Published in final edited form as:

J Oral Maxillofac Surg. 2018 December ; 76(12): 2611.e1–2611.e8. doi:10.1016/j.joms.2018.07.029.

Integrity of a Single Superior Border Plate Repair in Mandibular Angle Fracture: A Novel Cadaveric Human Mandible Model

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Abstract

Purpose: The purpose of this study is to compare the integrity of the human mandibular angle fracture after fixation with a single titanium plate along the upper lateral border to the native human mandible.

Materials and Methods: This cross-sectional anatomic study involved the left hemi-mandibles of sixteen human cadavers. They were selected and divided in two groups by remaining dental status. Additional predictor variables such as height of the left mandibular body and gender were noted. The left hemisected native mandibles were mounted at the condyle and loaded on an Instron 5565 mechanical unit until fracture. The fractured left hemi-mandible were fixated with a titanium mini-plate and screws. After plate fixation, each hemi-mandible was again loaded on an Instron 5565 until fracture. Data pertaining to primary outcomes of load application was recorded in newtons at three different displacement values: 3.0, 5.0, and 7.0 mm, as well as displacement at fixation failure. Primary outcomes of maximum load and displacement at the maximum load were recorded in newtons and millimeters respectively. Descriptive statistics were used to summarize the sample characteristics. Statistical comparisons were performed using a t-test, chi-squared (or

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Fisher's exact) test and linear regression. Pearson correlation was used to examine the relationships between select biomechanical measurements.

Results: The study comprised of 12 females and 4 males. Donors ranged from 54 to 95 years old at time of death with a mean age of 78.94 years. The mean maximum load in the native and plated hemi-mandibles was 943.56 and 292.57 N, respectively ($p < 0.0001$).

Conclusion: Key clinical findings of this project include the inability of single plate mandible fixation to restore the mandible to pre-injury levels and verification that gender, dental status, and height of the mandible do not alter the stability of a single plate fixated mandible.

Introduction

The mandibular angle fracture is a common problem encountered in the facial region. It has high complications and difficult surgical access to the site.^{1,2,3} There are many studies related to the human mandible in cranio-maxillofacial research. The literature demonstrates heavy use of human mandibular substitutes, such as polyurethane, in biomechanical studies. However, the various bone substitutes which have been used as human mandible replicas may present different biomechanical properties than human cadaveric bone. Biomechanical models using polyurethane mandibles and plate repairs have been utilized to evaluate the structural strength of mandibular angle fractures.^{4,5,6,7} The synthetic mandible has been fabricated and has attempted to duplicate the biomechanical properties of the human mandible. Because polystyrene mandibles are synthesized models, they represent a uniform plastic model with a unique mechanical strength. Several studies have demonstrated polyurethane synthetic mandible replicas (Synbone, Switzerland) failed between 350 and 675 N.^{8,9} while the human maximum bite forces have been recorded as being between 600–700 N.^{10,11,12}

Zech et al stated artificial calcanei (Sawbone, Synbone) showed different biomechanical characteristics than cadaver bones (embalmed and fresh-frozen) in an experimental set-up with biocompatible cyclic loading.¹³ These results do not support the use of artificial calcanei for biomechanical implant testing. Fresh-frozen and embalmed specimens seem to be equally adequate for biomechanical characteristics in human study comparing with artificial calcanei (Sawbone, Synbone). Therefore, polyurethane mandible replicas might not accurately represent the biomechanics of the human mandible.

The purpose of this study was to compare the integrity of the human mandibular angle fracture after fixation with a single titanium plate along the upper lateral border to the native human mandible. The investigators hypothesize that the single plated mandibles will have significantly decreased peak loads in comparison to native mandibles. The specific aims of the study were to 1) determine the correlation between gender, mandibular body height, and dental status with terminal (peak) load in native mandibles, 2) determine the correlation between gender, mandibular body height, and dental status with load values at various vertical displacements of single plated mandibles, and 3) compare peak loads and terminal vertical displacement of native and single plated mandibles.

Materials and Methods

Study Design:

To address the research aims, the investigators designed and implemented this cross-sectional cadaveric study as follows. Under federal law, research involving deceased persons generally is not human subjects research and does not require review IRB review and approval. The authors have read the Helsinki Declaration and have followed the guidelines in this investigation. Sixteen human cadavers were provided by the University of Alabama at Birmingham School of Medicine's Anatomical Donor Program between March 1st thru July 31st of 2017. For study control, only left hemi-mandibles were utilized. To be included in the study sample, individuals could be either male or female, with an intact edentulous, partially edentulous, or dentate left hemi-mandibles. Exclusion criteria of the donors included osteoporosis, metastatic bone cancer, metallic bone disorders, or mandibular tumors. Mandibles containing a third molar were excluded from the study. The personal identities of all donors were kept confidential. Ethnicity was not identified in this study. All cadaveric skulls and mandibles were previously hemisected in the midsagittal plane. Mandibles were dissected by skilled oral-maxillofacial surgery residents and faculty.

Variables:

In this study, the primary predictive variables for native mandibles (aim 1) and single plated mandibles (aim 2) are gender, mandibular body height in millimeters and dental status of the mandibular posterior. The primary predictive variable for native and single plated mandibles (aim 3) include presence of fracture and single superior border plating. The primary outcome variables for single plated mandibles (aim 2) include load in Newtons at 3, 5, 7mm, and terminal vertical displacement (mandible fracture) of the single plated mandibles. The primary outcome variable for native and single plated mandibles (aims 1 and 3) is maximal load.

Data Collection Methods:

Mandibles were divided in 3 groups by the remaining dental status. The edentulous mandible group (EM) had no dentition at the first and second molar position. If teeth were present at either the first or second molar region, the mandible was placed in the partially edentulous mandible group (PM). If teeth were present in both the second and first molar position, the mandible was placed in the dentate mandible group (DM). The left mandibular body height was measured at the area of confluence of the alveolar crest and external oblique ridge to the inferior border of the mandibular body (Figure 1). The height of the left mandibular body was measured twice and averaged.

Left hemi-mandibles were cleaned and mounted in acrylic bone cement in 9.5 cm × 3 cm × 3 cm block molds made of silicone. Acrylic was allowed to set in a pneumatic curing unit set to 20 psi for 5 minutes. The acrylic cement was placed from sigmoid notch to the angle encompassing the condyle and posterior border of the ramus. Upon acrylic setting, blocks with mounted hemimandibles were removed from their mold and labeled with the donor number. The bone cement at the condyle region was clamped in a custom-fabricated jig for vertical loads at the left first molar area (Figure 2). The custom-fabricated jig with a hemi-

mandible was fixated and compressive force was applied to the first molar region utilizing an Instron 5565 mechanical testing unit (Instron Corp, Norwood, MA, USA). The testing was done in compression mode at a crosshead speed of 1-mm/minute. A vertical mechanical force with a linear displacement was applied to the left first molar region. Data was acquired and stored through the use of Bluehill 2 software (Figure 3).¹⁴ The loading was continued at the aforementioned rate until mandibular fracture occurred. Maximal load is defined as peak force recorded prior to fracture (Figure 4 and 5). The maximal load of mandibular fracture was determined and recorded in newtons. Displacement at maximal load of intact hemi-mandible is the amount of vertical displacement present when mandible fracture occurs.

The proximal and distal segments of the fractured left hemi-mandible were reduced in anatomical position and fixated with a conventional curved titanium 2.0 six-hole noncompression mini-plate and six mono-cortical titanium fixation screws (KLS Martin) at the upper border of the left mandibular body (Figure 6). The plate is approximately 2.5 mm in width at the center of the plate. It is 35 mm in length and 1 mm in thickness. Each plated hemimandible was retested with the aforementioned biomechanical testing unit in the previously described manner until permanent distortion of the plate or screws occurred (Figure 7 and 8). Maximal load is defined as peak force recorded prior to permanent distortion of the plate or screws (Figure 8).

The data from the load application was recorded in newtons at three different displacement values: 3.0, 5.0, and 7.0 mm of Instron load-application rod displacement as well as displacement at fixation failure. The maximal load and displacement at the maximal load were determined and recorded in newtons and millimeters respectively. Displacement at maximal load of plated hemi-mandible is the amount of displacement present when permanent distortion of the plate or screws occurred.

Statistical Analysis:

Sample characteristics and biomechanical measurements of mandible fracture were summarized using descriptive statistics (mean and standard deviation for continuous variables; frequency and percentage for categorical variables). The differences in gender, mandible height, displacement and force between dental status were assessed using two-sample t-tests and chi-squared (or Fisher's exact) tests as appropriate. The associations between sample characteristics, biomechanical measurements and outcomes of interest were examined using linear regression. Further, the relationships between peak load plate/displacement peak load and mandible height/displacement/force were explored using Pearson correlation. Comparisons between mandibular displacement at peak load in plated and non-plated mandibles were analyzed using paired t-tests. Similarly the mandible height, displacement and force were compared between gender and dental status using the two-sample t-tests. A p-value < 0.05 was considered statistically significant in two-tailed statistical tests. All analyses were conducted using SAS 9.4 (SAS Institute, Cary, NC).

Results

The sixteen cadaveric donors ranged from 54 to 95 years old at the time of death (Table 1). The mean age was 78.94 years. Twelve donors were female and 4 were male. Each

biomechanical test concluded with complete fracture occurring at the mandibular angle. The mean displacement at maximal load in the native and plated hemi-mandibles was 4.5 ± 1 and 15.6 ± 5.4 , respectively. Age, gender, mandible height, displacement at peak load and peak load of non-plated mandibles did not associate with dental status (Table 2). There was no significant association between peak load and forces at 3mm, 5mm, and 7mm, displacement of plated mandibles with age, gender, mandible height, displacement at peak load, and peak load of non-plated native mandibles (Table 3). Maximal load in the native hemi-mandibles was higher before plating (943.6 ± 329.4 vs 292.6 ± 98.5 , respectively, $p < 0.0001$).

The mean of maximal load in male and female native hemi-mandibles was 1174.2 ± 300.7 and 828.1 ± 238.2 , respectively. Males showed significantly higher maximal loads of the native hemimandible than females ($p = 0.01$). There was no significant difference in mandible force nor displacement between dental status ($p = 0.63$). However, the mandible height was higher for mandibles containing molars, in comparison to those without molars (20.7 ± 4.3 vs 17.1 ± 3.8 , $p = 0.048$).

Discussion

The purposes of this study included 1) determining the association between gender, mandibular body height, and dental status with terminal (peak) load in native non-plated mandibles, 2) determining the associations between gender, mandibular body height, and dental status with load values at various vertical displacements of single plated mandibles, and 3) comparing peak loads and displacement at peak loads of native non-plated and single plated mandibles. The research team found no association between gender, mandibular body height, and dental status with terminal (peak) load in native non-plated mandibles. The team also discovered no significant association between gender, mandibular body height, and dental status with load values at various vertical displacements of single plated mandibles. Lastly, it was noted that the non-plated native human mandibles showed statistically higher peak loads and displacements at peak load than the plated mandibles.

No reported studies have utilized a cadaveric human mandible model to analyze the aforementioned associations.^{15,16,17} Synthetic polyurethane models as well as three-dimensional finite element analysis models have been utilized.^{4,5,7,8,9,18,19,20,21,22,23,24,25,26,27,28,29} Our team hoped to augment the current literature via providing a rarely utilized model for data extrapolation.

Limitations of this study include limited age range of donors, potential differences in biomechanical properties of formalin-fixed mandibles compared to in-vivo subjects, the presentation of data pertaining to only a single plating system, variations in bone density, and analysis of hemi-mandibles instead of intact mandible.

Key clinical findings of this project include the inability of single plate mandible fixation to restore the mandible to pre-injury levels and verification that gender, dental status, and height of the mandible do not alter the stability of a single plate fixated mandible. The accumulated data reinforce the notion of providing postoperative instructions of soft diet and light physical activity to prevent a failure of the mandibular fixation.^{30,31,32,33,34}

Particularly, the human maximum bite forces on the first molar have been documented between 600–700 N and the force required to chew an almond and gum was 373 and 238 N, respectively.^{10,11,12,35,36} Even though the cadaveric mandible is the most biomechanically appropriate model for the simulation of mandibular fractures and treatments. It is arduous in terms of storage, handling, reproducibility, and cost of procurement. Using a synthetic mandible is one option to avoid many of these difficulties. Future studies on this topic can assess differences in biomechanical response to load of cadaveric versus polyurethane replicas and compare different plating techniques on fixation of human mandibular angle fractures.

Acknowledgments

- Statistical analysis was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under award number UL1TR001417.
- We would like to acknowledge and express our gratitude with a great respect and admiration for the donors and family members selflessly volunteered.

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Figure 1. The left hemi-mandible height was determined from the area of confluence of the alveolar crest and external oblique ridge to the inferior border of the mandibular body.

Figure 2.
The mandible was loaded at the area of the first molar per the protocol.

Figure 3.
Instron machine setup for the testing of the intact left hemi-mandible.

Figure 4.
The left hemi-mandible was loaded to failure. The fracture propagated through the mandibular angle.

Figure 5.

A. Maximal load is defined as peak force recorded prior to fracture of the intact left hemi-mandible.

Figure 6.

- A. The left mandibular angle fracture plated using a 6-hole titanium KLS plate and screws.
B. Partially dentate left hemi-mandible loaded at the first molar region.

Figure 7.
The plated left hemi-mandible was loaded to failure until permanent distortion of the plate or screws occurred.

Figure 8.

Maximal load is defined as peak force recorded prior to permanent distortion of the plate or screws of the plated left hemi-mandible.

Table 1:

Descriptive statistics of donor mandibles, loads, and displacements

Donor Characteristics	mean±SD
Age at death	78.9±11.1
Gender	N=16
Male	4
Female	12
Dental Status	
No Molars	7
Molars	9
Mandible Height (mm)	17.9±3.6
Mandible Displacement at Peak Load With Plate (mm)	4.5±1
Peak Load Without Plate (N)	943.6±329.4
Peak Load With Plate	292.6±98.5
Force N (3mm)	51.7±40.5
Force N (5mm)	80.9±68.5
Force N (7mm)	110±86.3

Table 2:

Associations of dental status with age, gender, mandible height, displacement at peak load, and peak load of plated native mandibles

Donor Characteristics	Dental Status, mean±SD		
	No Molars	Molars	p
Age at death	76.8±11.5	81.1±19.4	0.32
Gender			0.39
Male	2	7	
Female	7	8	
Mandible Height (mm)	17.1±13.8	20.7±4.3	0.05
Mandible Displacement at Peak Load With Plate (mm)	5.4±11.7	4.7±11.2	0.28
Mandible Peak Load With Plate (N)	983.8±1303.6	321.2±182.9	0.76

Associations of peak load and forces at 3mm, 5mm, and 7mm, displacement of plated mandibles with age, gender, mandible height, displacement at peak load, and peak load of plated native mandibles.

Table 3:

Donor Characteristics	Peak Load Plate			Force N (3mm)			Force N (5mm)			Force N (7mm)		
	β -coe.	95% CI	p	β -coe.	95% CI	p	β -coe.	95% CI	p	β -coe.	95% CI	p
Age at death	-0.19	(-5.28, 4.91)	0.94	0.12	(-1.98, 2.22)	0.9	1.68	(-1.73, 5.1)	0.31	2.66	(-1.54, 6.86)	0.2
Gender (female vs male)	0.43	(-125.8, 126.6)	0.99	27.7	(-21.7, 77.2)	0.25	50	(-33, 132.9)	0.22	79.3	(-21.5, 180.1)	0.11
Dental Status (no molars vs molars)	43.5	(-63.7, 150.8)	0.4	11.8	(-33, 56.6)	0.58	8.35	(-68.1, 84.8)	0.82	0.94	(-95.6, 97.4)	0.98
Mandible Height (mm)	0.11	(-15.7, 15.9)	1	-2.82	(-9.11, 3.47)	0.35	-3.56	(-14.4, 7.23)	0.49	-6.59	(-19.9, 6.71)	0.31
Mandible Displacement at Peak Load with Plate (mm)	-18.9	(-73.6, 35.7)	0.47	-7.68	(-30.2, 14.8)	0.48	-26.2	(-61.9, 9.56)	0.14	-35.8	(-80.1, 8.56)	0.11
Mandible Peak Load with Plate (N)	0.07	(-0.09, 0.24)	0.36	-0.01	(-0.08, 0.06)	0.82	-0.03	(-0.15, 0.09)	0.61	-0.08	(-0.22, 0.07)	0.27