condylar/ramus/mandibular component of the TMJ prosthesis for reconstruction of left TMJ. Panels A and B show medial-anterior view and lateral-anterior view, respectively, of the prosthesis along with 3D anatomical model of the patient’s mandible after condylectomy. The osteotomy gap seen in the left mandibular body is due to removal of a tumor in that region. This osteotomy gap can be filled with a graft, and the mandibular component of this TMJ prosthesis is designed to provide mechanical support to the host bone and graft.
Figure 5. 7. Custom-designed condylar/ramus component of the TMJ total joint replacement prosthesis for left TMJ of a patient. Panel-A shows lateral view of the implant with screw holes. Panel-B shows an enlarged view of the screw holes, where the first superiorly located screw hole has threads to incorporate locking-plate-screw mechanism by engaging the threads on the head of a locking screw described in the text. Panel-C shows engineering dimensions of this patient-specific implant.
Figure 5.8. Shape outline of a custom-designed condylar/ramus component of the TMJ total joint replacement prosthesis for left TMJ of a patient. Panel-A shows anterior-lateral view of the implant with host bone after condylectomy. The posterior-medial view in Panel-B shows that the medial surface of prosthesis is shaped to accurately follow geometric contours of the lateral surface of mandibular host bone for optimal geometrical match between the implant and host bone. Panel-C shows lateral view of the prosthesis with screw holes. Dimensions of various parts of this patient-specific implant are shown in Panel-D.
Figure 5.9. Shape outline of a custom-designed condylar/ramus component of the TMJ total joint replacement prosthesis for left TMJ of a patient. Visuals in Panels A through E demonstrate that shape of medial surface of the prosthesis accurately follows the geometric contours of the lateral surface of the mandibular host bone, and maximizes the opportunity for optimal adaptation of implant to the host bone. The lateral surface of the implant is flat, condylar head is spherical, and the condylar neck has a curvature to avoid problems seen in most right-angled designs of orthopaedic implants.

An important advantage of our patient-specific design approach is that the components can be precisely designed to withstand the loads encountered by unique anatomic condition. For the custom-designed condylar/ramus component, the center of rotation of its head can be moved vertically to correct the open bite deformity. The prosthetic condylar head can be placed such that its center of location is located inferior to that of the natural condyle it replaced, thereby allowing low-wear articulation of the reconstructed total TMJ and natural movements of the non-replaced contra-lateral TMJ. Ramal component can be shaped to accommodate the amount of available mandibular host bone. The condylar heads can be designed in different shapes to offer larger articulating surface area to avoid stress concentration in small area of the articulating
condylar head and fossa as illustrated in Figure 5.10. Figures 5.4 to 5.12 show custom-designed condylar/ramus protheses of varying shape and size. These models demonstrate that our methodology of custom design enables the condylar component to conform to the anatomic situation of damaged and/or complex mandibular host bone. Though the shown designs of condylar component vary in size and shape per anatomic demands and surgeon’s prescription, an important common design feature among all these models is that each device provides accurate adaptation to the host bone.

One novel feature of our TMJ protheses is the perforated notches protruding into the host bone. Figures 5.11 and 5.12 show a condylar/ramus component with its medial surface accurately following the geometric shape of patient’s mandibular bone. Also seen protruding out of the medial surface of this device is a rectangular notch with perforations on its surface. This notch is intended to be placed in a custom-cut groove to be created on the lateral surface of mandibular ramus by the surgeon during implantation. Custom-designed cutting guides and templates can be provided to the surgeon to accurately create a small groove in the host bone. This intentional removal of native bone is performed in exchange of the opportunity for maximizing implant stability through bony ingrowth into perforated surfaces of the notch. Figures 5.11 and 5.12 show a perforated notch protruding from the inferior surface or collar of condylar neck. This notch is intended to be placed into a custom-cut groove in the superior surface of mandibular condyle/ramus resulting from osteotomy (performed to remove damaged condylar head/neck). In addition to providing better stabilization, the notches also provide an avenue for load transfer between the prosthesis and host bone. This will reduce forces and resultant stress experienced by fixation screws which act as the only mode of load transfer between most TMJ
prostheses, especially for the condylar devices in which the collar of condylar prosthesis does not adequately contact the host bone or the medial surface of the implant does not adapt accurately to the complex geometry of patient’s mandible. Though having both medial and superior notches in the condylar prosthesis is likely to be advantageous from biomechanical view point, this may make surgical implantation of the device more challenging for the surgeon. Therefore, it will be the surgeon’s choice to have either one or both notches for condylar implant.
Figure 5.10. Different shapes of the condylar head of the custom-designed condylar/ramus component of the TMJ prosthesis. Panel-A shows a prosthesis with spherical condylar head. Panels B and C show prostheses with elliptical head of different dimensions. The condylar heads are designed to offer larger articulating surface area to avoid stress concentration at small area which may lead to more wear of the articulating surfaces of reconstructed TMJ.
Figure 5.11. Modification of the custom-designed condylar/ramus component, shown in Figure 5.9, to include a novel feature – perforated notches protruding into host bone at implantation. Panel-A shows a groove in the flat lateral surface of the condylar implant. The opposite side of this groove, as shown in Panel-B, protrudes out of the medial surface as a notch with perforations. The enlarged views of medial notch and its perforations are shown in Panels D and E. The device also has pointed and perforated notch protruding from inferior surface of the implant’s collar/neck. Perforated surfaces of these notches are designed to permit bone in-growth into the prosthesis after implantation to provide added stability. Dimensions of these notches can be customized to fit the size and shape of patient’s native bone.
Figure 5.12. Modification and refinement of custom-designed condylar/ramus component shown in Figures 5.9 and 5.11. Panels A and C show pre-drilled screw holes and a groove in the lateral surface of implant. As shown in Panel-C, lateral surface of the device is flat and medial surface is shaped to match the host bone geometry. Panel-B shows a perforated notch each protruding from the medial surface of the ramus and inferior surface of the implant collar/neck.
5.2.1.3 Design of Fossa Prosthesis

Fitting the skull is a major problem in TMJ reconstruction patients because of the irregular shape of their TMJs. The patient-specific design approach enables developing accurately fitting models for the complex shape of patient’s fossa-eminence anatomy. Using a similar design approach discussed earlier for the condylar implants, patient-fitted custom designs of fossa prosthesis can be developed such that the device fits accurately to the available host bone. Such custom designed fossa implants can correctly adapt to the natural components of patient’s TMJ, and provide improved stability through locking screws and perforated notches fitting into patient’s skull. Figures 5.13 to 5.21 show different shapes and features of our custom-designed fossa prostheses.

Figure 5.13. A simple custom-design of the fossa prosthesis with screw holes. Panel-A demonstrates that the implant is designed for optimal usage of natural fossa eminence for fixation using screws. Panels B and C show different views of the implant illustrating the custom shape accurately conforms to the contours of host anatomy. The implant has constant thickness throughout its body, and the shape of articulating surface is same as that of the natural articular surface.
Figure 5.14. Patient-fitted design of a fossa prosthesis. Panels A, B and C illustrate accurate fit of the device to the patient’s natural fossa and eminence. The rectangular slot (with curved anterior and posterior edges) in inferior surface of the implant is designed to provide sufficient rotation and opportunity for anterior-posterior and medio-lateral translation of the matching prosthetic condylar head. The articular groove is designed such that it would prevent dislocation of the prosthetic condylar head during functional movements of the jaw. Visuals in panels D and E show that the superior surface of the implant is designed to accurately match the shape of natural fossa. Sufficient thickness is maintained for the lateral portion of implant to pre-drill screw holes which can host locking screws for better fixation and stability.
Figure 5.15. Patient-specific design of fossa prosthesis. Inferior rectangular surface of the device has a circular groove for articulation with condylar head. Visuals illustrate customized size and shape of the device for accurate fit and fixation to native anatomical structure. Superior edge of the lateral surface (which hosts screw holes) is custom cut to follow the curvature of native eminence and bone situation.

Figure 5.16. Patient-fitted fossa implant with circular inferior surface which also has a circular groove for articulation with condylar head. Visuals in panels A, B, C and D demonstrate the customized size and shape of the implant.
Figure 5.17. Patient-specific design of fossa prosthesis. The device has a rectangular groove (with curved anterior and posterior edges) in its inferior surface for articulation with condylar head. The uniquely designed articulating surface/hole is slanted in anterior direction. This anterior slope of articulating surface is intended to provide opportunity for anterior translation of the condylar head during movements of jaw. This feature of our fossa prostheses provides an advantage over currently available total TMJ implants which, when implanted, only rotate but do not translate during functional movements of the patient’s jaw.  

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Figure 5. 18. Custom-designed fossa prosthesis with circular articular surface. The device shown in panels A and B has relatively smaller articulating circular hole compared to the one shown in panels C and D. Additionally, articulating surface of the device shown in panels C and D is slanted anteriorly to augment anterior translation of condylar head during mastication.
Figure 5. 19. Patient-specific design of a fossa implant with circular articular surface/hole in the inferior face of the device. The device has a novel feature – perforated medial notches protruding into host bone at implantation. Each perforated notch is designed to fit into surgically created mating groove in the host bone, thereby maximizing device stability by allowing ingrowth of bone into the prosthesis after implantation. The notches also provide a mode for load transfer between the prosthesis and native bone, thereby reducing the amount of load and resultant stress acting on the fixation screws. The surgeons can be provided with custom-designed templates and cutting guides to accurately cut the slots in native bone to accommodate perforated notches.
Figure 5. 20. Shape outline of the patient-specific total TMJ prosthesis. Ramal component of the prosthesis is extended anteriorly up to the chin to support mandibular host bone and graft (with aesthetic dental implant) after removal of the imaginary tumor (shown in red) in the left mandibular body/molar region.
Figure 5.21. Patient-specific total TMJ prostheses.
5.2.1.4 Design of Screws

Unlike hip or knee joints, the bony anatomy of mandibular ramus and temporal glenoid fossa do not afford the use of modular stock components for TMJ TJR that can be stabilized initially with press-fitting or cementation. Therefore, TMJ devices have to rely only on screws for initial fixation and stabilization of their components. Clinicians have underlined the need for improved methods of internal fixation of prosthetic TMJ devices to minimize or eliminate implant loosening and joint failure. Hsu, et al. reported that the position of inserted screws was more important than the number of screws for stable fixation of the condylar TMJ prosthesis. Our methodology of designing patient-specific total TMJ prostheses based on anatomically accurate 3D models provides realistic and accurate options in deciding positions of fixation screws for the prostheses. The positions of pre-drilled screw holes in the prostheses can be selected to avoid unintentional injury to delicate structures in the vicinity while ensuring stable fixation of the devices. Moreover, unlike stock TMJ implants, the custom-designed TMJ prostheses do not have any unused screw holes which may act as stress-risers under functional in-vivo loading post-implantation.

Motion of implanted TMJ prosthesis under load can cause degeneration of the surrounding bone, which may lead to further device loosening and possible failure. Screws may loosen with time and function, requiring replacement. For long-term success of the TMJ implants, forces from the implant to the bone and vice versa must occur without relative motion or without intermittent loading. van Loon, et al. indicated that use of bone screws with sharp threads in TMJ implants prevents movement between the screw head and prosthesis. The custom-designed screws of our TMJ prostheses system provide optimal fixation through locking
mechanism – a unique feature not currently offered by any of the US FDA-approved TMJ TJR devices (see Figures 5.22 and 5.23). Threads on the screw-head surface provide high grade fixation by firmly engaging with the matching threads in the screw hole of either condylar/ramal or fossa implants. The possibility of movement between the screws and prosthesis can be eliminated by using such locked screws. In addition to the surgical condylectomy guides, our methodology also provides the surgeons with customized screw-drill-guides and templates for the TMJ prostheses. These drill guides are intended to create a hole of preferred dimension (diameter and depth), and at the accurate location and orientation for each screw as prescribed by the surgeon.
Figure 5.22. Custom-designed screws with locking mechanism. The threads on the screw-head surface provide improved/optimal fixation by firmly engaging in the matching threads in the screws holes of either condylar/ramal or fossa component of the total TMJ prosthesis.
Figure 5.23. A custom-designed locking screw for TMJ prosthesis. Visuals show different features of the screw. Total length of the screw depends on the size of prosthesis and native bone. The body/shaft of screw is designed long enough to utilize maximum amount of host bone (condyle/ramus or fossa eminence), but avoid protrusion of screws from medial surface of the bone. Length of the screw head varies depending on the thickness of condylar or fossa prosthesis in the particular screw-hole location. The outer diameter of screw is kept in the range of 1.5 mm – 3.00 mm as this range is reported to be optimal for the screws of TMJ implants. The screw has varying pitch, with more threads per unit length of screw-head than the body/shaft.
5.2.1.5 Implant Materials

Using advantageous physical characteristics of biocompatible materials is an essential aspect in the design and manufacture of a successful prosthetic device. Some of the important characteristics of materials used to manufacture the TMJ prostheses are biocompatibility, mechanical strength, low wear-rate, and harmless wear particles. Advancement in materials research has led to materials such as medical grade pure titanium (Ti), titanium alloy (Ti-6Al-4V), cobalt-chromium-molybdenum (Co-Cr-Mb), and ultrahigh molecular weight polyethylene (UHMWPE) becoming gold standard for low friction orthopaedic joint replacement.\(^{37}\)

Wrought Co-Cr-Mb is reported to have excellent wear resistance when articulated against UHMWPE in the non-movable articulating surface of most orthopaedic TJR devices.\(^{82}\) However, TMJ is a highly mobile joint in which articulating surfaces of the reconstructed joint undergo repeated mechanical stresses resulting from movement of the jaw. Metallurgical flaws, such as porosity, found in cast Cr-Co are suggested to cause the fatigue failure of Cr-Co TJR components resulting in noxious metallic debris in the patient’s body.\(^{82}\) Hence, we prefer not to use Co-Cr-Mb and Cr-Co for our TMJ prostheses.

Our choice of titanium alloy (Ti-6Al-4V) for condylar/ramus component and bone screws, and UHMPE for fossa component is based on their favorable characteristics and successful long-term applications reported in scientific and clinical literature. Unalloyed titanium reacts rapidly with oxygen in the air to form a thin (<10 μm) layer of chemically inert titanium oxide which provides a favorable surface for biointegration of prosthesis with bone.\(^{87}\) In addition to its biocompatibility and biointegration, Titanium also offers properties of strength, corrosion resistance, ductility, and machinability.\(^{82}\) UHMWPE is a linear unbranched polyethylene chain
with a molecular weight of more than one million. UHMWPE is shown to have excellent wear and fatigue resistance for a polymeric material.¹¹⁵ Till year 2011, no cases of UHMWPE particulation-related osteolysis have been reported in the TMJ prostheses literature.⁸⁷, ¹⁴⁸

5.2.2 FEA of Total TMJ Implant

Methods for biomechanical assessment of prosthetic TMJ must be developed to make the implantation outcomes more predictable and reliable, and to evaluate the methods of device fixation to minimize or eliminate implant loosening and joint failure.⁸⁶ We performed FE simulations of two patient-specific total TMJ prostheses – one device with medial notches fitting into the grooves created in the host bone (see Figure 5.24) and another ‘simple implant’ without such notches in the condylar and fossa components (see Figure 5.25) – using our validated methodology described in Chapter 4. The objective of this study was to investigate stress and strain distribution in prosthetic components and host bone surrounding the screws under normal and worst-case/over-loading conditions. To account for the user-induced errors due to variations in selecting the nodes of FE mesh for applying boundary conditions and loads, we performed three repetitions of FE simulation under each loading condition for both total TMJ prostheses systems. Results reported in Tables 5.4 and 5.5 are average of the values obtained from three runs of each FE simulation.
5.2.2.1 FE Modeling and Mesh Generation

Subject-specific 3D anatomical reconstruction of patient’s mandible and skull/articular eminence was performed using commercial software Mimics v14.12 (Materialise, Plymouth, MI, USA) from computed tomography (CT) scans of patient’s TMJ. Upon importing the patient’s CT images in Mimics, anatomical model comprising of patient’s mandible and fossa eminence was developed from the CT scan by performing a series of operations such as image processing, segmentation, mask formation for bone and teeth, region growing, and calculation of 3D equivalent similar to the 3D reconstruction method described in Chapter 4. Using the design methodology discussed in previous sections of this chapter, two patient-specific total TMJ prostheses systems – a ‘simple implant’ without notches, and another ‘implant with notches’ – were designed for total reconstruction of the patient’s left TMJ (see Figures 5.24 and 5.25). For FE simulations, volume bound within surfaces of anatomical components (cortical bone, cancellous bone, and teeth) and prosthetic components (condyle, fossa, and screws) were meshed. 3D volume mesh was generated for each of these components with ten-node quadratic tetrahedral elements of type C3D10 (see Figures 5.26 and 5.27). Mesh convergence was achieved using the technique discussed previously in Chapter 4. The finite element analyses were performed using a commercial FE package ABAQUS v6.10 (SIMULIA, Providence, RI, USA).
Figure 5.24. A patient-specific total TMJ prosthesis with medial notches in fossa and condylar components. Panel-A shows anterior-lateral view of the ‘notched implants’ with screw holes. Fossa prosthesis has two medial notches to be fit into host bone (Panels B and C). The articular surface of fossa implant has medio-lateral openings, and is designed to allow optimal anterior and medial translation along with rotation of the prosthetic condylar head along the medio-lateral axis.
Figure 5.25. A patient-specific total TMJ prosthesis. Panels A and B show two views of the ‘simple’ total TMJ prosthesis along with left fossa bone and mandible after removal of left condyle. Panels C and D show two views of the total TMJ along with screws.
Figure 5. 26. 3D finite element mesh of the host bone components prepared for total prosthetic replacement of the left TMJ. Panel-A shows FE surface mesh of left fossa, and panel-B shows a lateral cross-section of the 3D volume mesh of left fossa bone with screw holes. Similarly, panels C and D show surface mesh and anterior cross-section of volume mesh, respectively, of the mandible with screw holes and removal of damaged left condyle.
Figure 5.27. 3D finite element mesh of the components of patient-specific total TMJ prostheses. Panels A, B and C show FE mesh of the condylar/ramal component of the ‘simple’ TMJ implant (without notches). Panels D and E show FE mesh of the fossa component, and panel-F demonstrates FE mesh of a screw for device fixation.

5.2.2.2 Model Constraints and Loads

As illustrated in Figure 5.28, the condylar head of the prosthetic TMJ was allowed to rotate along the medio-lateral axis, and translate in anterior-posterior direction. Similarly, for the TMJ on contralateral side, the natural condylar head was allowed to only rotate along the medio-lateral axis, and translate in anterior-posterior direction. The incisor teeth were fixed so that they could not translate in three directions, but could rotate. The entire fossa host bone was constrained in all directions.
The interface between prosthetic condylar head and articulating surface of fossa prosthesis was modeled as sliding contact with a coefficient of friction of 0.3. The interface between the prostheses and bone in contact was modeled with contact elements having a coefficient of friction of 0.42 as reported in literature. The screw-to-prosthesis and screw-to-bone interfacial conditions were assumed to be bonded. Since use of locking screws eliminates the possibility of movement between screw and prosthesis, the interface condition between screw heads and TMJ prostheses (condylar and fossa) was assumed to be perfect bonding. Two oblique bite forces, each 200 N for normal loading condition and 400 N for over-loading/worst-case scenario, were applied to the mandibular model in the angulus area as shown in Figure 5.28.

Figure 5.28. Assembly of all parts of the FE model (including anatomic and prosthetic components), and schematic representation of model constraints and load application for FE simulation of total TMJ prostheses and anatomical components. Green arrows depict the location
and direction of bite forces applied in the angulus region on both sides of the mandibular mesh. The asterisks indicate constrained nodes at condyle, fossa, and incisor teeth. Left prosthetic condylar head and right natural condylar head were constrained such that they could only rotate along the medio-lateral axis and translate in anterior-posterior direction. The nodes at incisor teeth were so constrained such that they could only rotate. The entire fossa host bone was constrained in all directions. The interface between prosthetic condylar head and articulating surface of prosthetic fossa was modeled as sliding contact. The prosthesis-to-bone, screw-to-prosthesis, and screw-to-bone interfaces were assumed to be bonded. The interfacial and boundary conditions were kept similar for normal and over-load configurations; and only magnitude of applied forces was changed across the two loading configurations.

5.2.2.3 Material Properties

Young’s modulus and Poisson’s ratio of anatomical components (fossa and mandible bone with teeth), titanium alloy (for condylar component and all screws), and UHMWPE (for fossa component) were selected as listed in Table 5.3. All anatomical components of the model (i.e., cortical bone, cancellous bone, and teeth) were assigned properties of the cortical bone similar to other researchers\textsuperscript{45,109} who have previously followed this practice since variation in material properties of these components have negligible influence on biomechanics of the mandible. All materials used in FE models were assumed to be isotropic, homogeneous, and linearly elastic\textsuperscript{57}. Static FE simulations were performed using ABAQUS software. Three repetitions/runs of FE simulation under each loading condition were performed for both types of total TMJ implants to account for any user-induced errors such as variation in selecting exactly the same nodes of FE
mesh across different simulations. The results summarized in Tables 5.4 and 5.5 are average of three simulations for each loading condition for both types of total TMJ prosthesis.

<table>
<thead>
<tr>
<th>Part</th>
<th>Young's Modulus (Mpa)</th>
<th>Poisson’s Ratio</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Host bone</td>
<td>1.47E+04</td>
<td>0.3</td>
<td>Gröning, et al. (^{45}), Ichim, et al. (^{61})</td>
</tr>
<tr>
<td>Titanium alloy (Ti-6Al-4V)</td>
<td>1.10E+05</td>
<td>0.3</td>
<td>Ramos, et al. (^{109})</td>
</tr>
<tr>
<td>UHMWPE</td>
<td>830</td>
<td>0.317</td>
<td>Kurtz (^{89})</td>
</tr>
</tbody>
</table>

Table 5.3. Material properties for anatomical and prosthetic TMJ components.

5.3 Results

The von Mises stress and micro-strain in the TMJ prostheses (fossa and condylar), screws, and native bone in regions adjacent to screws were measured. Figures 5.29 and 5.30 show visuals of stress profiles in the anatomical components and simple TMJ prostheses, respectively. Figures 5.31 and 5.32 show visuals of stress profiles in the corresponding anatomical components and ‘notched’ TMJ prostheses, respectively. Table 5.4 summarizes peak von Mises stress occurred in prosthetic components and screws. Peak von Mises stress and strain developed in host bone surrounding the fixation screws of simple and notched TMJ prostheses under normal and worst-case/over-loading configuration are summarized in Table 5.5.
<table>
<thead>
<tr>
<th>Implant Type</th>
<th>Loading Type</th>
<th>Peak von Mises Stress in Implant Components (MPa)*</th>
</tr>
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<tr>
<td></td>
<td></td>
<td>Condyle/Ramus</td>
</tr>
<tr>
<td>Simple</td>
<td>Normal</td>
<td>44.3</td>
</tr>
<tr>
<td></td>
<td>Over-load</td>
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<td>With Notches</td>
<td>Normal</td>
<td>42.6</td>
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<tr>
<td></td>
<td>Over-load</td>
<td>59.1</td>
</tr>
</tbody>
</table>

*Average of three simulations performed under similar constraints and loading at three different times (to account for variations induced by the user/operator)

**Table 5.4.** Peak von Mises stresses developed in condyle/ramus and fossa components, and fixation screws of the simple and notched designs of patient-specific total TMJ prostheses during FE simulations under normal and worst-case/over-loading configurations.

<table>
<thead>
<tr>
<th>Implant Type</th>
<th>Loading Type</th>
<th>Peak von Mises Stress in Host Bone adjacent to Screw Holes (MPa)*</th>
<th>Peak von Mises Strain in Host Bone adjacent to Screw Holes (µStrain)*</th>
</tr>
</thead>
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<tr>
<td></td>
<td></td>
<td>Condyle/Ramus</td>
<td>Fossa</td>
</tr>
<tr>
<td>Simple</td>
<td>Normal</td>
<td>4.7</td>
<td>3.5</td>
</tr>
<tr>
<td></td>
<td>Over-load</td>
<td>13.6</td>
<td>7.4</td>
</tr>
<tr>
<td>With Notches</td>
<td>Normal</td>
<td>4.3</td>
<td>3.2</td>
</tr>
<tr>
<td></td>
<td>Over-load</td>
<td>12.5</td>
<td>7.1</td>
</tr>
</tbody>
</table>

*Average of three simulations performed under similar constraints and loading at three different times (to account for variations induced by the user/operator)

**Table 5.5.** Peak stress and strain developed in host bone surrounding the fixation screws of the simple and notched designs of patient-specific total TMJ prostheses during FE simulations under normal and worst-case/over-loading configurations.
Figure 5.29. Stress distribution in the host bone components during FE simulations of the total TMJ replacement with custom designed simple TMJ prostheses. Panels A and B show von Mises stress in the fossa bone under normal and worst-case/over-load configurations, respectively. Panels C and D show von Mises stress in the mandibular bone under normal and worst-case/over-load configurations, respectively.
Figure 5.30. Peak von Mises stress in patient-specific ‘simple’ TMJ prosthesis (without notches) during FE simulations of two different loading scenarios. Panels A and B show von Mises total TMJ prosthesis under normal loading configuration. Panels C and D show von Mises stress profile in the prosthesis during FE simulation of worst-case/over-loading scenario.
Figure 5. Stress distribution in the host bone components during FE simulations of the total TMJ replacement with custom designed TMJ prostheses with medial notches. Panels A and B show von Mises stress in the fossa bone under normal and worst-case/over-load configurations, respectively. Panels C and D show von Mises stress in the mandibular bone under normal and worst-case/over-load configurations, respectively.
Figure 5.32. Peak von Mises stress in patient-specific ‘notched’ TMJ prosthesis (with medial notches) during FE simulations of two different loading scenarios. Panels A and B show von Mises total TMJ prosthesis under normal loading configuration. Panels C and D show von Mises stress profile in the prosthesis during FE simulation of worst-case/over-loading scenario.

5.3.1 Stress and Strain in Native Bone

Small difference in the stress and micro-strain occurred in the host bone adjacent to screws in condylar and fossa components of both total TMJ prosthesis systems. For both types of implant designs, von Mises stress in the bone surrounding fixation screws was in the range of 3.2 – 4.7 MPa and 7.1 – 13.6 MPa under normal loading and over-loading, respectively (see Table 5.5, Figure 5.29, and Figure 5.31). These results are comparable to the findings reported by Roy Chowdhury, et al. who studied stress distribution in the screws of a condylar implant and host
von Mises strain in the bone surrounding prosthetic screws ranged from 1210 microstrain to 1983 microstrain during normal loading, and from 1564 microstrain to 3586 microstrain during over-loading condition. According to Roberts, et al., a strain higher than 4000 microstrain can cause hypotrophy of bone. The highest micro-strain in host bone in this study is below the hypertrophy limit. Moreover, use of more screws at appropriate locations would further lower the chances of higher strains capable of bone formation around the screws.

**Figure 5.** Peak von Mises stress in the mandibular and fossa bone adjacent to fixation screws of total TMJ prostheses during FE simulations under normal and worst-case/over-load configurations.
Figure 5.34. Peak micro-strain in the mandibular and fossa bone adjacent to fixation screws of total TMJ prostheses during FE simulations under normal and worst-case/over-load configurations.

5.3.2 Stress and Strain in TMJ Implants

FE simulations resulted in lower stress in anterior part of the condylar and fossa prostheses (see Figure 5.30 and Figure 5.32). This observation is similar to findings reported by Hsu, et al. and Ramos, et al., although their FE studies included only the condylar TMJ implants with different loading conditions. The von Mises stress found in condylar and fossa components of both types of implants were lower than the yield strength of their materials, Ti-6Al-4V and UHMWPE, respectively. The trends in the stress and strain profiles under normal and over-loading conditions were similar in both types of total TMJ prostheses. von Mises stresses of
higher magnitude were developed in condylar neck, posterior part of condylar head, and inferior region of ramal component compared with rest of the condylar/ramus prosthesis. For fossa component, magnitude of von Mises stress was higher in the posterior region on the articulating surface.

**Figure 5.** 35. Peak von Mises stress in condylar/ramus and fossa components of patient-specific total TMJ prostheses during FE simulations under normal and worst-case/over-load configurations.

Other than where the actual loads and constraints were applied, the stress concentration was highest around the inserted screw and the screw holes in the host bone. The medial notches in the
condylar and fossa prostheses are designed to provide improved stability by promoting post-
implantation bone growth into the perforated surfaces of the notches. Von Mises stress in the
notch regions of the condylar and fossa implants were less than that in the screw regions,
indicating that the notches may not act as stress risers in the device. Stress profile in the host
bone portion where the medical notches of the implant are inserted show stresses lower than that
at the screw holes, but higher than those in other parts of the host bone. This indicates that the
stress developed in the notches under functional loading may augment bone growth into the
perforated notches, thereby maximizing the opportunity for improved stability of the prostheses.
Also, in all simulations, the peak von Mises stresses in the condylar component were higher than
those in the fossa component of the total TMJ prostheses (see Figure 5.35). This may have
resulted from the model constraints which allowed mobility of the condylar/ramal prosthesis
along with natural mandible and kept the artificial fossa fixed in its position along with the host
fossa bone.

5.3.3 Stress and Strain in Screws

Peak stress and strain the implant fixation screws are summarized in Table 5.4 and Figure
5.36. In fixation screws for condylar and fossa components, the highest magnitude of stress
values occurred at the neck portion of screws. However, the highest stresses in all screws were
found to be less than the ultimate stress as well as yield point of the screw material (Ti-6Al-4V).
This trend of stress profile in screws is similar to that reported by Roy Chowdhury, et al.114 who
studied stress distribution in a stock condylar prosthesis and screws using FE method. The
highest von Mises stresses found in screws in the present study are much less than those reported by Roy Chowdhury, et al.\textsuperscript{114}. This discrepancy suggests that screws used for fixation of the condylar component of patient-specific total TMJ prostheses undergo less load and resultant stress while transferring the functional loads between implant and host bone. This further suggests that the custom-designed implants offer better adaptation to the host bone (compared to their stock counterparts) and partly transfer the load directly to the bone in contact (e.g., at the location where condylar collar of the implant sits superiorly on natural ramus after condylectomy), thereby reducing the exposure of screws to higher loads and stresses.

Among the screws, the highest stresses occurred in the neck portion of two condylar screws – one placed most inferiorly, and another placed most posteriorly and at the curvature of the ramal part of the implant. This is contradictory to findings by Kashi, et al.\textsuperscript{69} and Roy Chowdhury, et al.\textsuperscript{114} who reported highest stresses in the condylar screw placed most superiorly (near the neck of implant). However, both these studies included a stock condylar TMJ implant in which the implant collar did not contact or adapt to the host bone as it does in the present study. Also, these researchers applied a vertically downward force at the top of prosthetic condylar head whereas we applied load in mandibular angle region.

Screws used for both condylar and fossa components showed von Mises stresses of higher order at their interfaces with prostheses, especially in the region of screw neck and at the site of prosthesis-bone junction. This may have happened as the screws carried more load when they served as a medium of load-sharing between the prosthesis and host bone. As listed in Table 5.4, maximum von Mises stress generated in the screws was relatively higher than that in the corresponding prosthetic component these screws were used for fixation of.
Figure 5.36. Peak von Mises stress in the fixation screws for condylar/ramus and fossa components of patient-specific total TMJ prostheses during FE simulations under normal and worst-case/over-load configurations.

### 5.4 Discussion

In view of scarcity of published literature about design methods and biomechanical analysis of total TMJ implants, the present study provides good reference work for patient-specific design and biomechanical evaluation of such designs through FE simulations. Few published studies have investigated biomechanics of the artificial TMJ implants. In our knowledge, no study has reported FE analysis of total TMJ prostheses. The present study can serve as a reference for the
clinicians regarding advantageous features of the patient-specific total TMJ implants. Moreover, design methodology and FE findings of this study can provide industrial designers with reference data for improving their products, especially the custom-designed products intended for patients with complex and challenging anatomic situations.

Limitations of this study must be considered when reviewing implant designs and evaluating FE results. The main focus of this study was the patient-specific design and biomechanical analysis of the total TMJ prostheses. The skill of the surgical approach (preauricular incision or retromandibular incision) and patient-related issues such as long-term effects were not considered. Therefore, the surgeons should be careful when applying the findings from this study to clinical situation. The present study used only one set of material properties for patient’s host bone. Future investigations should assess effect of altered bone quality on the performance of total TMJ replacement. Also, material properties of bone were assumed to be homogeneous and isotropic. Although this represents a major simplification, other studies have demonstrated that this is acceptable.\textsuperscript{56, 57, 90} Only two loading conditions (with loads applied at the mandibular angle) were used in this study. Other muscle forces which are normally present would also affect the mandibular biomechanics. Although several studies have suggested that forces from other muscles do not exert major effects in the mandible,\textsuperscript{56, 57} future work should consider using more sophisticated FE models. It will be beneficial to evaluate the effect of screw positions on biomechanical performance of total TMJ prostheses. Future work should also include more comprehensive non-linear and dynamic FE simulations using different implant materials.

In summary, this study demonstrates that our custom-design approach offers potential for stable and durable total TMJ reconstruction, and that the FE models can reproduce information
useful in design and assessment of total TMJ prostheses. Findings of this study provide a good basis for future work focusing on developing a more refined and standardized method for custom design of total TMJ prostheses, and pre-clinical FE tests for design verification and validation.
6. SUMMARY, CONCLUSIONS, AND FUTURE WORK

6.1 Current state of the TMJ research

TMJ is a complex, delicate, and highly mobile joint. Structure and biomechanical behavior of bony components such as mandible and fossa; and soft tissue such as disc, ligaments, and muscles are critical to the functioning of TMJ. Research and advancement of treatment for TMD has not been contributed to by engineers, clinicians, and scientists as extensively as have been for other joints such as hip, knee, and shoulder. Published literature about mandibular and TMJ biomechanics is limited in amount and breadth of research scope. Most of the literature on experimental study of cadaveric mandible or TMJ includes one or two specimens tested for one loading condition under low magnitude forces. Relatively more studies on FE analysis of mandible and TMJ are reported in the literature. However, very few FE studies are validated against experimental or clinical findings. Limited information is available about strain development in mandible under multiple functional and para-functional loading scenarios. Much needs to be known about stiffness variation and microdamage development in human mandibular bone. In our knowledge, no published study comprehensively discusses the design methodology and biomechanical evaluation of total TMJ prostheses. Only one of the currently US-FDA-approved total TMJ prostheses provides custom-made designs. Life-expectancy of currently US-FDA-approved TMJ implants is reported to be between 3 to 14 years, and it needs significant improvement to reduce frequency of or to avoid the painful and expensive revision surgeries of reconstructed TMJ.
6.2 Dissertation research findings and contributions

In view of the above-mentioned need for more comprehensive biomechanical evaluation of human mandible and TMJ, this dissertation research undertook studies aimed at achieving the objectives discussed in Chapter 2 (see Section 2.7). During this research, we performed 3D anatomical reconstruction of the mandible and bony components of TMJ from CT images of several patients and cadaver specimens. Such 3D models provide valuable information about the structural state of these anatomic components necessary to make diagnosis and develop methods to prevent or treat the disorders. We performed experimental evaluation of 16 cadaveric human mandibles by conducting mechanical tests under four configurations of cyclic compressive loading conditions imitating functional and para-functional loads. During mechanical tests, experimental strain data were measured using strain gauges attached to the cortical surface of each cadaveric mandible at five different locations. Strains measured at condylar locations of the mandibles were found significantly different from those measured at other locations. This finding proved valuable for designing the total TMJ devices at later point of this dissertation research. One of the major aims through the present study was to characterize stiffness variation and micro-damage development in cadaveric human mandible under fatigue loading. From our experimental measurements, we derived stiffness variation and microdamage accumulation in mandibles under four cyclic compressive loading conditions. Analysis demonstrated that stiffness reduced steeply, initially, followed by a transition into constant magnitude. Analysis of micro-damage accumulation showed an abrupt increase, initially, which transitioned into the region of saturation with nearly no change in damage. Majority of damage accumulation was observed during first few hundreds of cycles of the fatigue loading. We attempted to develop
predictive numerical model for damage accumulation in the mandible using Michaelis-Menten equation and our experimentally derived data. Our methodology shows early promise, and needs further exploration for reliable prediction of mandibular bone damage.

Another key objective of this dissertation research was to develop a validated method of FE modeling and analysis for biomechanical evaluation of human mandible. We performed a combined experimental-analytical study in which the surface strains in the cadaveric human mandibles were measured through strain gauges under four configurations of cyclic compressive loads. FE models were generated from CT data of the cadaveric mandibles, and used to perform FE simulations accurately replicating the experiments. Strong statistical correlation and statistical agreement were found between the experimentally measured strain and FE-predicted strain data. This validated FE methodology and 3D models can be used for further evaluation of the complex biomechanical behavior of human mandibles. Our validated FE methodology may also prove valuable in assessing other anatomic parts such as spine.

We also developed a methodology to design patient-specific total TMJ prostheses on the basis of patient’s CT images and surgeon’s requirements. In addition to providing accurate fit to any challenging anatomic host bone situation, our custom-designed TMJ implant designs offer novel locking mechanism, perforated notches protruding into host bone, and customized osteotomy/cutting guides. The unique design characteristics of our TMJ prostheses have the potential for correct adaptation to host TMJ anatomy, and improved fixation and stability of the implants for challenging and complex anatomic situations. Following our previously validated FE methodology, we assessed stress and strain profiles in patient-specific total TMJ reconstruction through FE simulations under normal and over-loading conditions. Peak stresses
and strains in the prostheses and host bone were found to be within the limit of safety. The study demonstrated that our proposed methodology provides viable means for designing durable patient-specific total TMJ prostheses. This methodology can also be used for designing customized prostheses for other complex anatomic parts.

6.3 Future work

Non-linear models have the potential to better describe biomechanical behavior of bone. However, linear models have been used to study mandibular biomechanics. Our simplified linear FE models still are of value in evaluating biomechanical properties of the mandible and TMJ, but a better numerical prediction may be expected by analyzing these models beyond the linear region using non-linear and dynamic FE analyses. Moreover, our method of 3D anatomical reconstruction can be further extended to develop models of the entire TMJ including bones, articular fibro-cartilage, disc, and ligaments. FE analysis of such subject-specific 3D models of total TMJ, and its validation against experimental and/or clinical findings can potentially provide valuable insight into structural and functional aspects of the entire joint, necessary to better understand the onset and progression of the TMD.

Our technique of assessing TMJ prostheses can be built upon to perform comprehensive dynamic FEA of total TMJ prostheses and host anatomy by including non-linearity and anisotropy of the model components. Also, by defining the limits of maximum loading on these FE models, safe loading limits can be established to avoid failure of the reconstructed joints due to functional movements of the jaw. To bring our custom-design approach to reality, further
steps such as prototyping, cadaveric implantation studies, and subsequent design refinement are necessary. Experimental wear study and predictive numerical wear-rate modeling of TMJ implants will be very valuable.
REFERENCES


36. Frost, H. M. A brief review for orthopedic surgeons: Fatigue damage (microdamage) in bone


40. George, W. T. and D. Vashishth. Damage mechanisms and failure modes of cortical bone

Biomechanical Evaluation of Femurs Fixated with Cephalomedullary Nails. Journal of

42. Gerard, D. A. and J. W. Hudson. The Christensen temporomandibular joint prosthesis
2002.


tissues around temporomandibular joint prostheses after up to eight years of function. Int. J.

149. Wilkes, C. H. Arthrography of the temporomandibular joint in patients with the TMJ pain-

temporomandibular joint total joint prosthesis systems. J Oral Maxillofac Surg 61:685-690,
2003.


152. Wolford, L., M. Pitta, O. Reiche-Fischel, and P. Franco. TMJ Concepts/Techmedica


Kinematic study of the temporomandibular joint in normal subjects and patients following
unilateral temporomandibular joint arthrotonomy with metal fossa-eminence partial joint