Michaela Maintz*, Daniel Seiler, Florian M. Thieringer** and Michael de Wild**

Topology-optimized patient-specific osteosynthesis plates

Methodology to semi-automatically design additive-manufactured osteosynthesis plates for the fixation of mandibular fractures

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Abstract: Patient-specific osteosynthesis plates can be used to reduce complications related to bone fracture treatment, such as infection, malocclusion and fatigue fractures of plates and screws. However, the implant design process is tedious. We propose a semi-automatic workflow to computationally design patient-specific titanium osteosynthesis plates for mandibular angle fractures. In this process, the plate stiffness is maximized while the mass is reduced. Two plate designs with different numbers of screw holes (implant #1 with four holes, implant #2 with eight holes) were generated with identical topology optimization settings and compared in a finite element model simulating various biomechanical masticatory loads. Differences in von Mises stresses in the implants and screws were observed. The load case of clenching the jaw on the opposite side of the fracture showed the highest stress distribution in implant #1 and higher peak stresses in implant #2. Stress concentrations were observed in sharp corners of the implant and could be reduced using local stress-based topology optimization. We conclude that the design process is an effective method to generate patient-specific implants.

Keywords: Implant design, computational modeling, computational design, finite element analysis, topology optimization, 3d printing, additive manufacturing

** Co-Last authors

***Corresponding author: Michaela Maintz:** University of Applied Sciences and Arts Northwestern Switzerland FHNW, School of Life Sciences HLS, Institute of Medical Engineering and Medical Informatics IM², Hofackerstrasse 30, Muttenz, Switzerland, and Swiss MAM, University of Basel, Gewerbestrasse 14, Allschwil, Switzerland, michaela.maintz@fhnw.ch
Daniel Seiler: University of Applied Sciences and Arts Northwestern Switzerland FHNW, Muttenz, Switzerland
Florian M. Thieringer: Swiss MAM, Department of Biomedical Engineering, University of Basel, University Hospital Basel, Basel, Switzerland
Michael de Wild: University of Applied Sciences and Arts Northwestern Switzerland FHNW, Muttenz, Switzerland

1 Introduction

With 30-37%, mandibular fractures occur commonly among facial fractures [1]. They must be surgically treated when occlusion is not maintained and the bone segments are displaced [2]. Medical device manufacturers currently mass-produce commercial bone plates made of titanium and titanium alloys for surgical fixation of fractures in preset shapes and sizes. These plates need to be bent intraoperatively to conform to the surface of the patient's bone, which is often a time-consuming and challenging task, due to the material rigidity and the complex anatomy of the bone. Through plastic deformation in the bending process, residual stresses and defects can affect material stability in manually adapted regions [3]. As a result, the plates will be more susceptible to breakage. The patient's unique anatomy can be considered in the design process using Finite Element (FE) analysis to evaluate the stress distribution in bone and implant. The FE model discretizes a numerical problem to a finite number of elements, also called the FE mesh. The FE method can be combined with Topology Optimization (TO), which spatially distributes material according to an objective function to optimize implant stability while reducing the overall volume of the shape given as an input (design domain) [4]. Additive manufacturing (AM) allows the production of these patient-specific implants at a high level of design freedom and comparably low costs, unlike conventional methods such as milling or injection molding. AM methods show extraordinary potential for producing patient-specific implants at the point of care. However, these topology-optimized implants' mechanical stability and parametric TO-settings require validation. The mandibular angle is one of the most frequently fractured sites of the mandible with 27% occurrence [5, 6]. In this study, we propose a method to design, verify and manufacture topology-optimized osteosynthesis plates, which can be used to stabilize fractures of the mandibular angle. The goal is to investigate the effects of the design characteristics, FE and TO parameters on the design outcome.

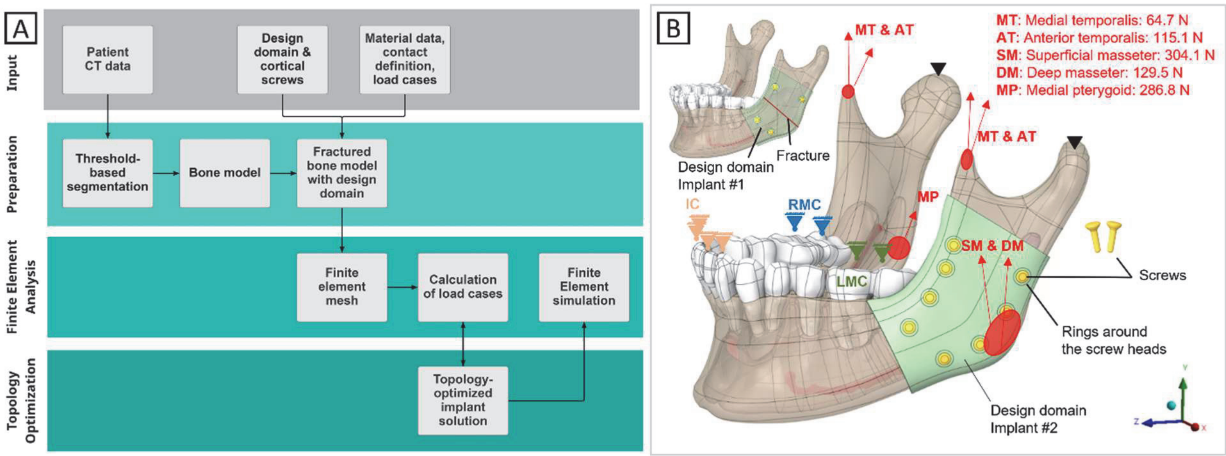

Figure 1: (A) Workflow to obtain patient-specific topology-optimized implants. (B) Implant #1 and #2 with the mandibular model in its initial design domain (light green) before topology optimization. Depiction of masticatory force vectors (red), fixation points of the condyles (black) and of the load cases: incisal clench (IC, orange), right molar clench (RMC, blue) and left molar clench (LMC, dark green). Full clench (FC) restrains occlusional areas of the teeth in y-direction. The muscle forces act symmetrically on both sides.

2 Materials and Methods

The process of implant design is illustrated in Figure 1(A). The mandible model was obtained from computed tomography data of a healthy, 19-year-old female patient. The cortical and trabecular bone structure and tooth geometries were obtained with a Hounsfield Unit threshold-based segmentation approach and converted into a Standard for the Exchange of Product Data (STEP) file. Using Ansys Spaceclaim 2021 R1 (Ansys Inc, Canonsburg, United States), the mandible was virtually cut in the mandibular angle region with a horizontally and vertically inclined unfavorable fracture characteristic, which would allow the displacement of the mandible fragments due to muscle pull of mastication [2, 7, 8]. Two design domains were created as the starting geometry for the TO (Figure 1(B)). The design domains of 1.5 mm thickness were created laterally to the fractured mandibular angle. Four, resp. eight screws were placed according to the craniomaxillofacial surgeon's experience. The osteosynthesis plates and screws of mandibular angle fractures of this fracture type are positioned along the external oblique ridge, and the lower border of the mandible as the major masticatory forces act compressively on the inferior border and the tensile forces affect the superior border (dental arch) of the mandible [9]. Cortical screws of diameter ø2 mm and length 6 mm were used to attach the plate to the bone. Implant #1 is fixed to the bone with four screws. Two of the screws are bonded to the proximal bone segment attached to the temporomandibular joint, and the other two screws are bonded to the distal segment bearing the teeth. Implant #2 is attached to the bone using eight screw holes with four screws bonded to the distal and proximal bone segment. To achieve sufficient stability of the screw heads to the plate, rings were constructed as part of the implant to surround the screw heads.

Multiple load cases were static-mechanically simulated using Ansys Mechanical 2021 R1 (Ansys Inc, Canonsburg, United States) by FE analysis, which involved incisal (IC), full (FC), right molar (RMC), and left molar jaw clenching (LMC), as well as no maxillary resistance. The starting geometries, load cases (IC, LMC, RMC), and boundary conditions can be seen in Figure 1(B). Full clenching (FC) restrains all occlusional areas in the vertical (y-) direction. The masticatory forces (see red arrows in Figure 1(B)), mechanical and material properties (Table 1), and boundary conditions were obtained from validated data in the literature [10, 11] and material data sheets of the material suppliers. The cortical, trabecular and dentine material properties were also obtained from the literature [11, 12]. The isotropic and linear elastic mechanical properties of the simulated materials, such as Young's modulus and Poisson ratio, are listed in Table 1. The screws were bonded to the bone and connected to the plate with their contact conditions set to "no separation", which allows tangential sliding, and prevents separation in the normal direction of the nodes. We performed the TO using the Solid Isotropic Material with Penalization (SIMP) method.

Table 1: Mechanical properties of simulated materials. [11, 12]

Material	Young's modulus (GPa)	Poisson ratio
Plates: Titanium grade 4	105.0	0.37
Screws: Titanium grade 23	113.8	0.34
Cortical bone	14.7	0.30
Trabecular bone	0.4	0.35
Dentine	17.6	0.25

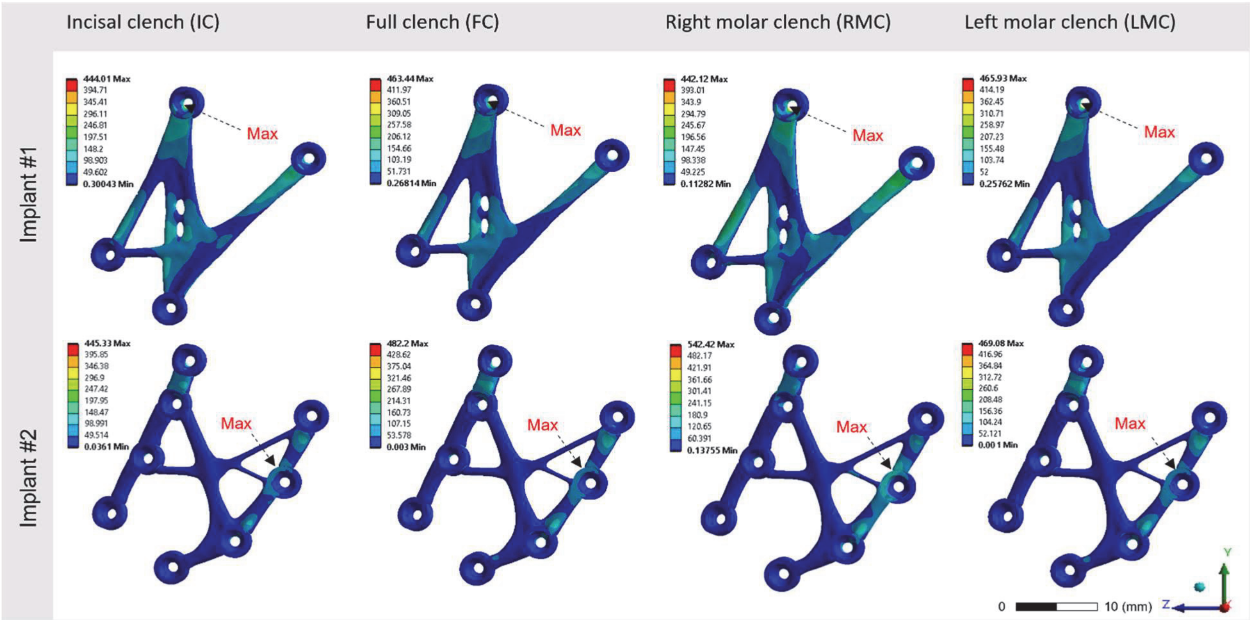

Figure 2: Finite element simulation: von Mises stress distribution for the masticatory load cases of incisal (IC), full (FC), right molar (RMC) and left molar jaw clenching (LMC) of implant #1 and #2

The optimization objective was set to minimize the mass of the implant while retaining the required mechanical stability, which is also referred to as "minimizing the compliance" [4]. All load cases were weighted equally. The retained mass was set to 12%. The rings around the screw heads were defined as exclusion regions of the design domain to obtain one coherent body after the TO process. The FE analysis with TO was calculated with a 12 CPU core desktop computer. The individual solving durations were recorded. To evaluate the preliminary static-mechanical stability of the osteosynthesis, the FE simulation was conducted by replicating four individual static masticatory load cases used in the optimization process. The implant stability for the load cases IC, FC, RMC and LMC was investigated. The boundary conditions remained the same and a frictional contact and the friction coefficient of 0.2 was used for the implant-bone and fracture interfaces. The four-node tetrahedral mesh resolution was 813'320 nodes and 546'398 elements for implant #1. For implant #2 a total of 1'018'178 nodes and 687'068 elements were used. The von Mises stresses of the plates and screws were evaluated for each load case separately.

3 Results

Figure 2 shows the TO implant geometries and the resulting von Mises stress distribution for the two osteosynthesis plate types, implant #1 with four screw holes and implant #2 with eight screw holes. The maximum von Mises stresses of the implants and screws are displayed in Table 2 along with the computing time to obtain the TO and FE simulation results. The highest stresses were observed in the right molar clenching load case, which produced the largest overall spatial stress distributions in implant #1 and a peak von Mises stress of 542.4 MPa in implant #2. The maximum stress values were obtained in the screw holes (implant #1) and connecting regions of the implant struts with the rings that were designed to support the screw heads (implant #2). The von Mises stress values of the screws of both implants remained in the range of 202.7 MPa up to 295.9 MPa. The screws of implant #1 display higher stresses than the screws of implant #2. The TO process of implant #1 required 20 iterations, and implant #2 required 15 iterations. The computing time to receive the

Table 2: Maximum von Mises stress of the finite element simulation of incisal (IC), full (FC), right molar (RMC) and left molar jaw clenching (LMC) and computing time of the topology optimization (TO) and finite element simulation of the four load cases.

	Maximum von Mises stress (MPa)				Computing time (hours and minutes)					
	IC	FC	RMC	LMC	TO	IC	FC	RMC	LMC	Total
Implant #1	444.0	463.4	442.1	465.9	2h 38m	48m	46m	60m	44m	5h 56m
Screws (4)	273.0	293.3	282.1	295.9						
Implant #2	445.3	482.2	542.4	469.1	2h 54m	55m	56m	54m	55m	6h 34m
Screws (8)	203.6	203.8	212.5	202.7						

topology-optimized implants, including four FE simulation , amounted to 5 hours and 56 minutes for implant #1 and 6 hours and 34 minutes for implant #2.

4 Discussion

This study demonstrates the workflow to generate patient-specific, topology-optimized implant designs for AM with a subsequent FE analysis to investigate the static structural stability. This method allows the simultaneous stabilization of tensile and compressive zones provided by the plate. Implant #1 seemed to perform the best with distributing the loads more homogeneously within the implant and lower peak stresses. However, it is atypical in surgical practice to use four screws due to the possible lack of stability if one screw fails. As it can be seen in Figure 2, higher von Mises stresses are observed in the screws of implant #1. The eight-screw version, implant #2, showed signs of slightly higher stresses within the plate, especially in the corner regions between the struts and the rings. The load case RMC seemed to torsionally stress both implants most significantly, possibly by leveraging effect due to the clenching on the opposite side of the jaw. Therefore, in this case, RMC can be considered to be the most critical load case. In the future, to reduce stress concentrations, we propose that an additional step of local stress optimization could distribute the material in regions of high stress. This would generate an implant that is more resistant to mechanical failure. Biomechanical testing of additive-manufactured bone plates is needed to validate these designs and FE calculations. We demonstrate that these implants can be designed with a standard desktop computer using TO in approx. three hours. With prior segmentation, model preparation, and simulated validation calculations, we estimate that the total time will amount to approx. six to seven hours.

TO implants show great potential because the manual process required to bend plates intraoperatively can be omitted, reducing cost and complications linked to prolonged surgeries. An implant that perfectly fits the patient's bone contour with a design that is engineered to withstand the forces of mastication will yield better postoperative results. This technology, combined with the growing AM capabilities in hospitals, holds great potential for the design and production of customized implants at the point of care.

Author Statement

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Conflict of interest: Authors state no conflict of interest.

References

[1] Lee K. Global Trends in Maxillofacial Fractures. Craniomaxillofacial Trauma & Reconstruction. 2012;5(4):213-22.

[2] Stacey DH, Doyle JF, Mount DL, Snyder MC, Gutowski KA. Management of mandible fractures. Plastic and reconstructive surgery. 2006;117(3):48e-60e.

[3] Park S-M, Lee D, Lee J-W, Kim Y, Kim L, Noh G, editors. Stability of the permanently bent plates used in mandibular reconstructive surgery. 2016 38th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC); 2016: IEEE.

[4] Sigmund O. Manufacturing tolerant topology optimization. Acta Mechanica Sinica. 2009;25(2):227-39.

[5] Morris C, Bebeau NP, Brockhoff H, Tandon R, Tiwana P. Mandibular fractures: an analysis of the epidemiology and patterns of injury in 4,143 fractures. Journal of Oral and Maxillofacial Surgery. 2015;73(5):951. e1-. e12.

[6] Brucoli M, Boffano P, Pezzana A, Benech A, Corre P, Bertin H, et al. The “European Mandibular Angle” research project: the analysis of complications after unilateral angle fractures. Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology. 2019;128(1):14-7.

[7] Mittermiller PA, Bidwell SS, Thieringer FM, Cornelius C-P, Trickey AW, Kontio R, et al. The comprehensive AO CMF classification system for mandibular fractures: a multicenter validation study. Craniomaxillofacial trauma & reconstruction. 2019;12(4):254-65.

[8] Fernández EC, Moreira EM, Martínez AP. Mandible fracture in children: a case report. South Sudan Medical Journal. 2020;13(3):116-9.

[9] Ehrenfeld M, Manson PN, Prein J. Principles of internal fixation of the craniomaxillofacial skeleton: Thieme; 2012.

[10] Ramos A, Marques H, Mesnard M. The effect of mechanical properties of bone in the mandible, a numerical case study. Advances in Biomechanics & Applications. 2014;1(1):67.

[11] Ramos A, Gonzalez-Perez LM, Infante-Cossio P, Mesnard M. Ex-vivo and in vitro validation of an innovative mandibular condyle implant concept. Journal of Cranio-Maxillofacial Surgery. 2019;47(1):112-9.

[12] Khiabani K, Keyhan SO, Razmdideh R, Chaleh ZC, Amirzade-Iranaq MH. Effect of different miniplate osteosynthesis in different mandibular angle fracture patterns on bite force: A 3D finite element analysis. Journal of oral and maxillofacial surgery, medicine, and pathology. 2018;30(4):324-9.