

Evaluation of CFR-PEEK Miniplates with Finite Element Analysis in Mandibular Angle Fracture

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Abstract

The purpose of this study is compare the biomechanical stability of the fixation system made of Carbon-fiber-reinforced polyetheretherketone (CFR-PEEK) and titanium alloy with the three-dimensional finite element analysis method (FEA) in the internal fixation of an unfavorable (inferior to superior, anteriorly oblique) mandibular angle fracture in which muscle tractions increase the amount of displacement.

Materials and methods: A virtual unfavorable fracture line was formed on the mandible models. Fracture lines were virtually fixed with 4-hole, 1.0 mm profile thickness mini-plates with bar and 5 mm long titanium screws. Mini plates were designed from two different materials (titanium alloy and CFR-PEEK). These plates were placed in three different positions (Position A: single miniplate from the lower side, Position B: double miniplate, Position C: single miniplate from the upper side). To simulate the bite forces, 200 N force (anterior incisor and posterior molar) was applied separately in the vertical direction.

Results: All-titanium miniplate systems could withstand 200N molar and anterior loads, but the double miniplate system showed the lowest stress value. CFR-PEEK plates could not show strength in single miniplate systems under 200N molar and anterior forces, they showed strength only in double miniplate systems. CFR-PEEK double plate system reduces the stress on the bone by approximately 40% in anterior and molar loadings compared to titanium miniplates placed in the same positions.

Conclusion: In a conclusion, to the titanium plates used in current practice, CFR-PEEK materials can also be used in the field of maxillofacial traumatology in the future.

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Keywords: Mandibular angle fractures, CFR-PEEK, titanium, finite element analysis, miniplates.

Introduction

The mandible is a bone with a unique articulation system, specialized musculature, and structures that support breathing, speech, swallowing, and chewing. Therefore, the treatment of mandibular bone-related problems and bone reconstruction are indispensable for traumatized patients. Historically and today, mandibular fractures have been one of the main areas of concern in maxillofacial surgery (1,2). Mandibular fractures are the second most common facial fractures that require surgery because of

trauma. These are followed by the maxilla and orbital fractures (3). When mandibular fractures are classified according to their anatomical distribution, it can be seen that angle fractures have an essential place (4,5).

Mandibular angle fractures can be defined as favorable or unfavorable. A favorable fracture is defined as the direction of the fracture in which movement of the masseter and medial pterygoid muscles helps to approximate the fracture lines.

On the other hand, the more common unfavorable fracture is defined as a fracture in which the proximal and distal segments are pulled apart due to muscle pull. In the presence of a horizontally unfavorable fracture, the masseter and medial pterygoid muscles' movement pulls the proximal segment upward and the suprahyoid muscles pull the distal segment downward (6).

Healing will be difficult in unfavorable fractures with increased displacement between the fracture lines. Therefore, the properties of the fixation system to be used in these fractures should be more stabilized (7). Current treatment methods for mandibular fractures are based on the principles of plate fixation defined by Champy (8). There are many plate systems used in treatment. Microplates, mini plates, locking mini plates, reconstruction plates, custom-made plate systems, and compression plates are some of them (9).

Most of the plate systems used in maxillofacial surgery are made from titanium alloys. Titanium osteosynthesis plates are preferred because they are clinically and biologically inert, do not cause local inflammation, and are biocompatible (10).

The mechanical biocompatibility of the material is another consideration and researched issue. However, Young's modulus (110 GPa) of titanium alloys (Ti-6Al-4V) used in fixation systems is well above Young's modulus (18 GPa) of cortical bone. For the prevention of bone resorption and better bone healing, it is thought that it would be more accurate to use materials with similar elasticity modules (11,12).

Complications and disadvantages of titanium osteosynthesis include infection, pain, soft tissue erosion, sensitivities due to thermal changes, plate palpability in sensitive areas of the face, nerve and tooth damage, spread of titanium particles in soft tissue and regional lymph nodes, and possible mutagenic effects. Some of these conditions result in the need for a second surgical operation to remove titanium hardware. In addition, secondary reconstructive or corrective procedures such as bone augmentation and osteotomies may not be possible in the presence of these plates. As a result, titanium plates and screws are removed with a second operation at varying rates of 0-33% of cases (13,14).

Polyaryletherketone (PAEK) materials are included in the group of biomaterials classified as

composites. PAEK materials were first used in the industrial field in the 1980s. One of the members of PAEK materials used for orthopedic purposes is Polyaryletheretherketone (PEEK). Young's modulus of PEEK material is 3-4 GPa but can be reinforced with carbon fiber (CFR-PEEK). After this procedure, it can become closer to the elastic modulus (18 GPa) of the cortical bone (15).

The absence of metallic content of CFR-PEEK prevents artifact formation in both computed tomography and magnetic resonance imaging technologies and allows post-operative examinations. Due to the chemical stability and durability properties of CFR-PEEK, it can be sterilized by common methods such as steam and gamma radiation. CFR-PEEK is easily tolerated by the body and resists wear and tear over a long period. In cases where CFR-PEEK plates are used for fixation, the risk of cold fusion between the plate and the screws is eliminated. Removal of the implant becomes easier and safer. In sensitive patients, the risk of an allergic reaction to metals is eliminated (16,17). PEEK materials are preferred in maxillofacial and cranial implants, spine surgery, orthopedic surgery (bone, hip prosthesis, fixation screws, plates), and cardiac surgery (18). PEEK materials are also used in dentistry and dental implantology (19). Unlike titanium alloys, publications reporting the use of CFR-PEEK material in the field of maxillofacial traumatology are limited in the literature.

Our study aims to compare the biomechanical stability of the fixation system made of CFR-PEEK and titanium alloy with the three-dimensional finite element analysis method (FEA) in the internal fixation of an unfavorable (inferior to superior, anteriorly oblique) mandibular angle fracture in which muscle tractions increase the amount of displacement.

Materials and methods

For the three-dimensional mandible model, computerized tomography (CT) images of a dentated model in the system archive were used. These images were analyzed in 0.3 mm sections. Images were saved in DICOM (Digital Imaging and Communications in Medicine) format, which is a medical image file format. These obtained CT data were transferred to the program named MIMICS 10.01 (Materialise, Leuven, Belgium). With this program, the data is converted into a 3D model. The resulting 3D model was transferred to Geomagic Studio (Raindrop Inc.)

as a file in stereolithography (*.stl) format. When creating the model, the outermost layer was created to be a 2 mm cortical bone. Then, a virtual fracture was created in the mandibular angle region. Ethical Approval is not required as the study design is based on the finite element analysis method.

In our study, an unfavorable fracture line was formed on the mandible model in the oblique direction from inferior to superior in the mandibular angle region. Fracture lines were virtually fixed with 4-hole, 1.0 mm profile thickness mini-plates with bar and 5 mm long titanium screws. Mini plates were designed from two different materials (titanium alloy and CFR-PEEK). These plates were placed in three different positions (Position A: single miniplate from the lower side, Position B: double miniplate, Position C: single miniplate from the upper side) (Fig. 1).

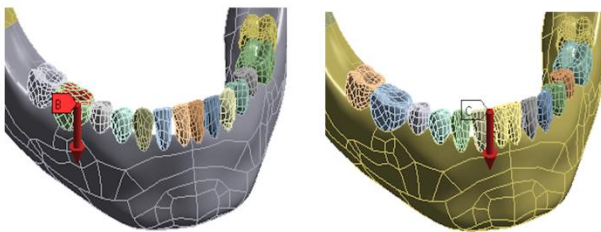


Figure 1: Plate positions (Position A (left): single miniplate from the lower side, Position B (middle): double miniplate, Position C (right): single miniplate from the upper side).

Cortical and cancellous bone structures were assumed to be homogeneous, isotropic, and linearly elastic, due to the lack of data on the precise organic properties of bone. The properties of bone, titanium alloy, and CFR-PEEK materials are given in Table 1.

The designed model is limited bilaterally in all directions from the parts of the mandibular condyle and coronoid process.

To simulate the bite forces, 200 N force (anterior incisor and posterior molar) was applied separately in the vertical direction (Fig. 2).

ANSYS Workbench 13.0 Static Structural analysis module was used to analyze the created models with the finite element method. Tetrahedral elements with 10 nodes were used to divide the model into finite elements. Stress distributions and deformation amounts under the applied bite forces of the miniplate and screw connections of the fracture line were investigated.

	Young's Modulus (MPa)	Poisson's Ratio	Bulk Modulus (MPa)	Shear Modulus (MPa)
Cortical Bone	17000	0.3	14167	6538,5
Cancellous Bone	300	0,3	250	115,38
Ti-6Al-4V	104800	0,31	91930	40000
CFR-PEEK	18000	0,39	27273	6474,8

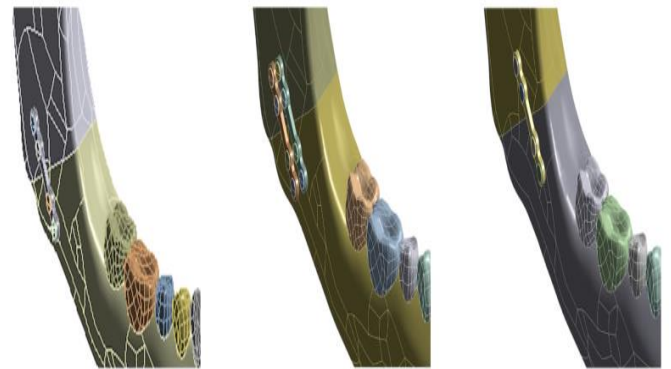


Figure 2: Force application points, left: posterior/molar, right: anterior/incisor.

Results

Finite element analysis investigations were evaluated according to the following criteria in both loading patterns;

- Von Mises stresses bone in the fracture area, to measure the strength of the bone

-Von Mises stresses on the plates; evaluated to measure the durability of the plate.

-Total deformation amount; to assess whether the fracture is stable enough to heal or not

As a result of finite element analysis, total deformation, Von Mises stress values in bones and plates are given in tables (2,3 and 4).

Table 2. Total Deformation (mm)

Plate Position	Force application point	Ti-6Al-4V	CFR-PEEK
Position A	Molar	0,37	0,57
	Anterior	0,42	0,57
Position B	Molar	0,39	0,54
	Anterior	0,46	0,57
Position C	Molar	0,52	0,67
	Anterior	0,57	0,68

Table 3. Von Mises Stress on The Plates(MPa)

Plate Position	Force application point	Ti-6Al-4V	CFR-PEEK
Position A	Molar	836,46	614,39
	Anterior	631,6	411,97
Position B	Molar	528,29	351,76
	Anterior	417,1	255,7
Position C	Molar	847,64	626,95
	Anterior	605,12	377,26

Table 4. Stress Value Transmitted To The Bone (MPa)

Plate Position	Force application point	Ti-6Al-4V	CFR-PEEK
Position A	Molar	123,94	207,6
	Anterior	90,17	136,65
Position B	Molar	197,49	120,33
	Anterior	148,15	85,33
Position C	Molar	152,2	167,01
	Anterior	92,06	84,31

Total Deformation

According to the results of our study, the total amount of deformation in titanium samples with forces applied from the anterior region was found to be higher than those applied from the molar region. In presence of forces applied from the molar region in the titanium group, the lowest deformation amount was measured at 0.37 mm in the single plate group placed on top. The double miniplate group is followed closely by a single miniplate placed on top with a value of 0.39 mm. However, an increase in deformation was measured with 0.52 mm in the miniplate group placed at the bottom. In the presence of forces applied from the anterior region, the increase in values is similar to the molar region. In the CFR-PPEK group, double miniplate fixation was demonstrated with the least deformation of 0.54 mm in the presence of forces applied from the molar region. The maximum deformation under the same force was measured with 0.68 mm in the single plate group placed at the bottom. Under anterior forces, the single plate and double plate groups placed on the top showed the least deformation with a value of 0.57 mm, equally.

Von Mises Stresses in Fixation Plates

FEA results show that in all plate models, the maximum Von Mises stress area is concentrated in the center of the plate which is over the fracture line under both anterior and molar loading (Figure 1).

Regardless of the force application points, the minimum Von Mises stress value was observed in double plate fixation for both titanium material and CFR-PEEK material. The maximum values were recorded for both materials with a single plate group placed at the bottom under molar forces, and with a single plate fixation on the upper side under anterior forces.

Lower Von Mises stress values were measured in CFR-PEEK plates compared to their equivalent titanium plates in all samples.

Stress Values in Bone

In the presence of forces applied from the molar region, the minimum stress values in the mandible were measured as 123.94 MPa in the titanium plates in the single miniplate group at the top, and 120.33 MPa in the double miniplate group in the CFR-PEEK plates.

The highest Von Mises values under the same molar force were measured in the double miniplate group with 197.49 MPa in titanium plates and the single miniplate group placed on top with 207.6 MPa in CFR-PEEK plates.

In the presence of forces applied from the anterior region, the minimum stress values in the mandible were measured at 90.17 MPa in the upper single miniplate group in titanium plates, and 84.31 MPa in the CFR-PEEK plates in the single miniplate group placed below.

Under the same anterior force, the highest Von Mises values were measured in the double miniplate group with 148.15 MPa in titanium plates, and in the single miniplate group placed on top with 136.15 MPa in CFR-PEEK plates.

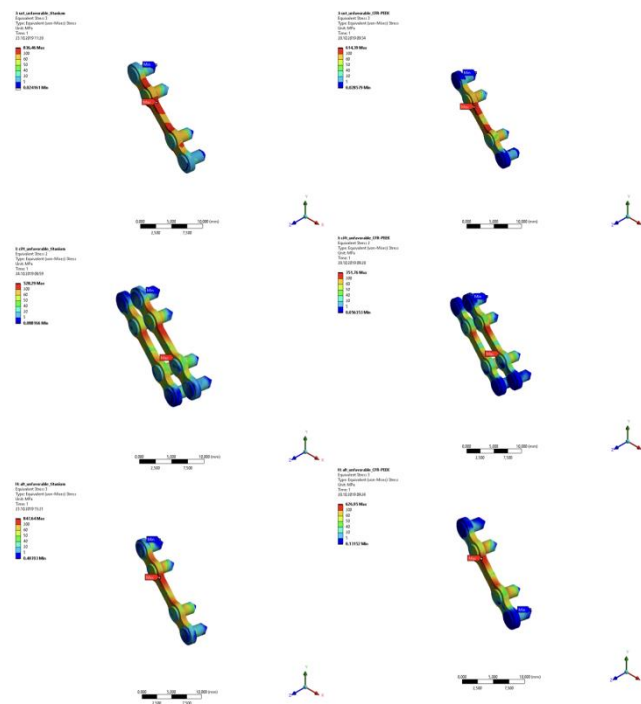


Figure 3: Stress distribution in plates under posterior forces (From left to right 1: titanium position C, 2: CFR-PEEK position C, 3: titanium position B, 4: CFR-PEEK position B, 5: titanium position A, 6: CFR-PEEK position A)

Discussion

Finite element analysis (FEA) is an effective method for analyzing stress concentration and displacements at fracture sites that are difficult to assess in vivo due to their ability to alter the

composition, configuration, and design. Many studies have reported the use of finite element analysis to evaluate rigid internal fixation techniques used in the treatment of facial fractures and osteotomies of the jaw (20,21).

Early complications arising from the fixation system should be avoided during the fracture healing period. Loads transmitted to plates should not exceed the strength limit of the material. Literature supports that stability at the fracture line is the best protection against complications (22). When metal implants, such as titanium mini plates and screws, whose Young's modulus is much higher than cortical bone are used for fracture fixation, a "stress shield" or "stress protection" occurs. Hard metal plates stabilize the fracture site, help maintain contact between bone fragments and share the load. However, as a result of the high stiffness of the implant and the reduced physiological load of the bone, bone resorption occurs and causes the loosening of the implant (23,24).

Currently, there are two typical treatment methods for mandibular angle fractures. The first technique uses a single mini-plate for fixation, which has been widely used in the last two decades. another approach is to use two mini-plates. In a single miniplate approach, the miniplate is placed on the upper part of the mandible, corresponding to the tension band. In the second technique, in which two plates are used, the upper miniplate is placed on the tension line, while the lower miniplate is fixed to the lower border of the mandible, which corresponds to the compression band (25). The positions of the plates in our study were determined according to these principles. The plates are fixated in 3 different positions. Bite forces were applied to the plates in these plates from the molar and anterior regions. In the samples in the same group, the geometric properties of the plates, the positions they are placed in, the screw diameter and lengths, and the amount of force were kept constant, only the material properties of the plate were changed. The biomechanical behavior of plates made of different (CFR-PEEK / Ti alloy) materials was evaluated.

Gerlach and Schwarz evaluated the bite force in patients who underwent fixation after angle fracture in their study. As a result, they measured the maximum bite forces in the molar and canine regions ipsilateral to the fracture line as 192N and 140N respectively, in 6 weeks period (26). For this reason, the amount of force used in our study was determined as 200 N, which would be higher than these forces.

It is expected from a fixation system to show

maximum strength, and at the same time, minimum stress transmission to the tissues it is in contact with is desired. In the studies, the highest stresses accumulated around the fixation system were observed in the screw-plate-bone regions close to the fracture line. It is predicted that the high amount of stress seen in these regions may cause bone resorption, which may trigger screw loosening (27,28).

The maximum bone stress transmitted to the mandible should be below 140 MPa to prevent bone resorption and ensure fixation stability. In studies, the critical stretching of human cortical bone was reported as 0.4%. According to the results of our study, the stress value in the bone was measured below 140 MPa in the double CFR-PEEK plate system, as in the titanium alloy plate system placed on top, at 200 N anterior and molar loading. These results suggest that a stable fixation can be achieved by reducing bone resorption with the use of double-placed CFR-PEEK plates (25).

In literature, screw loosening has been observed at a higher rate in fixations applied to osteoporotic bones, and new materials have been tried to solve this problem. Lill et al investigated the stiffness of different implants for the treatment of proximal humerus fractures. They found that implants with lower stiffness and more elastic properties reduce stress at the bone-implant interface, thus being more conducive to fracture healing in osteoporotic bones. They evaluated the CFR-PEEK material with elasticity modulus similar to the human bone for a more ideal healing. In cases where CFR-PEEK plates are used instead of titanium plates, it has been found that the rate of reduction loss with screw loosening is reduced. Accordingly, the incidence of varus deformity, which is a complication seen after internal fixation, was found to be lower in the CFR-PEEK plate group than in the conventional locking titanium plate group (29).

In their study published in 2018, Diker et al., the only study in the literature investigating the use of the CFR-PEEK fixation system in the field of maxillofacial traumatology, evaluated CFR-PEEK plates of different thicknesses (1.0, 1.5, 2.0 and 2.5 mm) on the atrophic mandible using the finite element analysis method. As a result, it was found that CFR-PEEK plates cause less stress transmission to the bone (30).

In our results, it was measured that the CFR-PEEK double plate system reduces the stress

on the bone by approximately 40% in anterior and molar loadings compared to titanium miniplates placed in the same positions.

It also appears that the lowest Von Mises stress in bone was measured when the CFR-PEEK plates were placed in the double plate orientation. It is important that reducing the stress on the bone will reduce bone resorption, which can reduce the loss of stabilization.

The results of our study are similar to the literature in terms of reducing the amount of stress transmitted to the bone when CFR-PEEK plates are used. In addition, in our results, it was observed that the highest Von Mises stress values in the plates were concentrated in the regions close to the fracture line, following the literature.

Our results support that the use of CFR-PEEK fixation systems with an elastic modulus close to the bone may be appropriate, because unfavorable angle fractures of the mandible are prone to reduction loss and displacement, as in osteoporotic bones.

In the literature, the yield strength of the titanium alloy is 880 MPa, and the yield strength of the CFR-PEEK material is 380 MPa (30,31).

Stresses below this threshold value on the plate will cause elastic deformation in the plate. If the stresses exceed this value, plastic deformation will begin to be seen in the plates. In the light of this information, according to the results of our study, all-titanium miniplate systems were able to withstand 200N molar and anterior loads (Von Mises stress value < 880 MPa), but the double miniplate system showed the lowest stress value.

In their study published in 2018, Ayali and Erkmen evaluated titanium miniplate systems in unfavorable angle fractures with the finite element analysis method and measured the lowest stress in the double miniplate system. The results of our study are similar to this study (32).

CFR-PEEK plates could not show strength in single miniplate systems under 200N molar and anterior forces (Von Mises stress value >380 MPa), they showed strength only in double miniplate systems. Therefore, it was concluded that if CFR-PEEK plates are to be used in unfavorable angle fractures, it would be more appropriate to use the double miniplate system to obtain similar mechanical performance to titanium plates.

According to Diker et al.'s study, they recommended the use of 2.0 mm thick CFR-PEEK mini plates with a thicker profile, since CFR-PEEK plates

thinner than 2.0 mm did not perform adequately in fixation of atrophic mandibular corpus fractures (30).

In our study, the plate thickness was kept constant, but the number of plates was increased. This situation shows that it may be beneficial to increase the plate profile thickness to use CFR PEEK material in a single miniplate system in unfavorable angle fractures.

According to the studies of Claes et al., it is possible to achieve primary healing of bone when the minimum bone spacing between fracture lines is below 150 µm and the fixation environment is stable. With a stable mechanical environment, it can provide good secondary healing when there is a small gap below 2 mm (33). In our study, in which open reduction was modeled in unfavorable angle fractures, any displacement that would prevent bone healing was not detected in any specimens.

CFR-PEEK materials are promising materials in the field of maxillofacial traumatology with their mechanical properties close to cortical bone. Our study showed by the finite element analysis method that CFR-PEEK material provides adequate material strength and bone healing conditions when used with double mini-plate orientation in unfavorable angle fractures of the mandible.

Conclusion

The use of CFR-PEEK plates, which are close to the bone elasticity module, will positively affect bone healing, prevent sensitivities such as hot-cold intolerance, contribute to stabilization by creating less stress on the temporomandibular joint, and prevent artifacts in radiographic examinations thanks to its radiolucent feature. Due to the lower modulus of elasticity properties of CFR-PEEK, stress distribution to the bone and reduction loss will be reduced. Thus, it is thought that the rate of needing a second surgery will decrease.

In our study, it was measured that a 1.0 mm thick CFR-PEEK mini-plate could not show strength according to single-plate fixation principles in mandibular angle fractures under 200 N chewing forces. Still, the use of double-plate mini-plate was recommended. It may be beneficial to increase the plate profile thickness by use the same material as the single miniplate method. In future studies, examining the biomechanical behavior of CFR-PEEK material in the field of maxillofacial traumatology will help adapt this material to

daily use and better clinical results in the area of traumatology.

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