

Evaluation of a New PEEK Mandibular Reconstruction Plate Design for Continuity Defect Therapy by Finite Element Analysis

Konrad Mehle, Alexander W. Eckert, Daniela Gentsch, Stefan Schwan, Christopher M. Ludtka, Wolf-Dietrich Knoll

Abstract—Jaw reconstruction following a significant loss of mandible bone, especially in the case of a mandibular angle defect, requires strict specifications for the inserted reconstruction plates and their fixation to the remaining healthy bone tissue. Despite great care being taken when using conventional titanium plates, plate failure can repeatedly occur in the form of fractures or loosening of the fixing screws. The aim of this study is to develop a 3-dimensional finite element model (FEM) of a human mandible angle fracture for the development of a new osteosynthesis plate system made of polyether ether ketone (PEEK). The jaw geometry of the model was reconstructed from anonymous computed tomography patient data, with a representative mandibular angle defect subsequently introduced. Based on this jaw geometry, three reconstruction plate types were integrally modeled and tested for fatigue fracture and screw loosening: a standard design titanium plate, a standard design PEEK plate, and a newly designed PEEK plate. To determine the forces acting on the jaw in the worst case scenario of clenching, individual muscle forces were separately calculated by a musculoskeletal model in the software AnyBody and applied as a changing dynamic load on the jaw models. Dynamic loading of the standard design Ti-plate demonstrated a maximum fatigue limit of 3.10×10^5 cycles and a stress of 25-50 MPa at the bone-screw interface. The alternative material presented here is the semi-crystalline thermoplastic polymer PEEK, which is particularly promising as a long-term implant due to its excellent biocompatibility and a similar elastic modulus to bone. By forming the same standard design out of PEEK, stresses at the bone-screw interface were reduced to 6.6-23.5 MPa. Based on this result, an alternative design for a PEEK reconstruction plate was developed with stiffness-adapted geometry and optimized to reduce the likelihood of fatigue fractures and screw failure. Consequently, tension at the fixation points was further reduced. FEM results confirm the validity of PEEK as a reconstruction plate material and the use of alternate plate designs. Redesigned PEEK plates represent a viable alternative to the standard design titanium plates currently in use.

Index Terms— Finite element analysis, Mandible reconstruction, Musculoskeletal mandible model, Polyether ether ketone (PEEK)

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I. INTRODUCTION

The full functionality, aesthetics, and form of the oral and facial area can greatly affect the quality of human life. Following significant mandibular injury resulting from trauma, tumor, or inflammation, an immediate bridging is necessary to prevent secondary damage. A mandibular angle defect represents an especially egregious loss of bone, which excludes the possibility of natural regeneration. Therefore a permanent, alloplastic reconstruction with titanium plates is required to stabilize the mandibular angle.

After ablative surgery of the mandible, angular-stable alloplastic reconstruction plates are commonly used [1]. Alloplastic reconstruction devices are the treatment of choice for many patients [2] with the gold standard being titanium reconstruction plates [3]. The most comprehensive overview of this process is given in [4]. Out of the 14 articles reviewed, 944 patients presented with a mandibular defect. Defects were most commonly lateral and received conventional bridging plates [4]. One of the best, if simple, clinical classifications dates back to 1989 and describes three types of defects: central [C-defect], hemimandibular [H-defect], and lateral [L-defect] [5]. However, reconstruction of mandibular defects with titanium bridging plates can have several complications such as plate exposure, plate fractures, and screw loosening [6]. The major plate-related complications are plate fractures and plate exposure [7].

Various clinical studies have shown that using commercially available titanium plates for this type of reconstruction has repeatedly led to plate fractures or screws loosening [8]–[11]. The reasons behind these failures originate in the intensive notch plate design, the mechanical overload from stress, the moderately unfavorable mounting to the bone, and the substantive preliminary damage resulting from manual molding to the individual jaw geometry by bending pliers [10],[12]. Additionally, a stress-shielding effect results from a combination of strong cyclic loading [13] and the mechanical incompatibility of titanium and bone, which causes the loosening of screws in the bone tissue [14].

In the development of a new reconstructive plate system, it is imperative to constructively consider the above-mentioned reasons for failure so that they may better inform the selection of a new implant material. As an alternative material to titanium, we suggest the semi-crystalline, thermoplastic polymer PEEK. Due to its favorable

Evaluation of a new PEEK Mandibular Reconstruction Plate Design for Continuity Defect Therapy by Finite Element Analysis

biocompatibility and a bone-like Young's modulus of 3-4 GPa [15], PEEK appears promising for use in permanent implants. PEEK has been established as an implant material in the neurosurgical field, for example as cage [16] or for cranial defects [17]. Additionally, there are preliminary clinical studies for mandibular reconstruction in the relevant literature [18],[19].

The dimensioning and optimization of a new reconstruction plate system made of PEEK will be presented based on a specially created finite element model. The aim is to carry out a comparative numerical study in contrast to the commercially available titanium plate system.

II. MATERIALS AND METHODS

Generating a realistic FE model provides the foundation for the design and development of an alternative implant system. The geometry is derived from a patient-specific computed tomography dataset, whereby the segmentation of the bone is done in AMIRA and the modification, or rather the conception, of the plate systems is realized in the CAD system CATIA V5. For consideration of the active load condition of clenching the jaw, a Ti standard design reconstruction plate (Design Medicon eG) with an overall thickness of 2 mm was analyzed. Based on this reference model, factors leading to failure were specified. To distinguish between the influence of material and design, two implants made of PEEK were investigated. The first plate was of standard design, only changing the material from titanium to PEEK. The second PEEK plate featured an alternative plate geometry designed with adjusted stiffness.

A. Image Processing

CT scans form the basis for creating the new plate geometry. Different datasets of women and men have been edited with the image editing software AMIRA (FEI Visualization Sciences Group, USA). The model in this present study is based on the dataset of an unidentified 40-year-old female patient which was recorded with a layer thickness of 1 mm.

With respect to occurring volume fractions of cortical and cancellous bone, the mandible was segmented based on grayscale threshold settings and converted to a STL (Surface Tessellation Language) file. The preparation and modification of the generated STL files (one per bone type) was carried out in the CAD system CATIA-V5 (Dassault Systemes, France). In this process the resulting point clouds for bone substance were transferred to solids and smoothed. Using Boolean operators (1. remove, 2. add) the compacta and spongiosa were blended together. This resulted in a model without flaws such as intersections and gaps which can arise through segmentation in Amira and must be avoided. To compensate for geometric discontinuities and to ensure a symmetrically consistent Finite Element mesh, a plane of symmetry was defined between condyles. The left half of the mandible was cut away and the right side mirrored on this plane so that the final outcome was a mandible with homogeneous geometry. To imitate real circumstances following mandibular sectioning, a mandibular angle fracture was simulated. The introduced defect had a length of 40 mm

along the centerline of the mandible profile. The new implant design features two elongated holes, parameterized dimensions (plate thickness, plate length, configuration of elongated hole and location), and variable fixation arrangement. The implant was attached to the fractured mandible, making it possible to derive how much each of these variables affects equivalent stress in the plate and bone.

B. Materials

X-ray attenuation was analyzed to describe the local bone material properties. The Hounsfield Units (HU) of the respective bone tissue was measured for each CT dataset. Based on this measurement, the bone density according to Rho [20] and the Poisson's ratio according to Krone and Schuuter [21] were derived. By applying Wirtz' theory [22] to the derived bone density, the Young's Modulus was calculated (Table 1).

Table 1: Material properties of the bone; local Hounsfield Units were measured and elastic material constants were calculated by correlations from the literature [20]–[22]

Material	HU	Density [kg/m ³]	Young's Modulus [MPa]	Poisson's ratio
Spongiosa	300	451.1	516	0.30
Compacta	1400	1624.8	9253.2	0.36

Table 2 specifies the isotropic, linear-elastic material properties used for the osteosynthesis plates made of PEEK and Ti Grade 2. The screws were abstracted to bolts and modeled from Ti Grade 5 in all examined cases.

Table 2: Material properties of the chosen osteosynthesis materials

Material	Young's Modulus [MPa]	Poisson's ratio	0,2% Yield Strength [MPa]	Source
PEEK	3700	0.42	100	[15]
Ti-Grade 2	105000	0.37	275	[23]
Ti-Grade 5	114000	0.34	758	[23]

Due to the dynamic stress resulting from jaw clenching, the dimensioning against fatigue fracture depends on Woehler lines [24]. Calculation of the tolerable load cycles for the PEEK implants was based on empirical manufacturer's information [15]. Necessary input data of stress amplitude ($\sigma_{a,t}$)/cycles (N) value pairs were derived from the following trend function.

$$\sigma_{a,t} = -1.64 \cdot \ln(N) + 85.14 \quad (1)$$

To estimate the plate lifetime, strain curves based on the Uniform Material Law (UML) were computed for Titanium. The elastic and plastic strain amplitude with double

logarithmic scale are approximatively described with two linear equations [24] and form the basis for the calculation.

$$\varepsilon_{a,t} = (\sigma'_f/E) \cdot (2N)^b + \varepsilon'_f \cdot (2N)^c \quad (2)$$

Baeumel and Seeger[25] previously published empirical values with high statistical validation for the fatigue strength exponent ($b = -0.95$), the fatigue ductility coefficient ($\varepsilon'_f = 0.35$), and the fatigue ductility exponent ($c = -0.69$). These material parameters for the Titanium material used are listed in Table 3.

Table 3: Parameter for strain based Ti life cycle calculation

Material parameters	Grade 2	Grade 5
fatigue strength coefficient σ'_f [MPa]	576.15	1494.65
cyclic strength coefficient K' [MPa]	646.68	1677.61
cyclic strain hardening exp. n'	0.11	0.11

C. Musculoskeletal Model

For replication and computation of the active muscle and joint forces, the AnyBody Modeling System (AnyBody Technology A/S, Denmark) was used. The solution of this statically indeterminate system, or rather the muscle activation, was calculated using a solver for inverse dynamics with optimization criteria [26]. A validated mandible model by Zee et al. [27] was used and adjusted to the specific scenario presented. The previously reconstructed STL dataset of the mandible was imported, including the attachment points of the main muscles responsible for closing the jaw. For simulation of the damage from the mandibular angle fracture, the respective muscles in the defect zone (M. masseter pterygoideus, M. masseter anterior, M. masseter pars superficialis) were excluded from further use based on a minimized cross-sectional area (Fig. 1a). In principle, the loading conditions could be distinguished between chewing and clenching, with significantly reduced chewing forces (only 30-40% of clenching forces) compared to those previously published [28]. Therefore the worst case scenario of jaw clenching was taken into consideration, because this action represented the maximum forces for the lower jaw in its occlusion. A constant clenching force of 180 N for the premolar on the right side has been previously defined[29].

D. Finite Element Analysis

The generated input data was implemented in the finite element software ANSYS (ANSYS Inc., USA) for structural mechanical testing and parameter optimization. The movement of the front teeth, notably the incisors, is suppressed in the positive z-direction while chewing. Clenching represents an extreme situation, so the

interlocking incisor contact must also be fixed in the x-direction (coordinate system positioning shown in Figure 1b). Furthermore, the condyles were locked in all degrees of freedom [30]. A mesh for the reconstruction plate was generated with an h-adaption (successive refinement for elements with high failure) and a 2% convergence criterion for equivalent stress in the plate. Depending on the plate design, 185,000 to 400,000 elements of a converging computation were used, respectively for the standard commercially available plate and newly designed PEEK plate. Subtracting the defect volume from a convergent full model of the jaw resulted in a current number of 2.5 million elements for the bony structure. The individual pins used 18,000 elements, having a fine meshing over their length. The solids were meshed with 10-node quadratic tetrahedron elements and the interfaces with 8-node quadratic surface-to-surface elements. The muscles and their application points form the basis for further calculations and are represented in Figure 1b.

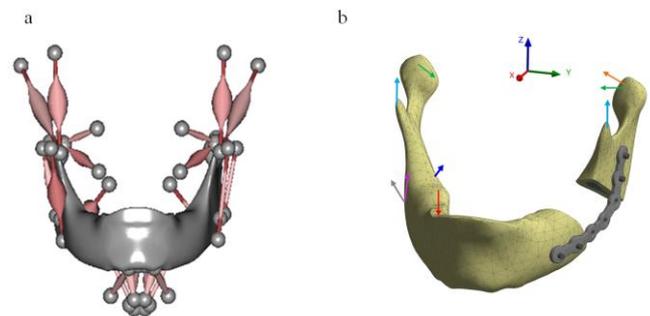


Fig.1. (a) Musculoskeletal asymmetric load condition used in AnyBody Model with minimized muscle cross-sectional area at the defect and (b) FE-model of the mandible with standard reconstruction plate, clenching force (red), and relevant muscle forces used in calculations: M. temporalis anterior (light cyan); M. pterygoideus lateralis, inferior (green), superior (orange); M. masseter anterior (magenta); M. masseter, superficialis (grey); M. masseter pterygoideus (cyan).

Fixation of the modeled implants was abstracted through pins with a diameter of 2.4 mm. This simplification can be taken because of the expected maximal stress peaks at the core diameter, caused through shearing between the mandible and plate of the real screw [30]. Thereby, the contact surfaces of the pins with all interfaces (plate, bone) are defined as bonded.

The concept used is based on numerical calculation of the local critical component stress (notch base concept), which is compared to S-N curves from unnotched specimens. Thus the failure criterion is the first crack or incipient damage point, which is expressed as a safety factor in regards to the fatigue strength limit. The values calculated in this manner were the key input parameters for constructing a new implant design.

III. RESULTS

The AnyBody computed muscle forces for the considered case of clenching were used as loading conditions (Table 4).

Evaluation of a new PEEK Mandibular Reconstruction Plate Design for Continuity Defect Therapy by Finite Element Analysis

Table 4: Resulting muscle forces for clenching

Muscle	X-Value [N]	Y-Value [N]	Z-Value [N]
M. temporalis anterior left	3.99	2.36	155
M. temporalis anterior right	5.69	2.69	54.0
M. pterygoideus lateralis, inferior left	23.6	-39.1	-12.5
M. pterygoideus lateralis, inferior right	5.48	6.80	-2.97
M. pterygoideus lateralis, superior left	4.04	-7.22	3.70
M. masseter anterior right	8.32	-2.13	17.1
M. masseter superficialis right	45.7	-15.9	118
M. pterygoideus medialis right	47.7	43.3	54.6

Fig. 2 lists the stresses in the pins and the resulting holes of the mandibular stumps for the Ti reconstruction plate.

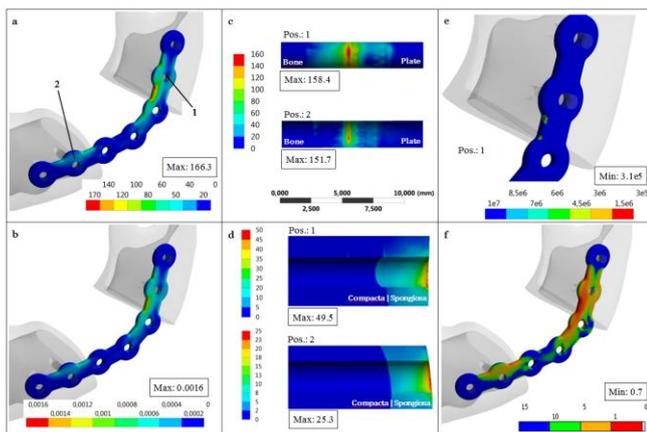


Fig. 2: Results of structure mechanical investigation of a commercially available stock reconstruction plate made of titanium Grade 2 with a thickness of 2 mm. a) Von Mises equivalent stress [MPa] inside the plate, b) Corresponding strain [mm/mm], c) Von Mises stress [MPa] inside fixation pins 1 and 2 (ASTM Grade 5) by monocortical fixation, d) resulting stress at the location of boreholes inside the bone, e) durability of critical spots in cycles, and f) fatigue safety factor

Here it is shown that the critical points in the reconstruction plate (Fig. 2a) occur between the geometric discontinuity (rounding radius) and location where the stiffness shifts as a result of fixation. Within the scope of static examination, the stresses inside the Ti plate are lower than the critical yield strength of 275 MPa by a safety factor of 1.7. In consideration of dynamically alternating loading caused by chewing, a bearable number of $3.10E+05$ cycles (Fig. 2e) could be proven with the used UML. Referring to a common fatigue strength criterion for metals of $1.00E+07$ load

cycles, corresponding to a life span of roughly 40 years [31], produces a dynamic safety factor of 0.7 (Fig. 2f). The resulting maximum equivalent stresses are located in the shearing cross section of the pin in Pos. 1 and measure from 150 MPa up to 160 MPa (Fig. 2c). This leads to a corresponding stress of 25 MPa to 50 MPa at the bone surface near the borehole (compacta). To determine the influence of material selection, the same standard design was recalculated using PEEK instead of titanium. The highest appearing equivalent stress in the PEEK plate was 21.5 MPa, which corresponds with a durability safety factor of 2.7 when referring to the criterion of fatigue strength. The maximum computed von Mises stress was 68 MPa (at Pos. 1) and 18 MPa (at Pos. 2) in the pins and 23.5 MPa (Pos. 1) and 6.6 MPa (Pos. 2) for the bone. Based on this background information, a stiffness-adapted plate system was developed by conducting a parametric study. Thereby an optimal geometry for an implant made of PEEK was designed according to the stresses inside the plate and the stress induction in the boreholes (Fig. 3). From a static point of view, the newly developed PEEK reconstruction plate design is 2 elongated holes with a triangular fixation arrangement (Fig. 3).

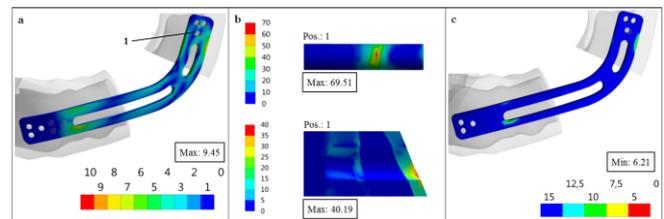


Fig. 3: Developed plate system with 2 elongated holes, 10 mm height and a thickness of 3 mm. a) Von Mises equivalent stress [MPa] of the plate, b) Von Mises equivalent stress [MPa] of borehole and pin at monocortical fixation, c) Resulting dynamic safety factor for the PEEK plate in comparison to an infinite durability of $1.00E+07$ cycles.

With a maximum allowable thickness of 3mm, a reconstruction plate was designed which induces a low stress level in the boreholes in combination with a high safety factor with respect to plate fatigue failure. This new implant geometry with two elongated holes provides considerably higher safety against static and dynamic failure than the Ti standard design reconstruction plate and is therefore more durable over the same period of time with respect to fatigue. The new design has a static safety factor of $S_{static}=9.45$ and a dynamic safety factor of $S_{dynamic}= 6.21$ (see Figs. 3a and 3c). Furthermore, the triangular pin-arrangement represents the best solution in regards to minimally invasive mounting and minimized plate stresses.

IV. DISCUSSION

The long-term success of mandible reconstruction depends heavily on the stiffness characteristics of the osteosynthesis plate system and the type of fixation. The currently used

standard design reconstruction plates made of titanium cause limitations in functional jaw continuity [12] as a result of mechanical incompatibility of titanium and bone material. In addition to selecting an appropriate osteosynthesis material, a suitable geometric shape must be chosen to minimize the risk of plate fractures and screw loosening.

These selection criteria were investigated and optimized in the present study by using numerical methods (FEM). The compilation process for geometry and material parameters were based on CT data. In contrast to previously published investigations where the assignment of bone characteristics was made pixel by pixel [32],[33] or based on an anisotropy material law [34], this study assigned values based on random samples. The moduli calculated by this method for compacta (9253.2 MPa) and spongiosa (516 MPa) conform with values from the literature [35].

A musculoskeletal model according to de Zee [27] was implemented by using AnyBody to determine the loads occurring under the constraint of specific degrees of freedom for the examined case of jaw clenching. As the original de Zee model simulated a healthy mandible, the optimization of the muscle activity due to symmetry had to be modified for the chosen defect situation. For the considered load case, muscle participation depends on muscle location and thickness. Therefore, the muscles that were removed during surgery were excluded from the process (without breaching the criteria of symmetry), which was implemented in the model by a major reduction in cross-sectional area.

The human chewing cycle can be divided into the opening phase, closing phase, and occlusion phase. Occlusion represents the worst case [36] and was therefore the only phase considered for construction of the plate design. A clenching force of 180 N was defined for the premolar on the right side [29].

The material description for the osteosynthesis plate is restricted by static low-cycle fatigue parameters and a remaining life assessment based on Woehler curves. The standard design reconstruction plate made of Ti Grade 2 was investigated by using a FE simulation to observe the distribution and gradients of stress as well as their cause.

The highest detected stress (166 MPa) was located at the geometric discontinuity next to the stiffness shift caused by the plate-mandible fixation. With a resulting safety factor of 1.7 (referring to yield strength) the common titanium plate system provides sufficient safety in regard to overload breakage.

For the assessment of remaining life under cyclic load conditions, a synthetically generated Woehler strain curve was implemented and the parameter of fatigue strength set to $1.00E+07$. Based on this threshold, a safety factor for the

most critical point in the reconstruction plate was determined. The safety factor was calculated as 0.7, or $3.10E05$ stress cycles, which corresponds to a life span of 1.24 years under the assumption of 250,000 damaging chewing cycles per year [31]. The calculated stress values and locations are in agreement with established literature [37],[38]. The Ti Grade 5 bolts used for fixation show a safety factor of 4.8 in terms of overload breakage and are durable to fatigue over the full lifespan considered. The stresses inside the bone, responsible for loosening of the bolts, amount to about 50 MPa at the monocortical fixation.

To estimate the material influence, the same standard design was calculated again using PEEK instead of titanium. PEEK's mechanical characteristics more closely resemble bone and consequently the static safety factor of the plate increased to 4.7 and the fatigue strength criteria was satisfied.

For developing a stiffness-adapted implant, the choice of osteosynthesis material and plate design has been improved. By using a parameter-optimized design the static safety factor increased from 1.7 for common plate systems to 9.5 and the dynamic safety factor from 0.7 to 6.2. Due to the lower stiffness, the maximum equivalent stress inside the fixation boreholes could be reduced which also reduces the risk of bolt loosening. Additionally, the maximum stresses of the commercially reconstruction plate on the site of the condyli were reduced by 20% by using the new PEEK plate design in place of the old version.

V. CONCLUSION

The results of this FEA study demonstrate the impact that design and material choice have on the stresses induced in plate-screw systems. This study demonstrated the feasibility of using PEEK as an implant material for reconstruction of the human mandible angle following a major fracture. Furthermore, it was shown that an alternative plate design can have a positive effect on the long term success of the implant, as modelled through our simulation.

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Evaluation of a new PEEK Mandibular Reconstruction Plate Design for Continuity Defect Therapy by Finite Element Analysis

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