Minimally Invasive Bioabsorbable Bone Plates for Rigid Internal Fixation of Mandible Fractures

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Objectives: To optimize design variables of a bioabsorbable bone plate using a finite element model of the mandible and to discover a minimally invasive bioabsorbable bone plate design that can provide the same mechanical stability as a titanium plate.

Methods: A finite element model of a mandible with a fracture in the body was subjected to bite loads. An analysis was run to determine the principal strain in the fracture callus and von Mises stress in a titanium plate. These values were then set as the limits within which the bioabsorbable bone plate must comply. The model then considered a bone plate made of the polymer poly(L-lactide-co-D,L-lactide) (P(L/DL)LA) 70/30. An optimization routine determined the smallest volume of bioabsorbable bone plate that can perform as well as a titanium bone plate when fixating mandibular fractures.

Results: A P(L/DL)LA plate volume of 315 mm³ with a thickness of 1.5 mm provided as much mechanical stability as a commonly used titanium strut structure of 172 mm². The peak plate stress was well below the yield strength of the material.

Conclusions: The P(L/DL)LA bioabsorbable bone plate design is as strong as a titanium plate when fixating fractures of the mandible body despite the polymer material having only 6% of the stiffness of the titanium. The P(L/DL)LA plate can be less than half the volume of its strut-style counterpart.


The use of permanent metallic hardware to treat facial fractures is controversial. Barring a rare secondary surgical intervention, this hardware remains indefinitely embedded in the patient. Large permanent implants can lead to problems due to migration, palpability, stress shielding, infection, thermal sensitivity, and general discomfort. One possible solution to avoid these potential sequelae is to use a bioabsorbable bone plate, which would perform its stabilizing function until the fracture is fully healed before being naturally eliminated from the body. Bioabsorbable plates and screws are most often made of the polymers polylactide and polyglycolide, as well as copolymers polyglycolide-co-polyactide and poly(L-lactide-co-D,L-lactide) (P(L/DL)LA). Depending on the material used, most bioabsorbable materials can be eliminated from the body in 8 months to 5 years.

The current perception is that absorbable bone plates do not provide enough fracture stability to be safely used in the load-bearing regions of most adult patients. Because the materials have low strength, bioabsorbable bone plates tend to be bulky and cumbersome. The materials are also associated with a significant amount of swelling, discharge, and osteolysis. Osteolytic changes around self-reinforced polylactide screws have been demonstrated to occur in 27% of cases. Large plates have been associated with swelling recorded up to 3 years after surgery. Furthermore, many bioabsorbable materials need to be heated to a temperature greater than the glass transition temperature to be molded into the required shape. Despite advances in self-reinforcement, absorbable plating has not seen widespread use because of these concerns.

Bioabsorbable bone plates are used mostly in the midface and skull, whereas thicker bone plates are being proposed for fixation of fractures in the load-bearing mandibular region. The major problem of existing bioabsorbable plate designs stems from the thicker profiles required to combat the materials’ low mechanical stability. Rudimentary design methods have resulted in larger and thicker bone plate designs, which have traditionally served to compensate for the lack of biomechanical understanding pertaining to fractures of this region. Because a longer amount of time is required to metabolically remove a thicker bone plate, the patient is subjected to a higher risk of infection. Fur-
thermore, the plates are cumbersome and difficult to implant during surgery, leading to longer surgical times. Ideally, the plates would be thinner and more pliable, effectively making them less cumbersome, less palpable, and capable of fast degradation. Modified plate designs are necessary to use these materials safely in the mandible. Plate design modification is a necessary step toward bringing these materials into widespread use. The present study was performed to determine a new, minimally invasive bioabsorbable bone plate design that can provide the same mechanical stability as a standard titanium bone plate. This was accomplished using an optimization procedure within a detailed finite element model of a fractured human mandible.

The study included 2 analyses that considered normal postsurgical patient loads. The first analysis determined pertinent stress and strain measures within a fractured human mandibular finite element model that is fixed with a standard titanium miniplate. The second analysis used the same modeling conditions to evaluate a bioabsorbable bone plate of an InterFlex design. The InterFlex plate design is an optimized structure for fractures of the mandibular body that is described in detail in a previous article from our group. Because of its ideal properties of the mandibular body that is described in detail in a previous article from our group.4 Because of its ideal properties, the InterFlex plate design was selected as the bone plate design to determine the thinnest, least cumbersome bioabsorbable bone plate design that can perform mechanically as well as its titanium counterpart.

### METHODS

#### FINITE ELEMENT MODEL CREATION

A finite element model of a human mandible was created for the purpose of designing and optimizing a new bone plate to fixate fractures of the mandibular body region. The model allowed examination of measures pertinent to postoperative complications commonly found with rigid internal fixation. The 2 primary measures examined in the present study were the first principal strain in the fracture region and von Mises stress in the fixation plate. The principal strain indicates whether a fracture is stable enough to heal. Too much instability can lead to infection and nonunion. In the fixation plate, von Mises stress will indicate whether the plate will yield and fail.

Computed tomography data were obtained in multiple sections every 1.3 mm in the horizontal plane for a full human skull (Somatome Sensation; Siemens AG, Erlangen, Germany). The data were obtained from a 22-year-old man with full dentition and normal occlusion. The computed tomography data were then imported into thresholding software (Mimics 7.3; Materialise, Ann Arbor, Michigan) in image format for conversion into a 3-dimensional Initial Graphics Exchange Specification format suitable for importation into any finite element analysis program. Line contours from Mimics were imported into engineering simulation software (ANSYS; ANSYS, Inc, Evanston, Illinois) representing the entities created for the outer body of the cortical bone. Areas were created by skinning a surface through the guiding contour lines to represent the shape of the mandible.

Lovat et al previously gave a full discussion of material property assumptions. In the present simplified model, the modulus of elasticity for bone is defined as $E=20,000$, and the Poisson ratio is defined as $\nu=0.3$.

The bite force used in the present model is a unilateral molar clench. This load has been determined in a previous study to create the most hazardous environment for fracture healing. Each bite force is simulated by restraining the mandible from displacement in all directions at the point of contact of the bite and then applying muscle force vectors that are experimentally derived for that specific bite. These forces pull the mandible into the constraint, which acts as a fulcrum for the mandible to bend around, simulating the bite. Each force has a direction, area of attachment, and magnitude. All data pertaining to the bite forces were taken from studies by Korieth et al. Full details of the boundary conditions are given in previous studies from our group. Last, the mandible is restrained from movement in all directions during loading at both condyles.

The fracture was created as a 1-mm-thick bony callus region on the sagittal plane. Material properties of initial connective tissue are used for the bony callus fracture region and are prescribed as $E=3$ MPa and $\nu=0.4$. To fasten each fixation plate to the mandible, we used virtual unicortical screws to secure the superior screw line of the plate and bicortical screws near the inferior border of the mandible. Screws were simulated as solid cylinders with a diameter of 2.3 mm. The unicortical screws extended the full length of the buccal cortical section. The bicortical screws each extended a safe distance between the edges of the lingual cortical section. All screws were inserted and perfectly bonded along their surface to the bone material using Boolean operations. Material properties for plates and screws are designated as those of titanium ($E=110,000; \nu=0.34$).

A number of tests were used for estimating numerical errors related to the mesh density of the models. The mesh size was varied in the regions of the bony callus (fracture region) and the titanium plate to determine whether there were enough elements to have a converged solution. All measures were seen to converge within a few percentage points after doubling the number of elements in the model. A similar model has been successfully used by our group in 4 previous studies.

#### BIOABSORBABLE PLATE OPTIMIZATION

The model was then used to optimize a bioabsorbable fixation plate to be equivalent in mechanical performance to its titanium counterpart. Two model setups were required to optimize the bioabsorbable plate design. In the first setup, a strut-style plate was used for the fixation hardware. The plate was designated with material properties of commercially pure titanium. A single analysis was run using the model to analyze the average first principal strain in the fracture callus and the overall plate volume. The titanium analysis was run to gather benchmark values to set limits for the performance of the bioabsorbable plate. The second setup was created with all the same modeling variables but substituting an InterFlex-style fixation plate given material properties of self-reinforced P(L/DL)LA ($E=7$ MPa; $\nu=0.3$). Figure 1 shows both meshed models.

An optimization routine was run on the bioabsorbable setup to determine the smallest bioabsorbable plate design that can perform as well as the titanium plate design according to the average first principal callus strain. The subproblem approximation technique was used for the optimization. This is an advanced zero-order method, meaning that the method requires only dependent variable values without their derivatives. During the optimization, the state variables and objective function values are replaced by approximations using quadratic least squares fitting. The error norm for each approximation is com-
puted using weights associated with each design set. More information on this method is found in the theory reference of the 11.0 release of the documentation for ANSYS.11

Measures gathered within the bioabsorbable analyses must be within the state variable limits determined from the titanium plate analysis. Furthermore, the yield strength of the bioabsorbable material must also be taken into consideration. Accordingly, the plate stress and callus strain limits were set as the state variable maximum values for the bioabsorbable plate optimization analysis. The plate thickness, the lateral bar width, and the cross bar width were chosen as the design variables. During the optimization analysis, values of the design variables were varied, and state variable values were calculated for each design set. The objective of the analysis was to minimize the overall plate volume. Upon convergence, the routine determined the smallest bioabsorbable fixation plate of the InterFlex-style structure that performed mechanically as well as a titanium strut plate. A tolerance of 2% was allowed near the peak stress and average strain limits. The tolerance allowed for minimization of the objective function was also 2%.

**RESULTS**

The basic titanium plate analysis was solved to gather pertinent stress and strain measures to form a basis of comparison for the bioabsorbable bone plate optimization. After solution convergence, it was determined that the fracture callus had an average first principal strain of 3.0% using a titanium strut miniplate. This is the same value and same model as a previous study by our group.4 Furthermore, P(L/DL)LA can be manufactured with a tensile yield stress of up to 359 MPa.12 These 2 values were set as the state variable maxima for the optimization analysis.

We then used an optimization routine to run the analyses for the bioabsorbable fixation hardware. The program converged after 12 analyses. The table shows the results of each analysis until the optimization convergence. The optimization determined that an InterFlex-style P(L/DL)LA plate volume of 315 mm³ and thickness of 1.5 mm can provide as much mechanical stability as a commonly used titanium strut structure with a volume of 172 mm³.

Peak von Mises plate stresses were examined to ensure that the material would not yield or fail during normal use. In all analyses, the peak plate stress was well below the yield strength of the material, leaving the fracture strain as the main driver for the convergence of the analysis. Figure 2 shows the contours for the opti-

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**Table. Design and State Variables and Outcomes Results for All Optimization Iterations**

<table>
<thead>
<tr>
<th>InterFlex Plate Analysis Iteration</th>
<th>Cross Bar Width, mm</th>
<th>Lateral Bar Width, mm</th>
<th>Thickness, mm</th>
<th>Volume, mm³</th>
<th>Average Fracture Strain, %</th>
<th>Result</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>1.10</td>
<td>1.10</td>
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<td>4.08</td>
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<td>2</td>
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<td>260</td>
<td>3.35</td>
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</tr>
<tr>
<td>3</td>
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<td>1.40</td>
<td>1.40</td>
<td>292</td>
<td>3.22</td>
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</tr>
<tr>
<td>4</td>
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<td>1.30</td>
<td>263</td>
<td>3.39</td>
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</tr>
<tr>
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</tr>
<tr>
<td>6</td>
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<tr>
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<tr>
<td>8</td>
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</tr>
<tr>
<td>9b</td>
<td>1.67</td>
<td>1.76</td>
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<td>315</td>
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<tr>
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<td>1.57</td>
<td>330</td>
<td>2.99</td>
<td>Feasible</td>
</tr>
<tr>
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<td>3.07</td>
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</tr>
<tr>
<td>12</td>
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<td>1.54</td>
<td>325</td>
<td>3.03</td>
<td>Feasible</td>
</tr>
</tbody>
</table>

*According to the peak fracture strain, designs were considered feasible or infeasible.

*b Indicates the feasible iteration with the optimal values.
The use of bioabsorbable materials in fixation plates for the treatment of mandibular fractures has not yet gained widespread acceptance. The benefits of these materials are abundant, most notably in the elimination of the need for a permanent implant. This can reduce the risks of implant migration, stress shielding of the underlying bone, interference with computed tomography and magnetic resonance imaging, and other aesthetic implications associated with removal of the devices.3,13 Despite material science–based advances in self-reinforcement of the absorbable materials, their use is still primarily inhibited by their low mechanical stability and large cumbersome nature. The present study has calculated an InterFlex-style bioabsorbable bone plate design that is as strong as a titanium plate when fixating fractures of the load-bearing mandible.

A number of studies have examined the use of bioabsorbable materials for the fixation of mandibular fractures. Cox et al14 used a finite element model to compare currently used plate designs consisting of titanium and resorbable polymer plates. Although the bioabsorbable devices passed the standard required by the authors, the study exposed a large performance gap between the different materials. Concerns associated with the performance gap were considered in a discussion by Shetty,13 and Tams et al16 performed a similar biomechanical study to determine the ability of small biodegradable plates to fixate fractures of the mandibular angle, body, and symphysis. The results determined that none of the degradable plate configurations were appropriate for fixation of unstable body or angle fractures. In a multicenter clinical study,4 devices made of a reinforced copolymer of polylactide and polyglycolide in a ratio of 80:20 were used to determine the efficacy of BioSorb plates and screws (ConMed Linvatec Corporation, Largo, Florida) in craniomaxillofacial osteotomy fixation. That study determined that complications were similar to those expected with titanium implants, although the study included mostly children in its sample. Kim and Kim3 studied the use of P(L/DL)LA 70:30 copolymer BioSorb plates (1 or 2 plates with thicknesses of 2.0 and 2.4 mm) in 49 adult patients with 69 fractures. That study reported acceptable results but used an indeterminate amount of intermaxillary fixation for many of the patients, limiting the generalizability of the results. Although the benefits of a short period of intermaxillary fixation have been discussed,17 its use in a protocol to determine the success of a particular fixation scheme needs to be highlighted. The time required to include intermaxillary fixation in a routine operation can be prohibitive and ultimately limit the use of bioabsorbable fixation devices if its inclusion is, in fact, required to achieve satisfactory outcomes. Lovald et al10 used a model similar to that in the present study to optimize a bioabsorbable strut-style plate. The authors determined that a strut-style P(L/DL)LA plate would need to have a volume greater than 690 mm³ to provide the same stability as a titanium strut plate.

The present optimization analysis determined that an InterFlex-style P(L/DL)LA plate with a volume of 315 mm³ can provide as much mechanical stability as a similar titanium design structure of 172 mm³. Although this bioabsorbable bone plate is a little less than twice the volume of a titanium plate, this difference could be considered a relatively small factor when considering that the P(L/DL)LA material has approximately only 6% of the stiffness of titanium. Furthermore, the present study determined that an InterFlex-style P(L/DL)LA plate can be less than half the volume of its strut-style P(L/DL)LA counterpart (690 mm³).10 This efficient allocation of the material volume is likely a result of the InterFlex design and the consideration of 3 design variables concurrently, increasing the effectiveness of the optimization routine. A reduction of the bulkiness of absorbable implants will ultimately lead to a less cumbersome implant and a more timely absorption with a lower risk of latent infection.

Complementary technology can be used to increase the efficacy of bioabsorbable bone plates. The smart design of the bone plate structure is an area that has seen little development in any osteosynthesis market. Lovald et al11 have previously shown that, with the same volume of implanted material, a properly structured bone plate can reduce fracture strain by nearly half and reduce bone plate stress to a mere quarter of its original value. The integration of complex geometry, material properties, and boundary conditions in a detailed finite element model of a fractured mandible is a very large step toward the appropriate design of fracture fixation plates. Modifying the bone plate design to complement a specific material is an exciting avenue that can help push bioabsorbable fixation plates into widespread use.

The design tool and process created in the present study might be used to base a determination of mechanical substantial equivalence for US Food and Drug Administration 510(k) regulation of bioabsorbable bone plate use in the load-bearing mandible. Because of the current standard of simple in-plane and out-of-plane bending tests to determine bone plate system equivalence, the consistently large and cumbersome titanium and bioabsorbable bone plates currently available are overcompensa-
tion for a lack of understanding of the actual load-bearing environment of the mandible. Not only will a detailed, realistic model of a fractured and loaded human mandible provide a better determination of bone plate performance, but it will likely also limit the bulkiness of many bone plate designs because the material will be more efficiently allocated.

The present study considered only static loading of the bioabsorbable implant immediately after its implantation. Ideally, results would also consider the possible fatigue failure of the implant as well. There are 2 reasons we did not perform this analysis. First, the peak stress in the bioabsorbable plate in relation to its yield stress was significantly lower than the corresponding peak titanium stress in relation to its yield strength. This suggests that the number of incidences of actual fatigue failure would be less than those for the titanium plate, which is itself a very small number. Second, it is very difficult to conduct a fatigue analysis over time when the actual mechanical strength of the bioabsorbable material will also change with time. This is compounded by the fact that the very nature of an optimization analysis is to vary design variables, a process that will itself affect the mechanical strength characteristics of the material. The information required to accurately perform this analysis is not fully available at this time. Despite having ignored fatigue failure of the bioabsorbable implant, this study is an important first step in the proper design of a safe, absorbable bone plate for fractures of the adult mandible.

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Financial Disclosure: Dr Lovald is a named inventor on a utility patent pending for the basic InterFlex design discussed in this article.

REFERENCES