# A Pilot Study of Contact Mechanics of Temporomandibular Joint Alloplastic Implants

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## 1) Abstract

**Title**: A Pilot Study of Contact Mechanics of Temporomandibular Joint Alloplastic Implants

**Objective**: Address the lack of knowledge concerning contact mechanics of temporomandibular joint (TMJ) alloplastic implants.

**Materials and Methods:** Subjects were enrolled based on inclusion criteria: age 18 years or older with a history of previous replacement surgery with alloplastic implants of the left, right, or both TMJs, an interval of at least 6 months since the last surgery. Exclusion criteria included pregnant, planning a pregnancy during the study, currently breastfeeding, drug or alcohol abuse, and conditions that would cause difficulty following procedures of the study, such as those with dementia, psychological disorders, or language barriers. Cone-beam computed tomography (CBCT) images taken and used to construct three-dimensional anatomical geometry files of the positions of the mandibular condyles, teeth, and positions and orientations of the medial and lateral pterygoid, masseter, temporalis, and anterior digastric muscles. Computer-assisted numerical models, with the objectives of minimization of muscle effort (MME) and minimization of joint loads (MJL), were used with subject-specific geometry files to predict TMJ loads for a static bite-force of 10 Newtons (N) applied at a range of biting angles on the mandibular right central incisor, canine, and molar. Numbers of predicted ecologically viable biting angles were counted by identifying biting situations when the lateral pterygoid muscle forces were predicted to be zero (% applied bite force) on the same side as the TMJ implant because in vivo, this muscle is removed when the implant is placed. Variables included predicted TMJ loads, lateral pterygoid muscle forces, and numbers of ecologically viable biting conditions being investigated. All variables were derived for the biting conditions being investigated, and were compared between models and sides using Analysis of Variance (ANOVA) and Satterthwaite’s t tests. Statistically significant differences were reported at $p<0.05$.

**Results:** Seven unilateral and eight bilateral TMJ implant replacement subjects met inclusion criteria and did not meet exclusion criteria. For unilateral implant subjects, significantly higher TMJ loads were predicted by MME versus MJL models in the contralateral TMJ for molar, canine, and incisor biting, and in the ipsilateral TMJ for incisor and canine biting. Additionally, significantly higher lateral pterygoid muscle forces were predicted by MJL versus MME models for molar, canine, and incisor biting. There was a significantly higher number of predicted viable bite-force angles at molar biting for MME versus MJL models. For bilateral implant subjects, significantly higher contralateral TMJ loads were predicted by MME versus MJL models for molar biting, and were predicted by MJL versus MME models for incisor biting, while significantly higher ipsilateral TMJ loads were predicted by MJL versus MME models for canine and incisor biting. There was no significant difference seen between MME and MJL models for number of viable bite-force angles at any of the bilateral tested biting locations.

**Conclusions:**

Comparisons between MME and MJL models in a bilateral TMJ replacement population showed:

- No significant difference for number of ecologically viable biting angles.
- Ipsilateral TMJ loads were not significantly different for molar biting but were significantly smaller during canine and incisor biting..
- Contralateral TMJ loads were significantly larger during molar biting. However, contralateral TMJ loads were not significantly different during canine biting and were significantly smaller during incisor biting.

Comparisons between MME and MJL models in a unilateral TMJ replacement population showed:

- Larger numbers of ecologically viable biting angles for biting at all three positions, although this was only significantly larger during molar biting.
- Larger ipsilateral and contralateral TMJ loads for biting at all three positions and these were significantly larger for all except for the contralateral TMJ during incisor biting.
- Significantly lower lateral pterygoid muscle forces for biting at all three positions.

Thus, bilateral and unilateral TMJ replacement individuals may exhibit increased TMJ loads depending on the operating neuromuscular objective and biting location. Additional studies are needed to verify the results of this pilot study.

# 2) Introduction

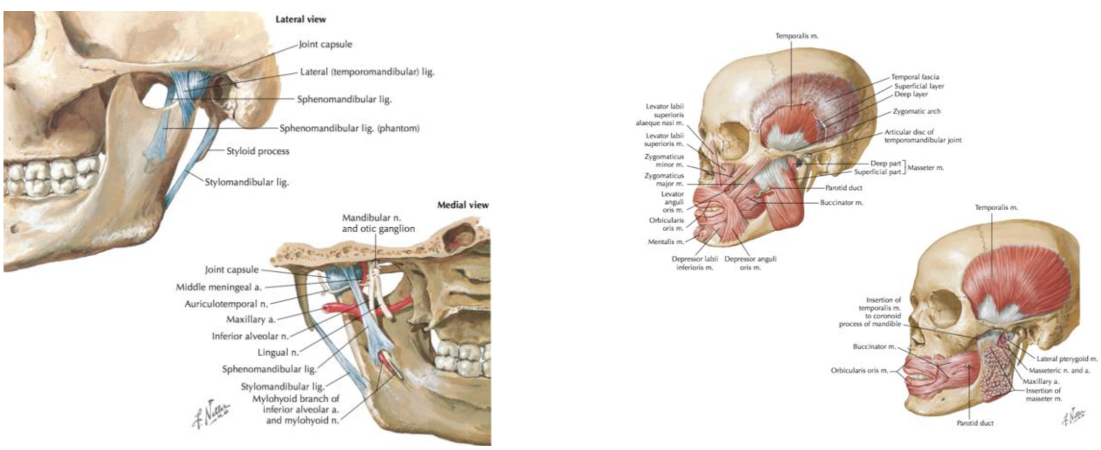
## 2.1 Temporomandibular Joint

The temporomandibular joint (TMJ), with both rotational and translational aspects, is one of the most complex joints in the human body (Figure 1). Normally, the TMJs are bilateral, and on one side, comprised of two bony components covered in fibrocartilage: the condyle of the mandibular bone and the glenoid fossa and eminence of the temporal bone, with a fibrocartilage disc in between. A functional TMJ plays a critical part in one's lifestyle and can strongly affect a person's quality of life, through its roles in mastication, swallowing, and talking. Its unique function as a synovial joint is to withstand large, repeated forces and remain durable, as it is expected to last for the entirety of a person's life. When the TMJ cannot meet these biological functions, temporomandibular disorders (TMDs) may arise. While the specific etiology of TMDs are unknown, influential factors include: TMJ trauma, autoimmune diseases (like juvenile rheumatoid arthritis), tumors, and connective tissue diseases. Additionally, the human TMJ system can be compromised by an absent or hypoplastic joint (causing hemifacial microsomia), idiopathic condylar resorption, degenerative joint disease, ankylosis, and previously failed autogenous and alloplastic TMJ implants.[1]

TMDs have been observed to affect females more than males, at a 2:1 ratio,[2] with osseous changes similar to late stage degenerative joint disease being found in the 20-30 year old demographic.[3] With reports of 5-12% of all people in the United States being affected by TMDs,[2] it comes as no surprise that this high prevalence has led to an estimated annual cost of $4 billion.[4] When the TMJ fails and palliative treatment is no longer a viable treatment, total joint replacement (TMJR) via surgery becomes an option. The goals of TMJR are to improve joint function, reduce disability, and maintain acceptable treatment costs.[5] As an alloplastic replacement, TMJR often occurs 2 decades earlier than other human joints, with the average age of replacement at 34.9 years.[6]

Diagnosis of joint degeneration of the TMJ is often reliant on a comprehensive exam by a specialist, including imaging examination. The increased usage of cone-beam computer tomography (CBCT) and magnetic resonance imaging (MRI) are important for identification of any anatomical abnormalities of the hard and soft tissues, respectively, that may exist within the TMJ. By analyzing both hard and soft tissues in three dimensions with serial imaging, CBCT and MRI imaging can provide more information about the TMJ than traditional X-Ray imaging, and help visualize abnormal disc anatomy, disc position, and osseous conditions in the joint.[7]

Figure 1: Anatomy of the Temporomandibular Joint: Anatomy of the TMJ is illustrated. With several ligaments and complex muscle coordination, synchronous harmony among all components is needed for efficient and healthy function.[8]




## 2.2 Significance

By 2030, it is estimated that 1500-2000 alloplastic implants will be placed in the United States.[9] However, the average US life expectancy is around 80 years and the average age of a patient requiring a TMJ implant is around 35 years. This may indicate that implant fatigue can lead to several revision surgeries in a patient’s lifetime. Since affected individuals may be expected to live most of their lives with TMJ implants, it is paramount to further examine the contact mechanics and joint loading for these subjects, as there is currently an absence of baseline information of in vivo dynamic contact mechanics associated with alloplastic TMJ implants.[10]

Joint loading data and composite loading profiles are required to understand the loading environment experienced by TMJ implants in vivo. There are currently no data for in vivo dynamic contact stresses that are likely to occur during function in cases of either bilateral or unilateral TMJ implants. During TMJ implant surgeries, the lateral pterygoid muscle is removed from the replaced/implanted side. For unilateral cases, this can result in greater translational movements and more force to the contralateral/non implanted side during loading. Due to the complexity of forces in both TMJs in unilateral implant cases, it is important to address the effects of asymmetric function on the joint contact mechanics and jaw-use behaviors (mechanobehavior) of the natural TMJ for unilateral implant patients.

There has been an increasing utilization of alloplastic TMJ implants, projected to be up 58% by the end of the decade.[9] However, despite this increase, there are many unknowns about the in vivo ecological environment in terms of joint contact loading and kinematics.[11] This is especially important for unilateral TMJ implants, as prognosis is hindered by the lack of data regarding TMJ mechanics and jaw-use behaviors of both the implant and natural TMJ. Consequently, the importance of understanding the loading mechanics of the TMJ can be important for understanding the long-term durability of the joint.

### 2.3 Numerical Modeling

The use of numerical modeling has been shown to be an accurate and reliable method of predicting joint loads and muscle forces used in an individual human masticatory system during static loading of the jaw.[12,13] Having previously been used on other joint systems like the shoulder, knee, hip, and spine, these computer models can calculate the unknown joint and muscle forces at known locations with either an external load or applied bite-force.[14-17] Due to the possibility of multiple combinations of joint and muscle forces used to create static equilibrium, numerical modeling serves to create a unique solution for this mechanical indeterminacy.[18] In this process, an individual's anatomy is characterized in three dimensions and described by a geometry file, which includes the relative positions of the TMJs, teeth, and masticatory muscle vectors. These are the main structures that are important to the stabilization of a static load applied to the jaw. By accounting for the unique anatomy of an individual, geometry files can be particularly helpful for representing abnormal facial relationships. Numerical modeling can be used to solve the mechanical problem of what TMJ loads and muscle forces are needed to stabilize, for example, a bite-force applied at a specific location and biting angle, based on a given geometry file. Moreover, because there are many possible solutions for this mechanical problem, in order to achieve a unique solution, the masticatory system requires a goal or neuromuscular objective function. These objective functions have biological importance through representation of theories of underlying neuromuscular control. Two objective functions include minimization of joint loads (MJL) and minimization of muscle effort (MME) (or minimization of the sum of squared muscle forces). Data from living humans have shown that neuromuscular control can follow either objective function, with evidence that the MJL model has greater consistency for predicting the articular eminence shape.[19] Conversely, MME model predictions have been shown to best match measured muscle forces during biting mechanics.[20] To validate the model results and show that the particular objective function is actually being used in vivo, numerical model predictions of muscle forces used for a given biting situation and given individual-specific geometry file can be tested with electromyography (EMG) data recorded from the individual during the same biting situation. If these predications reflect measured data for muscle forces, then it can be implied that the model-predicted TMJ loads for that biting situation also reflect the in vivo conditions. With these numerical model data, the TMJ contact mechanics affecting the hard and soft tissues of the joint can be estimated.[21]

The numerical modeling program can be used to derive ecologically viable biting situations (biting positions, bite-force angles) for an individual. Predicted ecologically viable biting situations are potential scenarios where the biomechanical behavior of muscles mimic *in vivo* situations for an individual. This is calculated by examining each muscle force for different biting angles at each biting location. For TMJR subjects, in vivo, no ipsilateral lateral pterygoid muscle activity is possible because this muscle is removed on this side (on implanted side). Therefore, only biting conditions where this muscle activity is predicted to be zero by numerical modeling are ecologically viable. Specifically, this can be done in vitro by examining the values where the lateral pterygoid muscle ipsilateral to the replaced TMJ has a model-predicted force of zero. That is, this would simulate a detached ipsilateral lateral pterygoid muscle, which is removed from the mandible during TMJR surgery. The number of ecologically viable bite-force angles for a given biting position can then be compared for each neuromuscular objective.

## 2.4 Aims and Hypotheses

As a first step toward addressing the lack of mechanobehavior data, the overall aim of this study is to use numerical modelling to examine the joint and masticatory muscle forces used during biting in subjects with bilateral and unilateral TMJ alloplastic implants. More specifically, the goal is to investigate the effects of bilateral or unilateral loss of function of the lateral pterygoid muscle on TMJ loads during biting in subjects with alloplastic TMJ implants. To address this goal, the investigation will test the following working hypotheses using numerical models with different neuromuscular objectives:

Working Hypothesis 1A: In subjects with bilateral TMJ implants, a larger number of ecologically viable biting situations (bite-force angles) are predicted by numerical models based on neuromuscular objectives of minimization of muscle effort compared to minimization of joint loads.

Working Hypothesis 1B: In subjects with bilateral TMJ implants, predicted ipsilateral TMJ implant loads are significantly larger from numerical models based on neuromuscular objectives of minimization of muscle effort compared to minimization of joint loads.

Working Hypothesis 1C: In subjects with bilateral TMJ implants, predicted contralateral TMJ implant loads are significantly larger from numerical models based on neuromuscular objectives minimization of muscle effort compared to minimization of joint loads.

Working Hypothesis 2A: In subjects with unilateral TMJ implants, a larger number of ecologically viable biting situations (bite-force angles) are predicted by numerical models based on neuromuscular objectives of minimization of muscle effort compared to minimization of joint loads.

Working Hypothesis 2B: In subjects with unilateral TMJ implants, predicted ipsilateral TMJ implant loads are significantly larger from numerical models based on neuromuscular objectives of minimization of muscle effort compared to minimization of joint loads.

Working Hypothesis 2C: In subjects with unilateral TMJ implants, i) larger contralateral TMJ loads (on the natural TMJ side) and ii) lower lateral pterygoid forces are predicted by numerical models based on neuromuscular objectives of minimization of muscle effort compared to minimization of joint loads.

## 3) Materials and Methods

### 3.1 Subjects

Data from University of Zurich School of Dental Medicine were analyzed in this retrospective study. Specifically, Digital Imaging and Communications in Medicine (DICOM) files from full field-of-view cone beam computed tomography (CBCT) scans of the head made using the same machine in individuals with either unilateral or bilateral alloplastic implants were used. Subjects were scanned with coronal Xray image stacks of 0.4mm x 0.4mm x 0.4mm voxels using a CBCT machine (KaVo 3D eXam 1; KaVo GmbH, Leutkrich, Germany) with subjects biting into a reference custom-made occlusal splint. The surgeries were performed at University Hospital of Zurich, University Hospital of Basel, and State Hospital of Aarau. Subjects received alloplastic total joint replacements between February 2005 and February 2015. Meta data were stripped from the DICOM files. No unique identifiers were present on the scans and these data sets and results were assigned a random identifier to prevent bias and maintain privacy. Inclusion criteria were subjects aged 18 years or older with a history of previous replacement surgery with alloplastic implants of the left, right, or both TMJs. Subjects had an interval of at least 6 months since the last surgery. Exclusion criteria were subjects who were pregnant, planning a pregnancy during the study, breastfeeding, drug or alcohol abusers, and those that would have difficulty following procedures of the study, like dementia, psychological disorders, or language barriers. This research study was approved by Oregon Health & Sciences (OHSU) Institutional Review Board (STUDY00025245, Appendix A).

3.2 Numerical Modeling of TMJ Loads and Muscle Forces

CBCT scans taken after alloplastic TMJ implant surgery were analyzed. Three-dimensional (3D) anatomy was characterized through the use of commercially available software (InVivo, Anatomage, Santa Clara, CA) based on previous methods (Appendix B).[22] Landmarks were plotted according to x, y, and z planes (Figures 2, 3), where the origin was between condyles and the x-z plane was parallel to the mandibular occlusal plane (Figure 3). Anatomical landmarks (Figure 2) included in the 3D geometry files were: the mandibular condyle, if present, and TMJ implant, mandibular incisor, canine, and molar teeth, along with the centroids of origins and attachments of the masseter, anterior temporalis, lateral pterygoid, medial pterygoid, and anterior digastric muscle pairs. The numerical models assumed dentofacial symmetry.

Anatomical landmarking for unilateral TMJR subjects was conducted on the natural TMJ side for either right or left TMJR subjects. After points were labeled, the numerical model was mirrored across the sagittal plane for the right implant subjects to have inverse z coordinates for anatomical and biting location points. This ensured that the right and left TMJR subjects had geometry files that were input to the same program in a comparable orientation. For the modeling, biting locations were on the right side, ipsilateral to the TMJ implant replacement, with the natural TMJ on the contralateral (left) side. For bilateral subjects, landmarking was conducted on the left side for all subjects, and similarly mirrored to the right side like the right unilateral implant subjects. Geometry files from bilateral TMJR subjects were similarly input to the numerical modeling programs to investigate biting locations on the right side.

From these landmarks, a 3D geometry file was derived and used in numerical models to calculate jaw muscle and TMJ implant/TMJ forces required to stabilize an applied bite-force of 100 units and meet the given neuromuscular objective function, either minimization of 1) muscle effort (MME), or 2) joint loads (MJL). In the numerical models, bite-forces of 100 units were applied over a large range of angles, accounting for those likely to occur during normal jaw activities: 0–350° in the occlusal plane ($\theta_{xz}$) in 10° steps, and angles relative to vertical (where $\theta_y = 0°$) of 0–40° in 5° steps (Figure 3) at three right-side biting positions on the mandibular central incisor, canine, and first molar. Predicted ipsilateral (right) and contralateral (left) TMJ implant/TMJ loads were calculated for the full range of biting angles at each biting position. Model-predicted TMJ and muscle forces were expressed relative to the applied bite-force of 100 units (%). Biting vectors were defined by occlusal plane (0-350º) and vertical (0-40º) angles. For each biting position in each subject, model results were examined and instances where the ipsilateral lateral pterygoid muscle force was predicted to be zero were identified as ecologically viable biting angles. For these biting angles at each biting position (molar, canine, incisor) model-predicted TMJ and contralateral muscle forces were averaged for each subject. Also, the number of ecologically viable biting angles was calculated by summing all instances where the ipsilateral lateral pterygoid muscle force was predicted to be zero (% applied bite force). These simulated biting conditions without input from the lateral pterygoid muscle as a result of removal of this muscle during the TMJR surgery. Thus, the maximum possible number of ecologically viable bite force angles would be 324, measured for each 10º interval (0 - 360º) in the occlusal plane and each 5º interval from vertical (0°) to 40º from the vertical. The predominant neuromuscular objective was then determined based on if the number of ecologically viable bite force angles was greater for MME or MJL.

Figure 2: Screenshots of left lateral (left), axial (middle), and frontal (right) views of a subject with a unilateral right temporomandibular joint implant where anatomical landmarks for the geometry file are labeled, showing condylions bilaterally and left side (L) centroids for origins (O) and insertions (I) of the muscles of mastication and tooth positions.

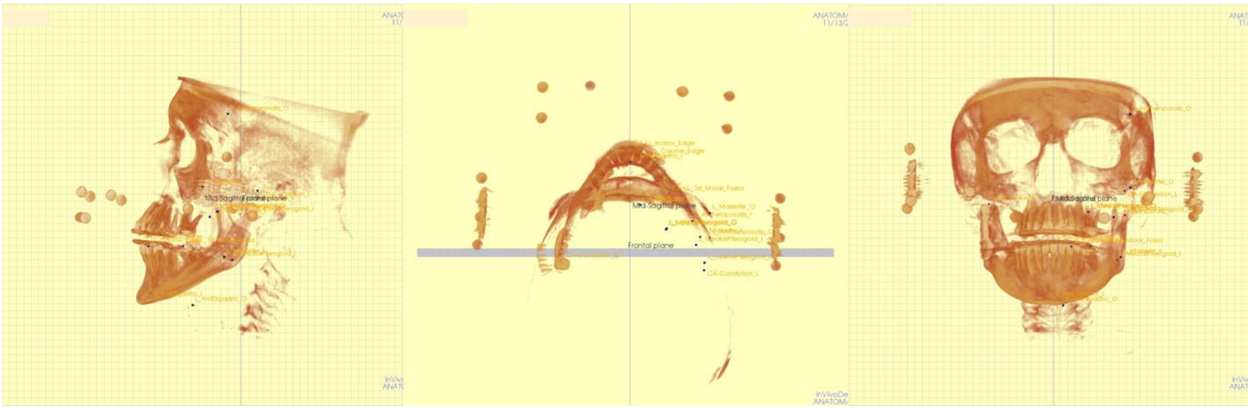
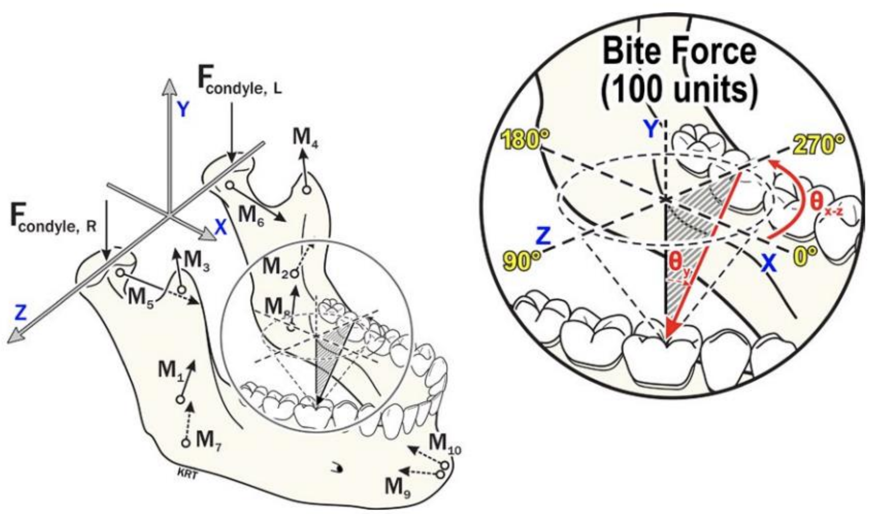


Figure 3. Geometry files consisted of coordinates of TMJs, jaw muscles and teeth relative to x-,y, and z axis. Each subjects' anatomy determined force vectors for: TMJs ($F_{condyle}$; R = right, L = left), five muscle pairs ($m_{1,2}$ = masseter, $m_{3,4}$ = anterior temporalis, $m_{5,6}$ = lateral pterygoid, $m_{7,8}$ = medial pterygoid, $m_{9,10}$ = anterior digastric), and biting characterized by occlusal plane ($\theta_{xz,}$ 0–350°) and vertical ($\theta_y$, 0– 40°) angles. Biting represented in this figure is shown at the right first molar. Modified from [23,24].



**4) Data and Statistical Analysis**

Analysis of numerical model calculations of mechanics were be based on neuromuscular objectives of

i) minimization of muscle effort (MME) or

ii) minimization of joint load (MJL).

Numerical model-predicted ecologically viable biting conditions on the right mandibular i) incisor, ii) canine, and iii) first molar were defined by the applied bite-force angles (out of 324 possible) which predicted no lateral pterygoid muscle forces, bilaterally in subjects with bilateral TMJ implants, or unilaterally, on the implant TMJ side, in subjects with a unilateral TMJ implant.

Statistical analyses were conducted to compare the following independent variables:

i. Model: minimization of muscle effort (MME) versus minimization of joint load (MJL)
ii. TMJ status: unilateral versus bilateral implants
iii. Lateral pterygoid muscle status: functional versus nonfunctional
iv. Biting position: Incisor, canine, versus molar

The measured variables (dependent variables) for each case were:

i. Number of ecologically viable biting angles: determined when no lateral pterygoid muscle forces were predicted bilaterally in bilateral TMJR cases and unilaterally on the implant side in unilateral TMJR cases
ii. Ipsilateral implant/natural TMJ loads: average expressed as % applied bite forces

iii. Contralateral implant/TMJ loads: average expressed as % applied bite forces

iv. Lateral pterygoid muscle force contralateral to the implant side: average expressed as % applied bite forces for unilateral implant subjects

Descriptive statistics including means and standard deviations were calculated for dependent variables, based on the biting angles that were ecologically viable for each biting position. Analysis of Variance (ANOVA) and Satterthwaite's t tests were used to determine effects of independent variables on the number of ecologically viable biting angles for each biting position, ipsilateral and contralateral TMJ loads (% applied bite force), and lateral pterygoid muscle forces contralateral to the implant side for unilateral implant subjects. The number of ecologically viable biting angles was determined by summing each numerical modeling instance where the ipsilateral lateral pterygoid muscle force was predicted to be zero (% applied bite force). These scenarios with no ipsilateral lateral pterygoid muscle forces were then compared to measure the ipsilateral and contralateral TMJ loads, and contralateral pterygoid muscle force in unilateral implant subjects. Statistically significant differences were reported at $p<0.05$.

## 5) Results

### 5.1 Sample Description

There were 15 subjects that met inclusion criteria and did not meet exclusion criteria. Of these subjects, eight had bilateral alloplastic implants and seven had unilateral alloplastic implants (Table 1). The mean age of subjects was 52 years (range 24-72 years), with the mean age of the time of surgery of 47 years (21-66 years). Mean time from operation to examination was 4.8 years for all subjects. Reported reasons for TMJ replacement include severe degenerative joint disease with compromised TMJ function, failed primary therapy after TMJ trauma, TMJ ankylosis, condylar resorption, pigmented villonodular synovitis, and mandibular keratocyst extending to the TMJ. TMJ prosthesis were from different manufacturers (Rotec, Weisendorf, Germany; TMJ Concepts, Inc., Ventura, CA, USA; Biomet, Jacksonville, FL, USA).[25]

Table 1: Demographic and baseline statistics for subjects included in this study.[25]

| Variables | Unilateral TMJ total joint replacement (*n* = 7) | Bilateral TMJ total joint replacements (*n* = 8) |
|---|---|---|
| Sex, *n* (%) | | |
| Male | 1 (14.3%) | 3 (37.5%) |
| Female | 6 (85.7%) | 5 (62.5%) |
| Age (years) | 55.1 (43.1; 69.7) | 44.6 (37.0; 65.7) |

5.2 Bilateral Implant Cases

The number of ecologically viable biting angles predicted by the numerical models varied between individuals for the three biting locations investigated (Table 2). For example, Subject 1403 had <13 (out of possible 324) from both models for molar and canine biting. Specifically, there were no viable biting angles predicted by the MJL model for canine biting and by either model for incisor biting. Hence for these circumstances there were no TMJ loads predictions for this individual , as no predicted ecologically viable biting angles were recorded while running the numerical modeling programs. Whereas, the highest number of viable biting angles was 152 for Subject 1417 for incisor biting using the MJL model. TMJ loads were then calculated for each ecologically viable biting angles and averaged for each model (Table 3). Statistical analysis was conducted between MJL and MME models.

Table 2: Numbers of viable biting angles predicted by minimization of joint loads (MJL) and minimization of muscle effort (MME) models for right molar, canine, and incisor biting in bilateral implant subjects. Average numbers of biting angles for each model with results from between-model comparisons are shown, where * indicates significant difference.

| Subject | Biting Tooth | Status | MJL Viable Angles | MME Viable Angles | | |
|---|---|---|---|---|---|---|
| 1403 | Molar | Bilateral | 2 | 13 | | |
| 1406 | Molar | Bilateral | 102 | 53 | | |
| 1408 | Molar | Bilateral | 36 | 89 | | |
| 1410 | Molar | Bilateral | 48 | 29 | | |
| 1412 | Molar | Bilateral | 54 | 46 | | |
| 1413 | Molar | Bilateral | 20 | 72 | | |
| 1416 | Molar | Bilateral | 53 | 26 | | |
| 1417 | Molar | Bilateral | 97 | 84 | | |
| | | AVERAGE | 52 | 52 | 1 | ns |
| 1403 | Canine | Bilateral | 0 | 3 | | |
| 1406 | Canine | Bilateral | 136 | 32 | | |
| 1408 | Canine | Bilateral | 11 | 49 | | |
| 1410 | Canine | Bilateral | 57 | 18 | | |
| 1412 | Canine | Bilateral | 24 | 24 | | |
| 1413 | Canine | Bilateral | 9 | 44 | | |
| 1416 | Canine | Bilateral | 24 | 12 | | |
| 1417 | Canine | Bilateral | 141 | 46 | | |
| | | AVERAGE | 50 | 29 | 0.29 | ns |
| 1403 | Incisor | Bilateral | 0 | 0 | | |
| 1406 | Incisor | Bilateral | 150 | 33 | | |
| 1408 | Incisor | Bilateral | 6 | 41 | | |
| 1410 | Incisor | Bilateral | 54 | 14 | | |
| 1412 | Incisor | Bilateral | 21 | 19 | | |
| 1413 | Incisor | Bilateral | 10 | 45 | | |
| 1416 | Incisor | Bilateral | 23 | 13 | | |
| 1417 | Incisor | Bilateral | 152 | 37 | | |
| | | AVERAGE | 59 | 29 | 0.25 | ns |

Bilateral Subjects: Biting Location at Right Molar

For unilateral molar biting for bilateral alloplastic implant subjects, the smallest ipsilateral TMJ loads observed was 23.1% applied bite force (BF) and highest was 65.8% applied BF for MJL models. The smallest ipsilateral TMJ loads observed for MME models was 23.9% applied BF and the highest was 59.8% applied BF. Whereas the smallest contralateral TMJ loads for MJL models was 13.0% applied BF, and the largest was 59.8% applied BF. The smallest contralateral TMJ loads for MME models was 17.5% applied BF, and the highest was 53.0% applied BF (Table 4). Overall, the MME model versus MJL model predicted statistically significantly larger loads for the contralateral TMJ (40.7 ± 13.5 versus 27.1 ± 13.2 % applied bite force, respectively; $p<0.0001$; Table 3, Figure 5). There were no statistically significant differences between MME versus MJL models for numbers of ecologically viable bite-force angles (51.5 ± 28.2 versus 51.5 ± 34.5 respectively; $p=1.00$; Table 3, Figure 4) and ipsilateral TMJ loads (33.0 ± 12.6 versus 32.7 ± 12.8 % applied bite force, respectively; $p=0.21$; Table 3, Figure 5).

Bilateral Subjects: Biting Location at Right Canine

For unilateral canine biting for bilateral alloplastic implant subjects, the smallest ipsilateral TMJ loads observed was 45.8% applied BF and highest was 84.8% applied BF for MJL models. The smallest ipsilateral TMJ loads observed for MME models was 51.5% applied BF and the highest was 86.6% applied BF. Whereas the smallest contralateral TMJ loads for MJL models was 30.1% applied BF, and the largest was 77.8% applied BF. The smallest contralateral TMJ loads for MME models was 25.7% applied BF, and the highest was 73.7% applied BF (Table 5). Overall, the MME model versus MJL model predicted statistically significantly smaller ipsilateral TMJ loads (53.1 ± 15.1 versus 58.9 ± 13.9 % applied bite force, respectively; p<0.0001; Table 3, Figure 5). There were no statistically significant differences between MME versus MJL models for numbers of ecologically viable bite-force angles (28.5 ± 17.0 versus 50.3 ± 57.0 respectively; p=0.29; Table 3, Figure 4) and contralateral TMJ loads (58.3 ± 17.6 versus 57.4 ± 14.8 % applied bite force, respectively; p=0.88; Table 3, Figure 5).

Bilateral Subjects: Biting Location at Right Incisor

For unilateral incisor biting for bilateral alloplastic implant subjects, the smallest ipsilateral TMJ loads observed was 49.4% applied BF and highest was 84.1% applied BF for MJL models. The smallest ipsilateral TMJ loads observed for MME models was 55.0% applied BF and the highest was 100.5% applied BF. Whereas the smallest contralateral TMJ loads for MJL models was 33.8% applied BF, and the largest was 79.3% applied BF. The smallest contralateral TMJ loads for MME models was 26.3% applied BF, and the highest was 72.3% applied BF (Table 6). Overall, the MME model versus MJL model predicted statistically significantly smaller loads for the ipsilateral TMJ (59.2 ± 17.0 versus 64.7 ± 15.1 % applied bite force, respectively, p<0.0001; Table 3, Figure 5) and contralateral TMJ (59.0 ± 17.3 versus 64.7 ± 15.1 % applied bite force, respectively, p<0.0001; Table 3, Figure 4). There were no statistically significant differences between MME and MJL models for number of ecologically viable bite-force angles (28.9 ± 13.3 versus 59.4 ± 64.4 respectively; p=0.25; Table 3, Figure 5).

Table 3: Summary of ipsilateral (IP) and contralateral (Cont) TMJ loads (Fc) predicted by minimization of joint loads (MJL) and minimization of muscle effort (MME) models for bilateral alloplastic implant subjects, including means, standard deviation (SD), standard (Std.) error, and

p-values for unilateral biting at different biting locations. “0” indicates the number of ecologically viable biting angles where the predicted lateral pterygoid muscle forces are zero.

| | | MJL | SD | MME | SD | Std. Error | p-value |
|---|---|---|---|---|---|---|---|
| Molar | "0" | 52 | 34 | 52 | 28 | 13 | 1.00 |
| | Fc IP | 32.7 | 12.8 | 33.0 | 12.6 | 0.65 | 0.21 |
| | Fc Cont | 27.1 | 13.2 | 40.7 | 13.5 | 0.73 | <0.0001 |
| Canine | "0" | 50 | 57 | 28 | 17 | 19 | 0.29 |
| | Fc IP | 58.9 | 13.9 | 53.1 | 15.1 | 1.14 | <0.0001 |
| | Fc Cont | 57.4 | 14.8 | 58.3 | 17.6 | 1.29 | 0.88 |
| Incisor | "0" | 59 | 64 | 29 | 13 | 24 | 0.25 |
| | Fc IP | 64.7 | 15.1 | 59.2 | 17.0 | 1.33 | <0.0001 |
| | Fc Cont | 64.7 | 15.1 | 59.0 | 17.3 | 1.34 | <0.0001 |

Table 4: Average ± standard deviation model-predicted ipsilateral (IP) and contralateral (CL) temporomandibular joint (TMJ) loads and CL lateral pterygoid muscle (LPM) forces for the ecologically viable biting angles at the right molar biting position for subjects with unilateral (U) and bilateral (B) TMJ implants. Loads and forces are expressed as % of applied bite-force. “n/a” indicates unrecorded data due to absence of LPM in bilateral TMJ replacement subjects.

| Right Molar Biting | | | | | | |
|---|---|---|---|---|---|---|
| Subject | Minimization of joint loads | | | Minimization of muscle effort | | |
| Implant | IP TMJ | CL TMJ | CL LPM | IP TMJ | CL TMJ | CL LPM |
| 1401 U | 31.6 ± 8.3 | 12.1 ± 3.7 | 16.0 ± 19.0 | 31.6 ± 8.3 | 12.1 ± 3.7 | 16.0 ± 19.0 |
| 1402 U | 31.5 ± 8.4 | 13.7 ± 5.1 | 8.5 ± 14.1 | 27.9 ± 12.3 | 31.5 ± 8.9 | 8.7 ± 12.7 |
| 1403 B | 51.3 ± 1.8 | 13.0 ± 2.2 | n/a | 66.4 ± 10.0 | 20.3 ± 15.1 | n/a |
| 1404 U | 41.1 ± 16.1 | 28.0 ± 10.9 | 69.8 ± 51.4 | 48.9 ± 32.1 | 58.9 ± 37.0 | 0.0 ± 0.2 |
| 1405 U | 26.4 ± 7.4 | 17.7 ± 6.1 | 16.3 ± 22.0 | 29.4 ± 12.1 | 23.9 ± 10.9 | 18.0 ± 20.5 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 1406 B | 34.0 ± 8.2 | 31.6 ± 11.8 | n/a | 23.9 ± 6.0 | 46.7 ± 8.3 | n/a |
| 1408 B | 43.1 ± 6.1 | 20.5 ± 4.9 | n/a | 38.0 ± 8.3 | 53.0 ± 5.0 | n/a |
| 1410 B | 65.8 ± 7.9 | 59.8 ± 7.2 | n/a | 65.6 ± 13.5 | 45.1 ± 17.1 | n/a |
| 1411 U | 27.5 ± 5.8 | 16.7 ± 5.4 | 15.8 ± 19.5 | 35.2 ± 13.0 | 17.5 ± 11.1 | 16.7 ± 17.6 |
| 1412 B | 26.4 ± 3.7 | 20.2 ± 4.3 | n/a | 34.8 ± 9.8 | 17.5 ± 12.6 | n/a |
| 1413 B | 38.5 ± 7.6 | 15.7 ± 6.4 | n/a | 40.0 ± 15.0 | 36.6 ± 13.4 | n/a |
| 1414 U | 38.8 ± 15.1 | 18.8 ± 8.6 | 12.5 ± 17.4 | 28.8 ± 13.6 | 49.1 ± 8.8 | 9.1 ± 13.3 |
| 1416 B | 44.7 ± 5.5 | 34.9 ± 6.2 | n/a | 53.2 ± 16.1 | 32.3 ± 14.7 | n/a |
| 1417 B | 23.1 ± 8.2 | 18.0 ± 10.4 | n/a | 26.3 ± 10.4 | 28.5 ± 8.7 | n/a |
| 1418 U | 40.4 ± 6.6 | 28.8 ± 10.1 | 16.6 ± 19.4 | 48.5 ± 18.2 | 27.5 ± 16.6 | 16.6 ± 15.8 |

Table 5: Average ± standard deviation model-predicted ipsilateral (IP) and contralateral (CL) temporomandibular joint (TMJ) loads and CL lateral pterygoid muscle (LPM) forces for the ecologically viable biting angles at the right canine biting position for subjects with unilateral (U) and bilateral (B) TMJ implants. Loads and forces are expressed as % of applied bite-force. “n/a” indicates unrecorded data due to no ecologically viable biting angles or absent LPM in bilateral TMJ replacement subjects.

| Right Canine Biting | | | | | | |
|---|---|---|---|---|---|---|
| Subject Implant | Minimization of joint loads | | | Minimization of muscle effort | | |
| | IP TMJ | CL TMJ | CL LPM | IP TMJ | CL TMJ | CL LPM |
| 1401 U | 54.7 ± 12.4 | 23.3 ± 7.9 | 30.2 ± 25.8 | 66.5 ± 16.8 | 47.4 ± 17.3 | 18.5 ± 18.5 |
| 1402 U | 46.8 ± 9.9 | 22.0 ± 7.2 | 12.5 ± 19.0 | 48.3 ± 11.8 | 42.4 ± 12.0 | 10.4 ± 14.9 |
| 1403 B | n/a | n/a | n/a | 76.3 ± 15.9 | 37.7 ± 15.9 | n/a |

| | | | | | | |
|---|---|---|---|---|---|---|
| 1404 U | 75.7 ± 16.3 | 49.5 ± 9.1 | 95.8 ± 73.4 | 106.0 ± 47.0 | 76.2 ± 46.9 | 0.0 ± 0.0 |
| 1405 U | 45.9 ± 7.6 | 37.7 ± 9.9 | 12.7 ± 20.7 | 51.7 ± 14.7 | 33.9 ± 14.8 | 19.5 ± 22.6 |
| 1406 B | 58.9 ± 10.7 | 56.4 ± 15.3 | n/a | 55.4 ± 8.3 | 58.2 ± 9.9 | n/a |
| 1408 B | 68.0 ± 11.2 | 41.6 ± 11.4 | n/a | 86.6 ± 16.7 | 73.7 ± 20.1 | n/a |
| 1410 B | 84.8 ± 15.7 | 77.8 ± 13.2 | n/a | 83.0 ± 19.7 | 51.8 ± 15.7 | n/a |
| 1411 U | 56.3 ± 10.4 | 43.6 ± 11.3 | 16.6 ± 16.5 | 68.0 ± 22.1 | 27.8 ± 21.0 | 21.1 ± 22.7 |
| 1412 B | 45.8 ± 9.1 | 35.8 ± 5.2 | n/a | 51.5 ± 17.6 | 25.7 ± 18.5 | n/a |
| 1413 B | 54.3 ± 11.7 | 30.1 ± 11.7 | n/a | 74.5 ± 18.6 | 47.9 ± 19.9 | n/a |
| 1414 U | 58.0 ± 20.3 | 46.3 ± 17.4 | 13.5 ± 14.8 | 67.7 ± 6.0 | 61.3 ± 6.8 | 7.6 ± 13.8 |
| 1416 B | 68.4 ± 10.8 | 54.7 ± 9.2 | n/a | 80.3 ± 20.4 | 37.3 ± 18.4 | n/a |
| 1417 B | 62.2 ± 12.6 | 58.3 ± 17.3 | n/a | 65.8 ± 15.4 | 53.6 ± 14.0 | n/a |
| 1418 U | 87.3 ± 13.6 | 72.7 ± 17.3 | 20.8 ± 16.6 | 102.4 ± 27.5 | 40.6 ± 25.5 | 27.5 ± 28.9 |

Table 6: Average ± standard deviation model-predicted ipsilateral (IP) and contralateral (CL) temporomandibular joint (TMJ) loads and CL lateral pterygoid muscle (LPM) forces for the ecologically viable biting angles at the right incisor biting position for subjects with unilateral (U) and bilateral (B) TMJ implants. Loads and forces are expressed as % of applied bite-force. “n/a” indicates unrecorded data due to no ecologically viable biting angles or absent LPM in bilateral TMJ replacement subjects.

| Right Incisor Biting | | | | | | |
|---|---|---|---|---|---|---|
| Subject Implant | Minimization of joint loads | | | Minimization of muscle effort | | |
| | IP TMJ | CL TMJ | CL LPM | IP TMJ | CL TMJ | CL LPM |
| 1401 U | 57.2 ± 14.9 | 28.9 ± 10.2 | 35.1 ± 28.6 | 76.8 ± 18.4 | 41.3 ± 17.0 | 19.0 ± 20.9 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 1402 U | 45.7 ± 15.9 | 32.7 ± 13.7 | 15.4 ± 19.6 | 62.7 ± 12.3 | 43.3 ± 13.9 | 9.7 ± 15.8 |
| 1403 B | n/a | n/a | n/a | n/a | n/a | n/a |
| 1404 U | 80.9 ± 16.3 | 53.4 ± 8.3 | 112.3 ± 81.5 | 119.6 ± 47.0 | 77.0 ± 49.9 | 0.1 ± 0.4 |
| 1405 U | 48.5 ± 9.0 | 42.6 ± 10.1 | 10.1 ± 18.4 | 61.4 ± 16.8 | 31.0 ± 14.5 | 20.1 ± 24.3 |
| 1406 B | 64.6 ± 11.9 | 62.4 ± 15.9 | n/a | 64.6 ± 10.0 | 58.9 ± 9.8 | n/a |
| 1408 B | 62.5 ± 16.4 | 55.6 ± 14.7 | n/a | 100.5 ± 21.1 | 72.3 ± 18.9 | n/a |
| 1410 B | 84.1 ± 17.7 | 79.3 ± 14.1 | n/a | 87.5 ± 21.9 | 52.7 ± 13.9 | n/a |
| 1411 U | 58.7 ± 12.9 | 47.6 ± 12.0 | 17.6 ± 20.8 | 75.4 ± 22.3 | 28.9 ± 19.1 | 18.1 ± 22.9 |
| 1412 B | 49.4 ± 10.1 | 39.1 ± 4.8 | n/a | 55.0 ± 19.2 | 26.3 ± 18.3 | n/a |
| 1413 B | 55.2 ± 13.9 | 33.8 ± 12.5 | n/a | 76.5 ± 18.9 | 44.6 ± 19.3 | n/a |
| 1414 U | 60.9 ± 20.4 | 49.9 ± 17.8 | 14.8 ± 15.5 | 73.8 ± 5.6 | 61.6 ± 6.8 | 7.7 ± 14.0 |
| 1416 B | 69.5 ± 12.4 | 58.6 ± 8.3 | n/a | 82.3 ± 22.6 | 36.7 ± 20.6 | n/a |
| 1417 B | 70.9 ± 13.8 | 67.8 ± 17.4 | n/a | 78.4 ± 19.5 | 51.1 ± 13.9 | n/a |
| 1418 U | 90.3 ± 14.3 | 75.8 ± 17.2 | 22.6 ± 16.5 | 106.4 ± 27.3 | 40.0 ± 24.6 | 26.9 ± 28.7 |

Figure 4: Means and standard deviations (SDs) of numbers of viable biting angles predicted by minimization of muscle effort (MME) vs minimization of joint load (MJL) models during unilateral right molar, canine, and incisor biting bilateral implant subjects. Standard deviations about mean values are indicated by vertical bars and * indicated significant difference defined by $p<0.05$.

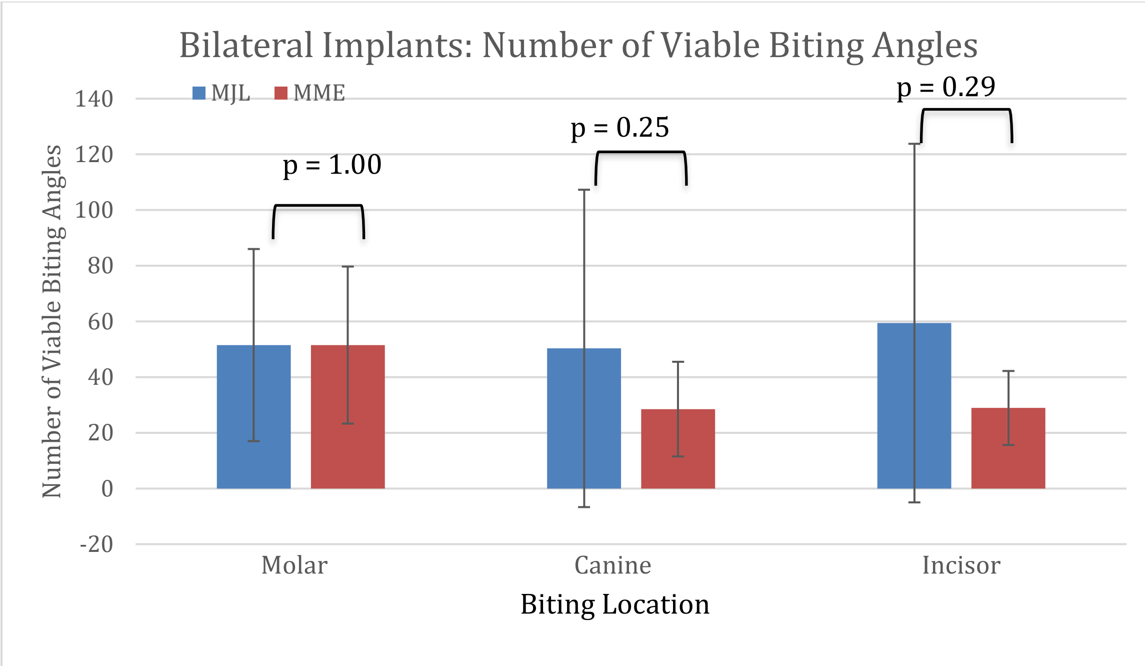
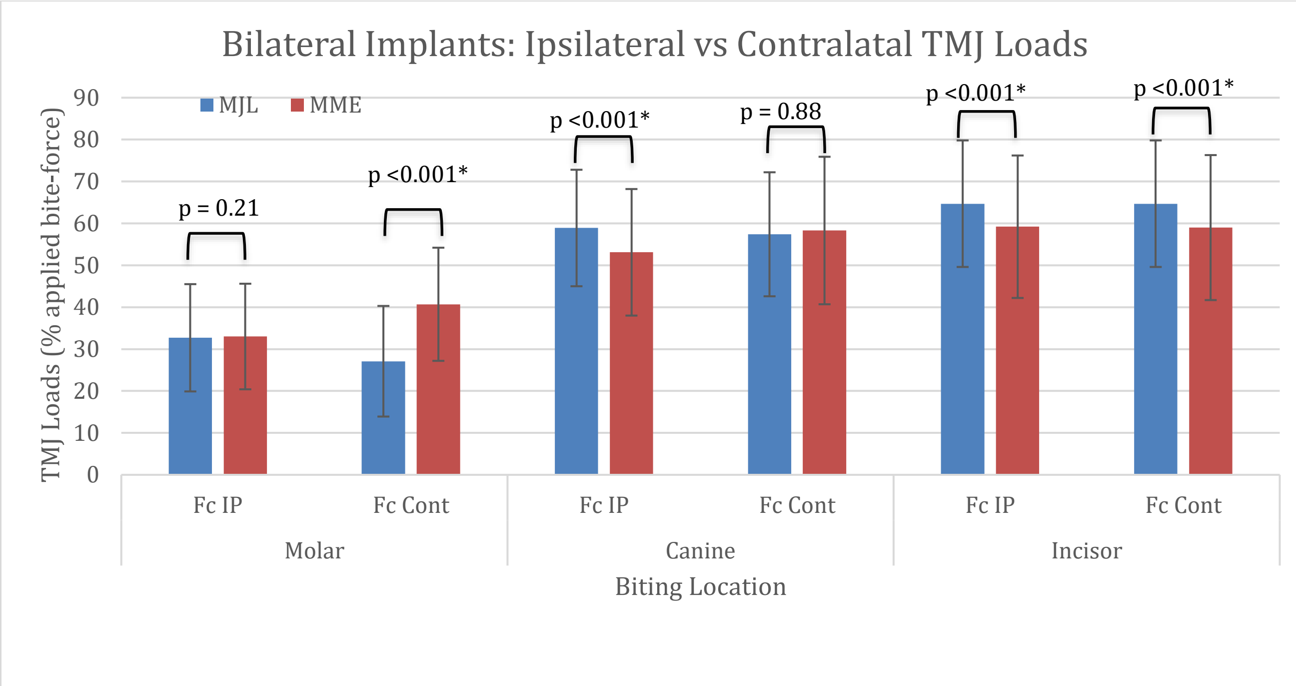



Figure 5: Means and standard deviations (SDs) of ipsilateral (IP) and contralateral (Cont) temporomandibular joint (TMJ) loads (% applied bite force) (Fc) predicted by minimization of muscle effort (MME) vs minimization of joint loads (MJL) models during unilateral right molar, canine, and incisor biting for bilateral implant subjects. Standard deviations about mean values are indicated by vertical bars and * indicates significance is defined by $p<0.05$.




5.3 Unilateral Implant Cases

The number of ecologically viable biting angles predicted by the numerical models varied between individuals for the three biting locations investigated (Table 7). For example, Subject 1401 had <196 (out of possible 324) from both models for molar, canine, and incisor biting. Whereas, the highest number of viable biting angles was <200 for Subject 1418 for all biting locations. TMJ loads and contralateral lateral pterygoid muscle forces were then calculated for each ecologically viable biting angles and averaged for each model (Table 8). Statistical analysis was conducted between MJL and MME models.

Table 7: Numbers of viable biting angles predicted by minimization of joint load (MJL) and minimization of muscle effort (MME) models for right molar, canine, and incisor biting in unilateral implant subjects. Mean numbers of biting angles for each model with results from between-model comparisons are shown, where * indicates significant difference.

| Subject | Biting Tooth | Status | MJL Viable Angles | MME Viable Angles | p value |
|---|---|---|---|---|---|
| 1401 | Molar | Unilateral | 71 | 71 | |
| 1402 | Molar | Unilateral | 88 | 254 | |
| 1404 | Molar | Unilateral | 88 | 294 | |
| 1405 | Molar | Unilateral | 232 | 262 | |
| 1411 | Molar | Unilateral | 176 | 225 | |
| 1414 | Molar | Unilateral | 207 | 276 | |
| 1418 | Molar | Unilateral | 189 | 200 | |
| | | AVERAGE | 150 | 226 | 0.045* |
| 1401 | Canine | Unilateral | 43 | 196 | |
| 1402 | Canine | Unilateral | 63 | 227 | |
| 1404 | Canine | Unilateral | 100 | 318 | |
| 1405 | Canine | Unilateral | 238 | 205 | |
| 1411 | Canine | Unilateral | 159 | 93 | |
| 1414 | Canine | Unilateral | 190 | 245 | |
| 1418 | Canine | Unilateral | 156 | 77 | |
| | | AVERAGE | 136 | 194 | 0.18 |
| 1401 | Incisor | Unilateral | 41 | 133 | |
| 1402 | Incisor | Unilateral | 67 | 191 | |
| 1404 | Incisor | Unilateral | 114 | 321 | |
| 1405 | Incisor | Unilateral | 226 | 137 | |
| 1411 | Incisor | Unilateral | 103 | 62 | |
| 1414 | Incisor | Unilateral | 190 | 238 | |
| 1418 | Incisor | Unilateral | 154 | 67 | |
| | | AVERAGE | 128 | 164 | 0.43 |

Unilateral Implants: Biting Location at Right Molar

For ipsilateral unilateral molar biting for unilateral alloplastic implant subjects, the smallest ipsilateral TMJ loads observed was 26.4% applied BF and highest was 41.1% applied BF for MJL models. The smallest ipsilateral TMJ loads observed for MME models was 27.9% applied BF and the highest was 48.9% applied BF. Whereas the smallest contralateral TMJ loads for MJL models was 12.1% applied BF, and the largest was 28.8% applied BF. The smallest contralateral TMJ loads for MME models was 12.1% applied BF, and the highest was 58.9% applied BF. The smallest contralateral LPM force for MJL models was 8.5% applied BF, and the largest was 69.8% applied BF. The smallest contralateral LPM force for MME models was 0.0% applied BF, and the largest was 16.7% applied BF (Table 4). Overall, the MME model versus MJL model predicted statistically significantly larger numbers of ecologically viable biting angles (226 ± 75.2 versus 150 ± 66.0 respectively, p=0.04; Table 8, Figure 6), larger ipsilateral TMJ loads (36.0 ± 20.5 versus 33.6 ± 11.8 % applied bite force respectively; p=0.01; Table 8, Figure 7), larger contralateral TMJ loads (35.0 ± 24.3 versus 19.9 ± 9.42 % applied bite force, respectively; p<0.0001; Table 8, Figure 7) and smaller contralateral lateral pterygoid muscle forces (11.2 ±16.1 versus 19.3 ± 28.2 % applied bite force, respectively; p<0.0001; Table 8, Figure 8).

Unilateral Implants: Biting Location at Right Canine

For ipsilateral unilateral canine biting for unilateral alloplastic implant subjects, the smallest ipsilateral TMJ loads observed was 45.9% applied BF and highest was 87.3% applied BF for MJL models. The smallest ipsilateral TMJ loads observed for MME models was 48.3% applied BF and the highest was 106.0% applied BF. Whereas the smallest contralateral TMJ loads for MJL models was 22.0% applied BF, and the largest was 72.7% applied BF. The smallest contralateral TMJ loads for MME models was 27.8% applied BF, and the highest was 76.2% applied BF. The smallest contralateral LPM force for MJL models was 12.5% applied BF, and the largest was 95.8% applied BF. The smallest contralateral LPM force for MME models was 0.0% applied BF, and the largest was 27.5% applied BF (Table 5). Overall, the MME model versus MJL model predicted statistically significantly larger ipsilateral TMJ loads (72.8 ± 34.4 versus 60.5 ± 20.0 % applied bite force, respectively; p<0.0001; Table 8, Figure 7), larger contralateral TMJ loads (52.0 ± 30.9 versus 45.7 ± 19.2 % applied bite force, respectively;

p<0.0001; Table 8, Figure 7), and smaller contralateral lateral pterygoid muscle forces (11.7 ± 18.7 versus 24.4 ± 38.4 % applied bite force, respectively; p<0.0001; Table 8, Figure 8). There were no statistically significant differences between numbers of ecologically viable biting force angles for MME versus MJL model (194 ± 84.7 versus 136 ± 70.1 % applied bite force, respectively; p=0.18; Table 8, Figure 6).

Unilateral Implants: Biting Location at Right Incisor

For incisor biting for unilateral alloplastic implant subjects, the smallest ipsilateral TMJ loads observed was 45.7% applied BF and highest was 90.3% applied BF for MJL models. The smallest ipsilateral TMJ loads observed for MME models was 61.4% applied BF and the highest was 119.6% applied BF. Whereas the smallest contralateral TMJ loads for MJL models was 28.9% applied BF, and the largest was 75.8% applied BF. The smallest contralateral TMJ loads for MME models was 28.9% applied BF, and the highest was 77.0% applied BF. The smallest contralateral LPM force for MJL models was 10.1% applied BF, and the largest was 112.3% applied BF. The smallest contralateral LPM force for MME models was 0.1% applied BF, and the largest was 26.9% applied BF (Table 6). Overall, the MME model versus MJL model predicted statistically significantly larger ipsilateral TMJ loads (85.6 ± 36.6 versus 63.8 ± 21.7 % applied bite force, respectively; p<0.0001; Table 8, Figure 7) and smaller contralateral lateral pterygoid muscle forces (10.4 ± 18.7 versus 28.7 ± 46.8 % applied bite force, respectively; p<0.0001; Table 8, Figure 8). There were no statistically significant differences between MME versus MJL models for numbers of ecologically viable bite-force angles (164 ± 93.4 versus 128 ± 66.1% applied bite force, respectively; p=0.43; Table 8, Figure 6) and contralateral TMJ loads (53.8 ± 34 versus 50.4 ± 19 % applied bite force, respectively; p=0.16; Table 8, Figure 7)

Table 8: Summary of ipsilateral (IP) and contralateral (Cont) TMJ loads (Fc) and contralateral lateral pterygoid muscle forces (ContLatPt) predicted by minimization of muscle effort (MME) and minimization of joint load (MJL) models for unilateral alloplastic implant subjects, including means, standard deviation (SD), Standard (Std.) error, and p-values for unilateral biting at different locations. "0" indicates number of viable biting angles for each biting location when the lateral pterygoid muscle forces equal 0. This is due to the inactivity of the muscle since its function is removed during surgery.

| | | MJL | SD | MME | SD | Std. Error | p-value |
|---|---|---|---|---|---|---|---|
| Molar | "0" | 150 | 66 | 226 | 75 | 30 | 0.04 |
| | Fc IP | 33.6 | 11.8 | 36 | 20.5 | 0.65 | 0.01 |
| | Fc Cont | 19.9 | 9.42 | 35 | 24.3 | 0.67 | <0.0001 |
| | ContLatPt | 19.3 | 28.2 | 11.2 | 16.1 | 0.87 | <0.0001 |
| Canine | "0" | 136 | 70 | 194 | 85 | 42 | 0.18 |
| | Fc IP | 60.5 | 20 | 72.8 | 34.4 | 1.01 | <0.0001 |
| | Fc Cont | 45.7 | 19.2 | 52 | 30.9 | 1.06 | <0.0001 |
| | ContLatPt | 24.4 | 38.4 | 11.7 | 18.7 | 1.26 | <0.001 |
| Incisor | "0" | 128 | 66.1 | 164 | 93.4 | 42.8 | 0.43 |
| | Fc IP | 63.8 | 21.7 | 85.6 | 36.6 | 1.13 | <0.0001 |
| | Fc Cont | 50.4 | 19 | 53.8 | 34.0 | 1.20 | 0.16 |
| | ContLatPt | 28.7 | 46.8 | 10.4 | 18.7 | 1.56 | <0.0001 |

Figure 6: Means and standard deviations (SDs) of numbers of viable biting angles predicted by minimization of muscle effort (MME) vs minimization of joint load (MJL) models during unilateral right molar, canine, and incisor biting for unilateral alloplastic implant subjects. Standard deviations about mean values are indicated by vertical bars and * indicates significant difference defined by $p<0.05$.

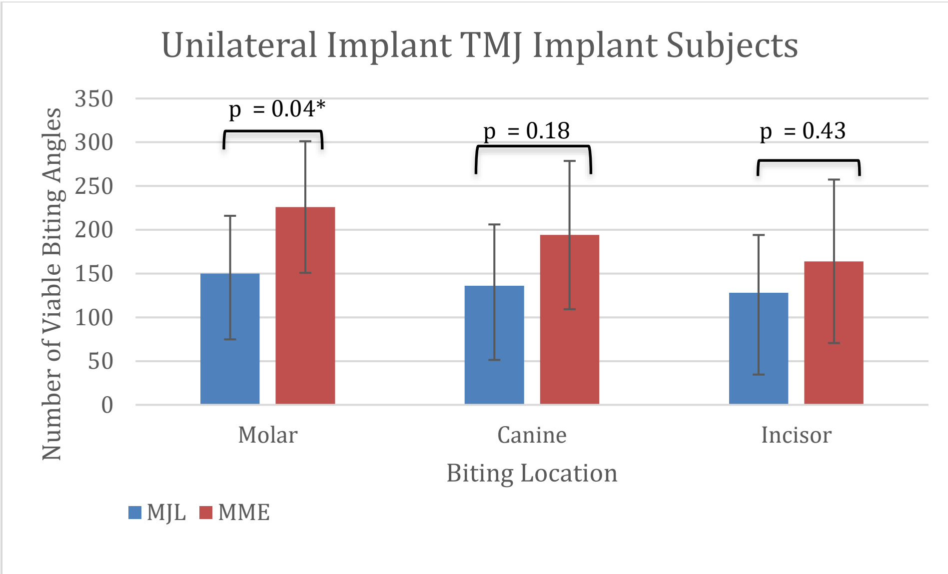



Figure 7: Means and standard deviations (SDs) of ipsilateral (IP) and contralateral (Cont) temporomandibular joint (TMJ) loads (% applied bite force) (Fc) predicted by minimization of muscle effort (MME) vs minimization of joint load (MJL) during right molar, canine, and incisor biting for unilateral implant subjects. Standard deviations about mean values are indicated by vertical bars and * indicates significance is defined by p<0.05.

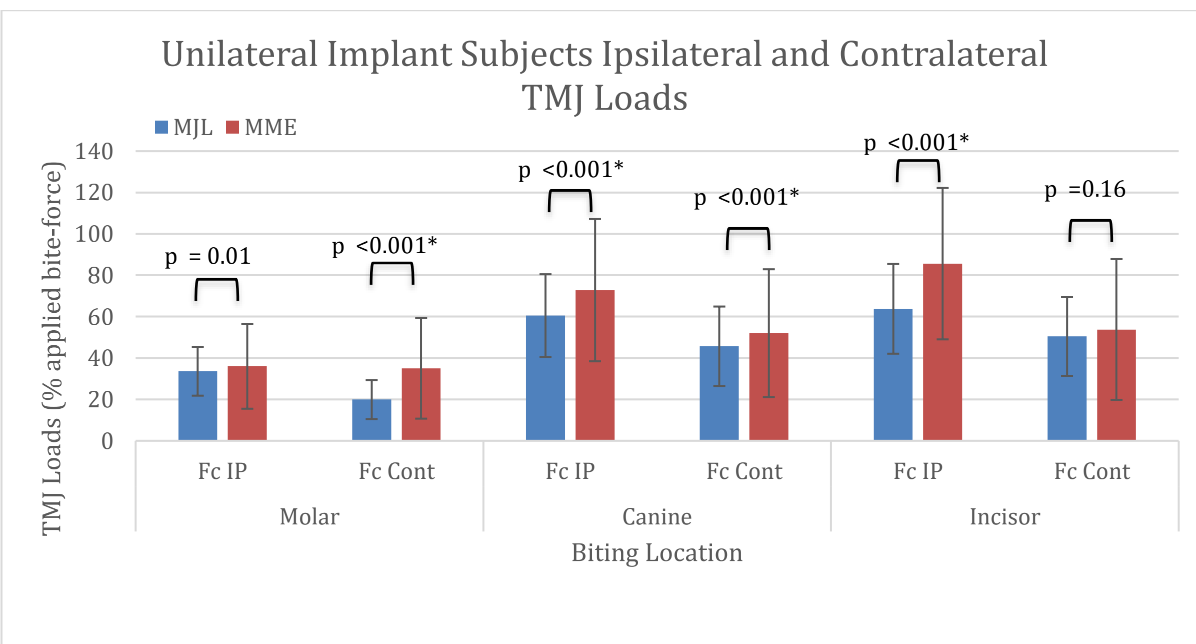
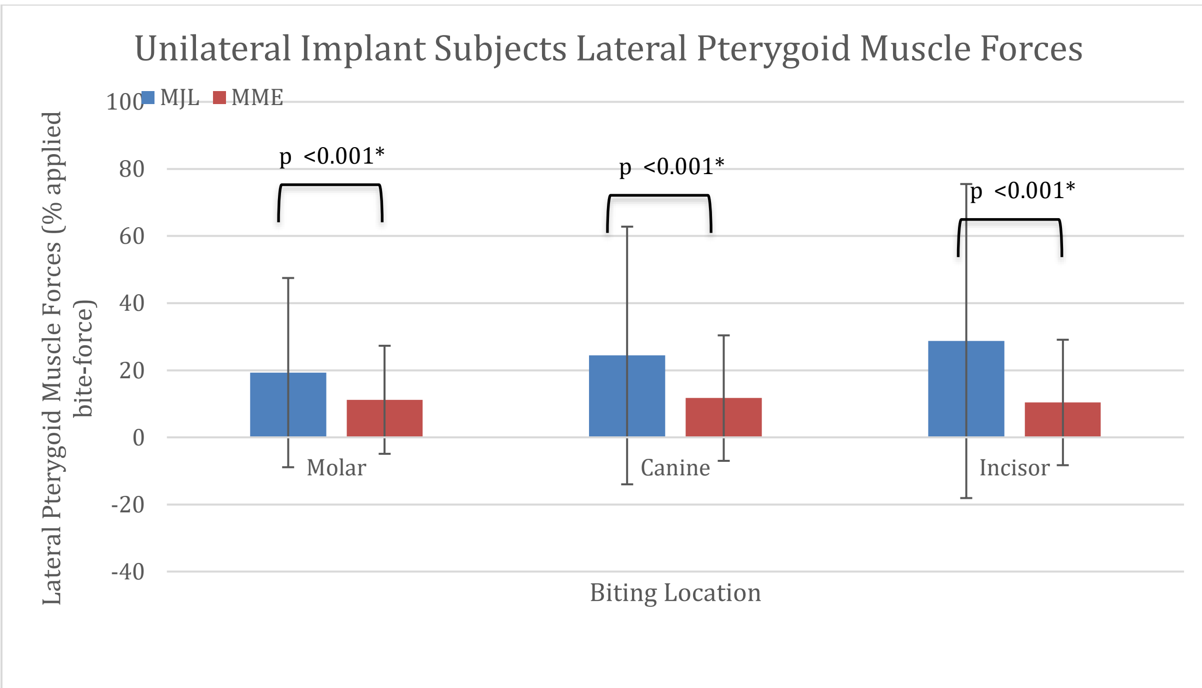


Figure 8: Means and standard deviations (SDs) of lateral pterygoid muscle forces (% applied bite force) predicted by minimization of muscle effort (MME) vs minimization of joint loads (MJL) models during unilateral right molar, canine, and incisor biting for unilateral implant subjects. Standard deviations about mean values are indicated by vertical bars and * indicates significance is defined by p<0.05.




## 6) Discussion

This pilot study examined the TMJ loads and neuromuscular systems of TMJ replacements with numerical modeling. Ultimately, the goal was to fill the void of absent loading data surrounding bilateral and unilateral TMJ implants. This study operated under the assumption that an increased number of ecologically viable biting angles would correlate with the neuromuscular objective that would most likely be used during biting for an individual.

The number of ecologically viable biting angles favored MME over MJL models at molar biting in unilateral implant subjects. This may indicate that MME predominates as the neuromuscular objective for biting at this location, which is similar to data observed in a healthy TMJ population.[26] However, when MME is the objective and TMJ loads are not minimized, this may lead to relatively larger TMJ forces used for the same functional tasks and could correspond to natural side TMJ mechanical fatigue, which could wear down a healthy articular disk. This can be concerning, as it can cause irreversible damage that would lead to a possible eventual need for TMJ replacement. The TMJ has a limited ability for repair, which increases the importance of reducing the amount of mechanical fatigue the joint experiences. Thus, the larger TMJ loads from operating with the objective of MME could be detrimental to the TMJs over the long term and could increase the risk of the individual needing to undergo another invasive and irreversible surgery to replace their natural TMJ and have bilateral TMJ replacements.

For canine and incisor biting for unilateral TMJR subjects, neither MME nor MJL models had a significantly greater number of ecologically viable biting angles. This finding is also similar to previous studies, which report that the more anterior the biting location, the more individual variation is observed between MME and MJL models.[12] It has also been found that different uses of neuromuscular objectives can correspond to different eminence shapes. It is likely that the individuals in this study have variability in eminence shapes on the natural TMJ side due to the different joint load directions and muscle recruitment between individuals.[21] However, if stresses of long duration, high frequency, or abnormally high magnitude can produce damaging changes in the joint, it becomes more important to provide low TMJ loads to protect the prognosis of the TMJ replacements. It may also be possible that the neuromuscular objectives of an individual can change over time, either due to injury or other anatomical changes. This may potentially lead to greater TMJ loads, especially on the replaced TMJ side due to the accompanying loss of the lateral pterygoid muscle. With the loss of a muscle's function, it has been previously reported that other muscles can act in conjunction with each other to achieve a similar function.[27] It has also been considered that the mechanism of feedback and central pattern generator control of muscle recruitment probably relies on periodontal ligament receptors, with these receptors organized into fields to detect general sensitivity. [28] If these concepts apply for the muscles of mastication, this may also lead to changes in neuromuscular objective and overall muscle activity to keep the joint and muscles functioning.

For right molar biting for unilateral implant subjects, the results from the MME model showed significantly higher loads in ipsilateral and contralateral TMJs compared to the MJL model. This may be expected and supported by MME's objective for less muscle exertion at the potential "cost" of greater TMJ loads than the MJL objective function. Additionally, the results are validated by a past study that reports MME has led to an increase in contralateral TMJ loads in those with healthy TMJs.[29] According to these results, then many unilateral implant replacements can eventually cause the non-affected TMJ to experience increased forces which could lead to breakdown of the joint. Thus, the data presented by this study of increased TMJ loads in the contralateral TMJ for most biting locations can be problematic for the long-term prognosis of the joint, and lead to a possible need for replacement. As such, this may justify why bilateral implant replacements are more prevalent than unilateral, and that those with unilateral replacements may have to have their natural TMJ replaced in the future.

It may also be possible that some of the subjects used in this study operated under a predominate MME objective prior to joint replacement surgery. If these individuals continue to primarily use this neuromuscular objective after the unilateral implant was placed, this could result in a continuation of increased ipsilateral TMJ loads (on the replaced joint). This may lead to further degradation of the artificial joint, and a possible revision surgery in the future to alleviate material failures. [30]

Significantly lower lateral pterygoid muscle forces were predicted by the MME model compared to MJL model for molar, canine, and incisor biting in unilateral implant replacement subjects. This was expected and is supported by the objective of MME models. Due to the function of only one lateral pterygoid muscle, it may be possible that asymmetric activation of muscle vectors can increase joint loads due to the amount of reciprocal lateral movement needed by other muscles during biting movements. This may be evidenced by past literature which describe that the opening pattern of those with unilateral replacements demonstrate increased deviation upon opening and closing.[25] It has been thought that the lateral pterygoid muscle is the main muscle involved with translation of the condyle, as evidenced that the lateral pterygoid muscle is the most active during the actions of jaw opening and mandibular protrusion against resistance.[12] However, the loss of the lateral pterygoid and the anatomy of the new artificial joint prevent translational movement.[31] Since biting at a canine or incisor may involve more protrusive movements, the remaining muscles of mastication may rely on different neuromuscular mechanics to achieve the same function by operating as a unit to achieve this similar goal.[32] Incisor biting is thought to be the most protrusive movement of the mandible, and thus led to similar TMJ loads for both MME and MJL models. A previous study showed that upon jaw opening, natural TMJs in unilateral replacements demonstrated more anterior movement to maintain a normal mandibular range of motion.[25] This may indicate that increased protrusive vectors on the natural condyle are needed to maintain normal function of the mandible. Additionally, canine and incisor biting may also utilize more lateral movement than molar biting. This can also lead to increased activation of other muscles, like suprahyoid muscles, to substitute for the nonfunctioning ipsilateral lateral pterygoid muscle.[31] Consequently, the remaining contralateral lateral pterygoid muscle may have increased activation in conjunction with the other remaining muscles of mastication to substitute for the detached ipsilateral lateral pterygoid muscle, or there may be a decrease in the protrusive function of the individual.[25]

For bilateral implant subjects, increased TMJ loads for molar biting may indicate similar reasons as the unilateral replacement data for the increased contralateral TMJ loads for MME compared to MJL models. However, for canine biting for bilateral TMJR subjects, there were significantly higher ipsilateral TMJ loads predicted by MJL compared to MME models. This was not expected and could be potentially harmful for bilateral implant subjects. This is because the MJL model is typically thought to have lower mechanical TMJ loads than MME. It is unknown if the implant joint can withstand heavier joint loads than a natural TMJ. However, the concern persists as joint loads increase there can be increased mechanical fatigue of the new joint, and raise the possibility of a revision surgery. It has also been thought that if the effective eminence shape in an individual is inconsistent with MJL, then that individual may be at increased risk for degenerative TMJ changes due to increased forces during jaw loading conditions. Thus, protection of the articular disc is of upmost importance due to its function as a source of lubrication and stress distribution between highly incongruous anatomical structures. [19] This is especially important for the eminence crest, where a previous study has shown that this area is the least consistent with MJL and subject to the most TMJ cartilage degeneration.[19] This may apply to Subject 1403, who recorded zero ecologically viable biting angles at incisor biting for both models, and canine biting for MJL models. It may possible that this individual's unique variation in anatomy and function may prohibit biting at these locations, and thus the joints may not be protected from loads under MJL or MME models during anterior biting. While it has been shown that TMJ replacement failure typically occurs at the site of screw placement, it remains to be seen if an artificial condyle experiences similar effects.[33] Further examination and studies are needed to test the long-term durability of the implanted joints and the effects of neuromuscular function on their long-term prognosis.

For incisor biting for bilateral TMJR subjects, there was an increase in TMJ loads for both the ipsilateral and contralateral TMJs for MJL compared to MME models. This may be due to the amount of protrusive movement involved with incisor biting, similar to the unilateral TMJR subjects' results. In a previous study, it has been found that the more relatively posterior positioned the condylar position, the more optimized MJL models become. In particular, it was found that the MJL model remains stable up to 3 mm of protrusion, which can be within the range of incisor biting.[19] Thus, it may be concerning that bilateral TMJR individuals operating under a predominate MJL model can experience greater TMJ loads which would be normally optimized during incisor biting, The reason for this is unknown, but may be related to changes in activation for the muscles of mastication. Specifically, it may be possible that the inactivity of both lateral pterygoid muscles could lead to differences in neuromuscular activity, and it is unknown if changes in neuromuscular activity are helpful or harmful in decreasing TMJ loads. Additionally, another reason for concern is that the predicted MJL loads may underrepresent the *in vivo* loads of an individual. A previous study also indicates that predicted muscle output for incisor biting underestimates the real output that would be observed in an individual.[12] This could be detrimental because the increase in joint loads may be even higher than what would be predicted for incisor biting.

Results from the bilateral subjects also support that TMJ loads may vary depending on biting location and angulation. This aligns with data from a previous study where individual variations in the patterns and magnitude of predicted muscle forces were observed.[29] While the amount of each muscle activation is unknown, healthy TMJ data may allow possible interpretation for these results. Past studies found that the mix of muscle and TMJ forces depends on anatomy and the specific bite-force angle applied to the biting location.[29] The ipsilateral masseter, medial pterygoid, and lateral pterygoid muscles showed increased activation during buccal directed forces. Conversely, the ipsilateral anterior temporalis muscle showed an increase for lingual directed forces, with a crossover occurring at vertical biting. [29] If this is true for the individuals in this study, then the loss of lateral pterygoid muscle function may be compensated for by the ipsilateral medial pterygoid, ipsilateral masseter, and contralateral temporalis muscles.[34,35] However, it should also be noted that those with TMJ replacements demonstrate lesser biting forces than those with healthy TMJs, due to increased hypotrophy of the remaining muscles and increase in scar tissue.[31,36,37] This increases importance for future analysis, as a future prospective study can examine any correlations between healthy and replaced TMJs.

It may also be possible that since most ecologically viable biting forces occur for healthy TMJs with the MME model, the bilateral implant subjects may have relatively lower TMJ loads if they are operating under the MME model. This may be indicative of the loss of function of both lateral pterygoid muscles, as a bilateral loss of function can be symmetrically compensated for by the remaining muscles of mastication. It was previously seen that the stress magnitudes in articular tissues are proportional to the condylar load magnitudes and inversely proportional to the area bearing the load. If the load bearing area is increased in implanted subjects, the TMJ loads may be dispersed over a greater surface area and lead to less mechanical wear on the joint.

It has been seen that bilateral and unilateral implants demonstrate a similar opening pattern, with a decreased range of motion when compared to healthy TMJs.[25] Furthermore, lateral movements, protrusion, and overall rotation remain less for TMJ replacements when compared to healthy TMJs.[38,39] Even with decreases in forces and movement for individuals with TMJ replacements, the duration, frequency, and concentration of work on the mechanical surfaces may still cause detrimental wear to their artificial joints. Further inspection into the muscles of activation would be needed, as well as further examination into the anatomy of the artificial joint, and measuring of the frequency of jaw muscle use. This can help mitigate the high complication rate of TMJ replacements, which has been reported to be as high as 56%.[40]

Future studies can expand on this pilot study comparing the TMJ stresses and lateral pterygoid muscle activity in unilateral and bilateral implant subjects prospectively. TMJ compressive stresses relate to the magnitude of jaw loading behaviors, and a more accurate analysis of the frequency of jaw loading behaviors and durations of jaw muscle activities could be measured as well using ambulatory electromyography (EMG). Future studies can gather EMG data to verify the predicted data from numerical modeling. These data can help to further examine the numerical modeling relation to individual angulations and locations. Additionally, the numerical modeling data gathered from this study can be combined with dynamic stereometry data, which involves using CBCT data and jaw tracking data, linking these via a common reference system.[25] This allows a visual representation, like an animation of how the components of an individual TMJ move in relation to one another, that allows measurement of the size and movement of the stress-field (minimum contact distance between joint tissues) during jaw functions. For example, dynamic stereometry can show how the condyle rotates and translates in a specific joint during different jaw movements. This can provide a more comprehensive analysis of jaw loading behaviors through qualitative and quantitative ways to compare contact relationships and mechanics in natural TMJs versus TMJRs. A more comprehensive analysis of jaw loading behaviors could also include both numerical modeling and dynamic stereometry for the calculation of energy densities (measure of the mechanical work input per volume of disc cartilage between the condyle and the temporal eminence loading areas, $mJ/mm^3$) and jaw muscle duty factors (muscle activity/total recording time, %), as described by a previous study.[41] A mechanobehavior score (MBS) can then be calculated as a product of the magnitude and frequency of jaw loading behaviors ($MBS=ED^2xDF$, $(\frac{mJ}{mm^3})^2\%$). This could be used in a prospective study with the goal of examining if high MBS scores lead to earlier breakdown of the TMJ, and lead to a possible earlier need for TMJ replacement.

A limitation of this study was that numerical modeling is a simplification of the joint and muscle forces. Furthermore, symmetry was also assumed to run the numerical modeling. However, due to the anatomy of the patients and the etiologies that may be associated with TMD, asymmetries may be present in subjects' anatomies. There may be left and right asymmetries and articular eminence anatomy variability, which may be similar to what was observed in those with disc displacement.[19] This study also had limitations because it was retrospective and the accuracy of the model-predicted TMJ eminence shapes and muscle forces could not be validated by measuring these in each subject. A small sample size of subjects made the comparisons between sexes difficult, and pre-surgical CBCTs were unavailable. It is possible that subjects that receive TMJ implants may have anatomical and neuromuscular predispositions for higher TMJ mechanical fatigue, and the replacement of the joint does not change their preexisting neuromuscular functioning. These shortcomings can be addressed through a continuation of this pilot study with the recruitment of more subjects with EMG recordings preand post-surgery to assess correlations and possible changes in TMJ loading. This would be important, as it can allow examination of if and when changes in neuromuscular activation occurs. It may be possible that the longer duration after the replacement surgery may lead to more time for the remaining muscles of mastication to adapt to their new function. MBS scores can also be calculated to encompass both the magnitude and frequency of jaw loading behaviors as described in previous literature.[41,42] While it may be challenging to conduct a longitudinal prospective study and find qualified subjects, especially for unilateral implant replacements due to the rarity of the procedure, the importance of additional studies are paramount in understanding the biomechanics of TMJ replacements.

## 7) Conclusions

Comparisons between MME and MJL models in a bilateral TMJ replacement population showed:

- No significant difference for number of ecologically viable biting angles; therefore, Hypothesis 1A was refuted.
- Ipsilateral TMJ loads were not significantly different for molar biting but were significantly smaller during canine and incisor biting. Therefore, Hypothesis 1B was refuted.
- Contralateral TMJ loads were significantly larger during molar biting, which supported Hypothesis 1C. However, contralateral TMJ loads were not significantly different during canine biting and were significantly smaller during incisor biting, which refuted Hypothesis 1C.

Comparisons between MME and MJL models in a unilateral TMJ replacement population showed:

- Larger numbers of ecologically viable biting angles for biting at all three positions, although this was only significantly larger during molar biting, so Hypothesis 2A was supported for molar biting.
- Larger ipsilateral and contralateral TMJ loads for biting at all three positions and these were significantly larger for all except for the contralateral TMJ during incisor biting. Thus, Hypotheses 2B and 2Ci were mainly supported.
- Significantly lower lateral pterygoid muscle forces for biting at all three positions, so Hypothesis 2Cii was supported.

Thus, bilateral and unilateral TMJ replacement individuals may exhibit increased TMJ loads depending on the operating neuromuscular objective and biting location. Additional studies are needed to verify the results of this pilot study.

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# Appendices

## Appendix A: Institutional Review Board Forms

### Notification of Not Human Research Determination

**To:** Jeff Nickel

**Link:** STUDY00025245

**P.I.:** Jeff Nickel

**Title:** Mechanics of Temporomandibular Joint Alloplastic Implants

**Description:** The committee reviewed this submission and assigned a determination of Not Human Research. For additional details, click on the link above to access the project workspace.

**Oregon Health & Science University**
Research Integrity Office
3181 SW Sam Jackson Park Road - L106RI
Portland, Oregon 97239-3098
(503)494-7887 irb@ohsu.edu

**VA Portland Health Care System**
Research and Development Service
3710 SW U.S. Veterans Hospital Road - R&D
Portland, Oregon 97239-2999
(503)273-5125 pvamc-irb@va.gov

### Request for Determination Form

OREGON HEALTH & SCIENCE UNIVERSITY

Research Integrity Office
Mail Code L106-RI
Portland, Oregon 97239-3098
Phone: 503.494.7887
Fax: 503.346.6808

Version 1.1
Updated 5.28.2019

PI Name: NICKEL, Jeffrey          eIRB: ______

Project Title: A Pilot Study of Contact Mechanics of Temporomandibular Joint Alloplastic Implants

***INSTRUCTIONS***

***Use this form when:***

- *You are not sure if your project requires IRB oversight, or*
- *You would like a formal determination from the IRB as to whether the project requires IRB oversight, or*
- *You are conducting research with samples or data that are not individually identifiable to the research team, but the project involves genetic research.*

***Complete the entire form unless your response to a particular question instructs you to skip ahead.***

***Upload the form to the eIRB in place of, or in addition to, a protocol.***

***If your project meets the definition of Research (Section 1), includes Human Subjects (Section 2), and OHSU is Engaged in the research (Section 3), you should submit a new study with a full protocol instead of submitting this form.***

Section One – Research

**Research** is a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**.

☒ This project is research. → **Skip to Section Two.**

☐ I don't think this project is research, or I am not sure. → **Answer the questions below:**

1.1. Is this a case study of a single patient or a case series of three or fewer patients? If so, describe. *Note: Inclusion of more than three patients is generally considered research.*

1.1.1. If yes, will it involve testing of biological specimens for non-clinical purposes? If so, describe.

1.2. Is this a quality improvement/quality assurance, program evaluation, or public health project? If so, explain. (*These types of activities may not meet the definition of research. See the Quality Improvement or Research? Quick Guide on the IRB Policies and Forms web page for more information.*)

1.3. Will individuals, groups, or institutions/organizations be randomized or otherwise designated to receive different interventions that will be compared? If so, explain. *Note: Randomization or comparison against a control tends to indicate a systematic investigation, which may be research.*

1.4. What are you hoping to learn from this project? Will the knowledge you gain be generalizable to other contexts or situations?

1.5. What will you do with the results? *Note: Whether you intend to publish does not itself determine whether your project is research.*

## Section Two – Human Subjects

A **human subject** is a **living individual** about whom an investigator conducting research obtains:

- Data through **intervention** or **interaction** with the individual, or
- **Identifiable private information** (*information is identifiable if the identities of the subjects are* ***readily ascertainable*** *to the investigator, either directly or indirectly through a coding system*)

☐ This project involves human subjects. → **Skip to Section Three.**

☐ This project is not research. → **Skip to Section Five.**

☒ This project is or may be research, but I don't think it involves human subjects, or I am not sure. → **Answer the questions below:**

2.1. Are all of the subjects in the research known to be deceased? *Note: Decedents are not considered human subjects.*
**Subjects are alive.**

2.2. Describe the data and/or specimens to be used for the project.
**We plan to use cone beam computed tomography (CBCT) derived images which have all the meta data removed.**

2.3. Are all of the data and/or specimens pre-existing or going to be collected for some purpose other than this project? **YES, pre-existing**

**If yes:**

2.3.1. What is the original source of the data and/or specimens? How will they be provided to the investigators?
**The original source of the data are existing CBCT DICOM files from a data bank at the University of Zurich.**

2.3.2. Are all of the data and/or specimens de-identified such that none of the investigators working on the project could readily ascertain the identities of the subjects, either directly or indirectly through a coding system? Explain. *Note: If investigators have a way of identifying individual subjects, the project likely involves human subjects.*
**All the CBCT DICOM files that will be used in this project have been stripped of meta data. There is no mechanism to ascertain identities.**

**If no:**

2.3.3. How will the investigators (at OHSU or another institution) collect the data and/or specimens? *Note: If investigators will intervene (including both physical procedures and manipulations of the subject or subject's environment) or interact (including all forms of communication or interpersonal contact) with individuals in order to collect information about them, this project likely involves human subjects.*

## Section Three – Engagement in Research

OHSU is **engaged** in a research project if **OHSU employees, students, or other agents** do any of the following:

- **Intervene or interact** with human subjects for the research,
- Obtain **individually identifiable private information** about human subjects for the research, or
- Obtain the **informed consent** of individuals for participation in the research.

There are exceptions for certain recruitment activities and for performance of some protocol-required procedures as a commercial service or on an emergency or temporary basis.

☐ This project is research and OHSU is engaged in the research project. → **Skip to Section Four. If the project also involves human subjects, STOP and complete a new study submission.**

☒ This project is not research, or it is research that does not involve human subjects. → **Skip to Section Four.**

☐ This project is or may be human research, but I don't think OHSU is engaged in the project, or I am not sure. → **Answer the questions below:**

3.1. Describe OHSU's and any other institutions' roles in the research, including which investigators will interact with human subjects, obtain subjects' identifiable private information, or obtain informed consent for the research. *Note: If OHSU investigators will do any of these things, OHSU is probably engaged in the research.*

3.2. Will OHSU employees, students, or agents obtain ***only de-identified data or specimens*** (that is, the data/specimens are completely anonymous or the data/specimens are coded and OHSU investigators will not have access to the key to the code)? *If so, OHSU is probably not engaged in the research.*

3.3. Will OHSU employees, students, or agents ***only release pre-existing data or specimens*** to investigators at another institution (that is, OHSU investigators will have no part in testing of specimens or data analysis)? *If so, OHSU is probably not engaged in the research.*

## Section Four – Oregon Genetic Privacy Law

**Genetic Research** is research using human DNA samples, genetic testing, or genetic information. **Genetic information** is information about an individual or the individual's blood relatives obtained from a genetic test. For more details, see our Genetic Research web page.

☒ This project does not involve genetic research. → **Skip to Section Five.**

☐ This project involves genetic research. → **Answer the questions below:**

4.1. The specimens/data are (check one):

☐ Anonymous (meaning the identity of the individuals or their blood relatives cannot be determined by anyone, including through a code or other means of linking the information to a specific individual)

☐ Coded (meaning that some link exists that would allow re-identification of the data/specimens, even if the OHSU investigators will not have access to it)

*NOTE: If the specimens or data are individually identifiable, you are likely conducting human research. **STOP and complete a new study submission.***

4.2. For coded data/specimens, describe the method of coding and steps you will take to ensure data security. (See HRP-461 WORKSHEET – Oregon Genetic Research – Anon-Coded on the IRB Policies and Forms web page for specific criteria regarding coded genetic research.)

4.3. In Oregon, the individuals who originally provided the data/specimens must have consented to genetic research, or you must verify that the individuals have not "opted out" of genetic research at OHSU (see our Genetic Research web page for more information). Indicate how your project complies with this requirement (check one):

☐ Subjects consented for this project specifically
☐ Subjects consented for future genetic research generally
☐ Subjects did not consent, but we will exclude any subjects who opted out of coded/anonymous genetic research – Describe your plan to verify opt-out status:

☐ None of the specimens/data are from subjects in Oregon
☐ Other – Describe:

## Section Five – HIPAA

**Protected Health Information (PHI) = health information + one or more of the 18 identifiers.** See our HIPAA and Research web page for more details.

Even if your project is not human research or OHSU is not engaged in the research, you may have requirements under HIPAA if you are using, obtaining, or releasing/disclosing PHI.

All HIPAA forms linked below are available on the IRB Policies and Forms web page. Upload them on the ***Recruitment, Consent and Authorization*** page of the IRQ.

☒ This project does not collect any health information. → **Stop here, no HIPAA requirements.**

☐ This project collects health information, but does not involve access to or recording of any of the 18 individual identifiers, and therefore does not involve PHI. → **Stop here, no HIPAA requirements.**

☐ Investigators on this project will only have access to data/specimens already at OHSU and that meet the definition of a Limited Data Set *(no direct identifiers such as name, MRN, initials, or street address, but* *may include dates and geographic subdivisions smaller than a state*), and the Limited Data Set will NOT be sent outside OHSU. → **Stop here, no additional HIPAA requirements.**

☐ PHI will be accessed, used, and/or sent outside OHSU, but not for research purposes (examples: case reports, QA projects, public health reporting). → **Stop here, comply with OHSU HIPAA policies for non-research activities.**

Investigators who wish to publish a case report that is not completely de-identified to the standards of the HIPAA Privacy Rule (contains any of the 18 individual identifiers, photos or illustrations that contain identifiable features such as pictures of a patient's face or tattoos), must first obtain each patient's authorization. In the case of deceased individuals, consent might be obtained from the next of kin.

Authorization to Use and Disclose Protected Health Information Form

☐ PHI will be accessed only for purposes preparatory to research, such as preparing a protocol or compiling a recruitment list, and the PHI will not be released outside OHSU. → Prep to Research **form required.**

☐ This project is research and will collect and use PHI, but all subjects are known to be deceased. → Decedents Representation **form required.**

☐ This project is research and will collect PHI, but only for the purpose of preparing a Limited Data Set to send outside OHSU. → Data Use Agreement **required.**

☐ This project is research and OHSU will receive a Limited Data Set from another institution for this project. → **Data Use Agreement may be required by the other institution. If so, submit DUA for review and signature to the office that handled the contract for the project (if there was one, or to OPAM if there was no contract). DUAs for OPAM should be directed to Contract-triage@ohsu.edu.**

☐ This project is research, PHI will be accessed, used, and/or sent outside OHSU for purposes of this study, and none of the above options apply. → **You most likely need a** Waiver or Alteration of Authorization**. Any disclosures outside OHSU must be tracked in the** Accounting of Disclosures System**.**

☐ Other – Explain:

Appendix B: Geometry Landmarking Protocol

1. Open InViVo Anatomage software

2. Navigate to “3DAnalysis” tab and select “Create Tracing”

3. Landmarks are customized under “Tracing Tasks” tab for this project

    a. Right condylion (supero-anterior-most point)
    b. Left condylion (supero-anterior-most point)
        i. *This is best visualized via axial clipping using “Teeth” filter to locate superior-anterior-most point.*
    c. Left mandibular central incisor (midpoint of incisal edge)
    d. Left mandibular canine (cusp tip)
    e. Left mandibular first molar (mid-buccal point)
    f. Left masseter muscle “insertion”
        i. *Centroid of muscle attachment to the lateral surface of the inferior ramus, anterior to the angle of the mandible.*
    g. Left masseter muscle “origin”
        i. *Centroid of muscle attachment to the zygomatic arch,inferior to the maxillary process of the zygomatic bone.*
    h. Left medial pterygoid muscle “insertion”
        i. *Centroid of muscle attachment to medial surface of the inferior ramus, anterior to the angle of the mandible*
    i. Left medial pterygoid muscle “origin”
        i. *Centroid of muscle attachment to the medial surface of the lateral pterygoid plate.*
        ii. *This is best visualized via axial clipping using the “Bone” filter*
    j. Left lateral pterygoid muscle “insertion”
        i. *Centroid of muscle attachment to the medial-tending concavity of the condylar neck of the mandible.*
    k. Left lateral pterygoid muscle “origin”
        i. *Centroid of muscle attachment to the anterolateral surface of the lateral pterygoid plate.*
    l. Left anterior temporalis muscle “insertion”
        i. *Centroid of muscle attachment to the lateral surface of the coronoid process of the mandible.*
    m. Left anterior temporalis muscle “origin”
        i. *The field of view on most CBCT images used does not extend to temple area; therefore, landmark positioned posterior to the orbit to estimate direction of muscle pull from “insertion” to “origin”.*
    n. Left anterior digastric muscle “origin”
        i. *Point above the superior-lateral surface of the hyoid bone lateral to the base of the lesser horn, representing the fibrous loop which the intermediate tendon passes through. The intermediate tendon links anterior and posterior digastric muscles.*

   o. Left anterior digastric muscle "insertion"
      i. *Centroid of muscle attachment to the left digastric fossa of the mandible*
4. "Coord_sys Widget" used to establish coordinate planes
   a. Axial (x-z): best fit with mandibular occlusal plane intersecting incisor, canine, and molar landmarks
   b. Coronal (y-z): plane that intersects right and left condylions (superoanterior points of condyles) and perpendicular to axial plane
   c. Midsagittal (x-y): plane that bisects inter-condylion distance and perpendicular to axial and coronal planes
      i. Note: Origin of x-y-z planes is mid-point between right and left condylions
5. Click on "Visual Preferences" tab and display grid planes at 25% opacity
6. Capture screenshots from postero-anterior (PA), axial, and left lateral views of CBCTs with landmarks and coordinate planes labelled.
7. Save screenshots in designated folder
   a. Name .jpg files according to subject identification and view (ie. MMG###PA, MMG###Axial, MMG####Lat, for PA, axial, and left lateral views respectively)
8. Screenshot files ready to be accessed in separate software program to generate geometry files.

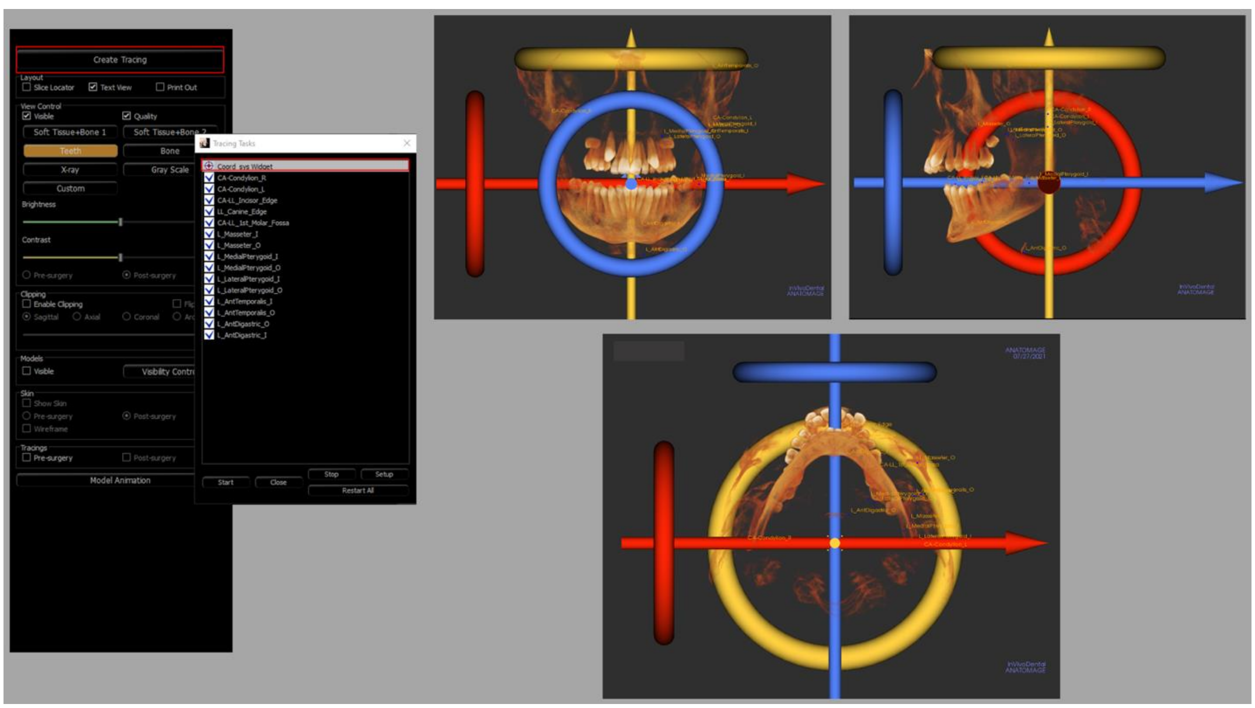


Figure 1: Coordinate planes established using coordinate system widget (Coord_sys_Widget) on InVivo Anatomage. Using the 3DAnalysis feature, cone beam computed tomography (CBCT) calibrated such that the following coordinate planes established: axial (x-z) plane along best fit of

mandibular occlusal plane (blue line), coronal (y-z) plane intersecting right and left condylions and perpendicular to occlusal plane (red line), and midsagittal (x-y) plane bisecting inter-condylion distance and perpendicular to axial and coronal planes.

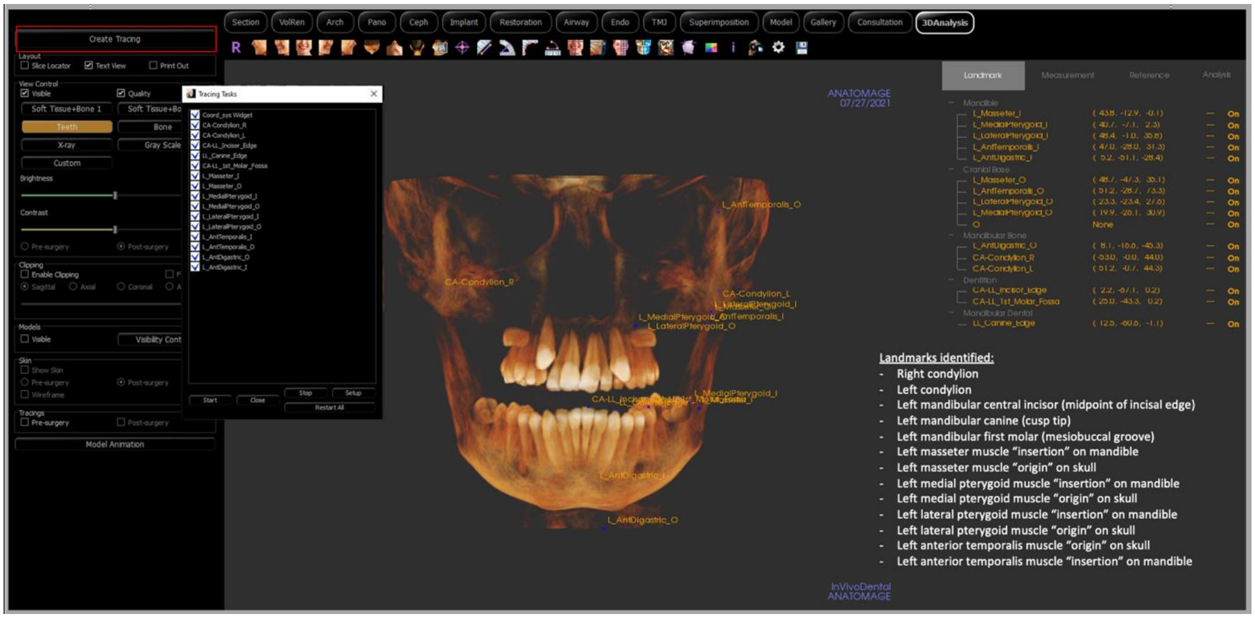


Figure 2: 3D landmarks (blue points) identified on CBCT with InVivo Anatomage. Using 3DAnalysis feature, condyles, teeth, and insertions of muscles of mastication were identified.

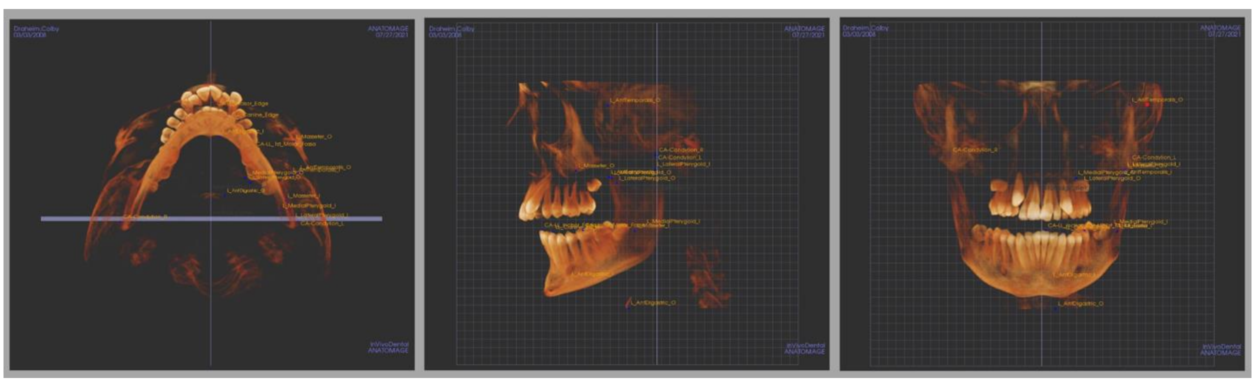

Figure 3: Resultant screenshots of the traced CBCT in the axial, lateral, and posteroanterior, respectively, views to be used in the creation of anatomical geometry files. Grid planes visualized.