Biomechanical Evaluation of Fixation Techniques for Bridging Segmental Mandibular Defects

Jonathan M. Doty, MD; David Pienkowski, PhD; Michele Goltz, BS; Richard H. Haug, DDS; Joseph Valentino, MD; Oneida A. Arosarena, MD

Objective: To compare biomechanical properties of currently available plating systems used to reconstruct segmental mandibular defects.

Design: Controlled in vitro investigation.

Setting: Academic medical center laboratory.

Interventions: Thirty-two polyurethane mandibles were equally divided among 4 groups: mandibles with a 4-cm lateral segmental defect that was bridged with a (1) 3.0-mm locking-screw reconstruction plate, (2) 2.4-mm low-profile reconstruction plate, or (3) 2.4-mm reconstruction plate and (4) uncut (control) mandibles. All plates were contoured and secured to the synthetic mandibles with 4 bicortical screws on either side of the defect. Three constructs from each group were subjected to contralateral-molar single-load-to-failure testing. Mean yield displacement, yield load, and bending stiffness were quantified and compared among the 4 groups. The single-load-to-failure data were used to establish conditions for fatigue testing; such testing was then performed on the remaining 5 samples in each group. Mean cycles to failure were measured and compared among the 4 groups.

Results: Mean yield displacement, yield load, and bending stiffness were comparable among the plated groups. Both the 3.0-mm locking-screw and 2.4-mm low-profile reconstruction plate designs withstood 1580 and 1124 times more cycles to failure, respectively (P=.005), than did the control group. The other reconstruction plate was also superior to the unplated controls, offering an 865-fold improvement.

Conclusions: All 3 mandibular fixation device systems tested produce comparable levels of single load to failure biomechanical integrity; however, the higher-profile plating system design offered slightly superior fatigue performance. No differences in performance were observed between the locking and nonlocking designs; neither failed at the screw-substrate interface.

Arch Otolaryngol Head Neck Surg. 2004;130:1388-1392

Bridging reconstruction plates for repair of segmental mandibular defects following trauma or ablative surgery for oral malignancies have been used since the 1980s. Shockley et al1 and others2-5 advocated the use of reconstruction plates for the immediate restoration of mandibular continuity, noting the lack of donor site morbidity, expediency, and excellent restoration of mandibular contour afforded. However, no single method of reconstruction results in the replacement of tissue that precisely matches the quantity or structural qualities of native mandibular bone. The use of reconstruction plates has several attendant risks, including plate exposure, plate and screw fracture, screw loosening, infection, fistula formation, and limited aesthetic and functional restoration.

Numerous in vitro studies6-9 have compared plating constructs in the settings of mandibular fracture repair and orthognathic surgery in a static situation and have been useful in assessing the problems of plate fracture and failure at the screw-substrate interface. A model that incorporates cyclic fatigue testing of various mandibular plating constructs, however, has not been developed to date. Plate fracture is due to repetitive stress over time and continues to be a relatively late complication in the reconstruction of segmental mandibular defects. Blackwell et al3 reported a 6% rate of plate fracture using AO (Arbeitsgemeinschaft für Osteosynthese-Fragen) plates and vascularized bone-containing free flaps to bridge segmental mandibular defects that occur at a mean of 17 months after implantation. The fracture rate of AO plates used in conjunc-
tion with soft tissue containing free or pedicled flaps has also remained comparable at 3% to 10% in multiple studies.\textsuperscript{5,3,10,11} Although this concern is partially mitigated by the limited life expectancy of patients with oral malignancies, it is an issue when such fixation techniques are applied to trauma patients.

The size of bridged defects has been found to correlate with the incidence of hardware-related complications in that patients with defects longer than 5 cm are more likely to have plate failures. Some authors\textsuperscript{5,11} have also documented unacceptably high rates of hardware-related complications with anterior mandibular defects compared with lateral defects. As a result, bridging plate reconstruction is not currently recommended for defects that involve the central mandible.

Currently, vascularized bone grafts are the preferred method for reconstructing segmental mandibular defects (with a success rate approaching 96%).\textsuperscript{5} Despite the increased technical expertise, additional surgical time, and potential donor site morbidity associated with bone-containing free flaps, their use has been associated with better quality of life and fewer postoperative complications. Nevertheless, the use of bridging reconstruction plates is indicated for patients with small lateral defects, advanced disease, or medical conditions that preclude prolonged general anesthesia.\textsuperscript{11} Advances in bone tissue engineering, which enable induction of local bone growth and a progression toward a more ideal method of mandibular repair, will not obviate the need for bridging reconstruction plates, because such devices will be needed to achieve short-term mechanical stabilization while bony regeneration occurs. The goal of the present study was to test the null hypothesis that there are no differences in static or cyclic biomechanical performance of 3 currently available implants for stabilizing mandibles with segmental defects.

**METHODS**

This randomized in vitro laboratory investigation used 32 synthetic polyurethane mandibles (Synbone AG, Malans, Switzerland). The use of polyurethane mandibles was consistent with previous studies and allowed controlled replication of the clinical situation in which plate bending for contouring to the mandible can affect the physical properties of the plate.\textsuperscript{6,9,12} These synthetic mandibles were anatomically and biomechanically similar to bone; they have a dense outer layer and a porous inner layer that replicate the cortical and cancellous components of bone.\textsuperscript{6,7} Their uniformity ensured a consistent sample population and minimized the sample size needed. These synthetic mandibles also have an established history of prior testing.\textsuperscript{6,9,12} This model also enabled imitation of the screw-bone interface as shown by Bredbenner and Haug,\textsuperscript{12} who demonstrated that the screw (2.4-mm diameter) insertion torque and pull-out strength for Synbone material were similar to cadaveric bone. Preliminary experiments performed with less dense polyurethane mandibles (Sawbones; Pacific Research Laboratories, Vashon, Wash) showed that they were incomparable to cadaveric bone with respect to fracture load and screw pull-out strength.

A plaster fixture was designed and created so that a 4-cm segmental defect was uniformly created between the canine tooth and mandibular angle of the synthetic mandible specimens to which plates were applied. This defect was chosen to represent the typical ostectomies performed during the surgical treatment of advanced oral squamous cell carcinomas.\textsuperscript{6,11} The 24 defect-laden mandibles were then equally divided into 3 study groups to which each of the 3 reconstruction plate designs (Figure 1) were applied: osteotomized synthetic mandibles with 2.4-mm low-profile reconstruction plates (Stryker Corp, Kalamazoo, Mich), osteotomized synthetic mandibles with 3.0-mm locking-screw reconstruction plates (Stryker-Leibinger), and osteotomized synthetic mandibles with 2.4-mm locking-screw reconstruction plates (Synthes Maxillofacial, Paoli, Pa). The reconstruction plates were secured to the synthetic mandibles with four 2.4-mm bicortical screws on each side of the defect (8 screws per sample). A fourth group of uncut mandibles without reconstruction plates served as the control.

Three samples of the 8 from each study group were subjected to torsional single-cycle bend testing (static testing) via contralateral molar loading to determine the proof or yield load (ie, the load at which permanent deformation begins). This permanent deformation was identified as the point at which the slope of the load vs displacement curve became nonlinear (Figure 2). If plate breakage occurred during bend testing, then the break load was used to quantify the strength of the plate. In the event that failure at the screw-substrate interface occurred before significant plate deformation or breakage, the load at which screw pull-out began was used as the failure load. Contralateral molar loading was used rather than incisal edge vertical loading, because preliminary experiments with the latter resulted in repeated mandible fractures before the plates fractured (or irreversibly deformed) or before screw fixation failed. Thus, contralateral molar loading rather than incisal edge loading was used exclusively.

**Figure 1.** Sample construct with the 2.4-mm locking-screw reconstruction plate (Synthes Maxillofacial, Paoli, Pa).

**Figure 2.** Load vs displacement diagram demonstrating point of irreversible plate deformation.
The condylar region of the reconstructed side of the synthetic mandible was secured with a stainless steel rod through the coronoid, allowing the condyle to function normally. A cable was anchored to the mandible using a bolt with eyelets on each end, and this cable was then secured to the actuator of a servohydraulic materials testing machine (Model 1331; Instron Corp, Canton, Mass). Loads were generated to the contralateral molar regions of the constructs at a rate of 1 mm/min to a maximum of 500 N (Figure 3). Data were acquired and analyzed using statistical software (FastTrack 8800, Instron Corp). Failure load, location, and mode of failure were recorded for each sample. The bending stiffness was calculated by using the slope of a best-fit approximation of the linear portion of the load vs displacement curve. Yield displacement was also determined for each group.

The static testing data were used to establish the parameters for cyclic fatigue testing of the remaining 5 samples from each group of 8. These samples were subjected to torsional fatigue testing between 8% and 80% (8 to 88 N, a clinically relevant value) of the average proof load for the group as per American Society for Testing and Materials guidelines. This load produced a bending moment of approximately 0.72 to 7.92 N/mm. The constructs from each group were placed in the custom testing fixtures described for static torsional loading, and cyclic loads were applied at a rate of 2 Hz to the contralateral molar region. This rate was sufficiently fast to imitate typical bite speeds but not fast enough to adversely affect the clinical relevance of the system owing to undesired heating from frictional forces. The number of cycles to construct failure (defined as plate breakage or failure at the screw-substrate interface) along with failure location and mode were recorded for each sample.

Data analysis was performed with Statview statistical software (SAS Institute Inc, Cary, NC). One-way analyses of variance were used to identify differences in mean values for the bending stiffness, failure loads, yield displacements, and fatigue lives. The Bonferroni-Dunn test was used to identify significant pairwise differences and to correct for multiple group comparisons. P ≤ .05 was considered indicative of statistically significant differences.

RESULTS

The test protocol used successfully replicated human cortical mandibular bone, because there were no short-term failures at the screw-substrate interface. Static testing resulted in mandibular fracture at the left parasymphyseal region in all 3 control constructs, whereas the mode of failure was irreversible plate deformation in the plated constructs. The control group had 3.8 to 4.0 times greater yield loads than the plated experimental groups (P < .001) and 4.7 to 5.7 times the bending stiffness of the plated groups (P < .001). This represents differences in rigidity between the uncut control polyurethane mandibles and cut polyurethane mandibles augmented by the titanium plating systems. All 3 plate designs showed comparable biomechanical stiffness and yield loads, and in addition, no differences in yield displacements were evident between the plated groups and the control group (Table).

We were able to consistently fracture all tested systems with cyclic fatigue testing in the contralateral molar region. During fatigue testing all control constructs fractured at the left mandibular ramus, whereas the plated constructs failed primarily by plate fracture through the lateral first screw. Two exceptions were noted in the 3.0-mm locking-screw reconstruction plate group in which fracture occurred at the rod in the coronoid region and the bolt in the posterior contralateral body region (ie, the plate was stronger than the testing fixture). All of the plated experimental groups demonstrated greater fatigue lives than the control group (P < .005). The 3.0-mm locking-screw reconstruction plate and the 2.4-mm low-profile (non-locking-screw) reconstruction plate groups had 1580 and 1124 times as many cycles to failure as the control group, respectively (P < .001 and P < .008, respectively). The 2.4-mm locking-screw reconstruction plate group demonstrated 865 times as many cycles to failure as the control group, but the Bonferroni-Dunn test did not show a statistical difference from the control group. Although the plated groups all had comparable fatigue lives, the higher-profile 3.0-mm plating system displayed a trend toward a slightly superior fatigue performance when compared with the lower-profile reconstruction groups (Table). No failures were noted at the screw-substrate interface.

### Table. Biomechanical Testing Results*

<table>
<thead>
<tr>
<th>Construct</th>
<th>Mean Yield Load, N</th>
<th>Mean Yield Displacement, mm</th>
<th>Mean Stiffness, N/mm</th>
<th>Cycles to Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>379 ± 51.3</td>
<td>42.7 ± 5.1</td>
<td>10.4 ± 1.76</td>
<td>5.6 ± 3.7</td>
</tr>
<tr>
<td>Locking-screw reconstruction plate†</td>
<td>99.7 ± 0.4</td>
<td>54.6 ± 5.1</td>
<td>1.8 ± 0.1</td>
<td>8849.0 ± 5994.9</td>
</tr>
<tr>
<td>Low-profile reconstruction plate†</td>
<td>99.8 ± 0.3</td>
<td>49.6 ± 7.6</td>
<td>2.0 ± 0.3</td>
<td>6296.8 ± 2671.2</td>
</tr>
<tr>
<td>Reconstruction plate‡</td>
<td>94.0 ± 15.5</td>
<td>42.2 ± 4.1</td>
<td>2.2 ± 0.3</td>
<td>4846.2 ± 561.7</td>
</tr>
<tr>
<td>P value (compared with control)</td>
<td>&lt;.001</td>
<td>.08</td>
<td>&lt;.001</td>
<td>.005</td>
</tr>
</tbody>
</table>

*Data are given as mean±SD.
†Stryker Corp, Kalamazoo, Mich.
‡Synthes Maxillofacial, Paoli, Pa.
Although multiple studies address the biomechanics of plating systems used for fracture repair and orthognathics, to our knowledge this is the first biomechanical study of such plating systems used to bridge segmental mandibular defects. The results of this study show that all 3 plating designs have approximately equivalent biomechanical properties when tested in a single-load-to-failure test mode, but the high-profile system has a slightly superior fatigue performance. The reconstruction plates failed by deformation in the static portion of our study; they failed by fracture in the fatigue portion, and this is consistent with other studies previously reported. Shibahara et al14 reported 8 fractured plates in a series of 110 patients (failure rate of 7.3%) who were followed up for an average of 50 months. Fractures primarily occurred with angular-type plates bridging lateral defects within 6 months after surgery in patients who were not reconstructed with bone grafts. Yi et al13 reported 3 fractures (4%) in 68 patients and screw loosening in 22 patients (32%) with similar lateral reconstructions. They concluded that stress is concentrated in the angle, leading to metal fatigue. They also demonstrated bone resorption around the loose screws, which was most pronounced in patients who had undergone irradiation. Lindqvist et al16 compared 4 different locking-screw plating systems in a sheep model and noted plate fracture in 6 (38%) of 16 plates at 2-month follow-up. Fractures occurred in all 4 systems with which 3- to 4-cm lateral defects were reconstructed. Irish et al17 reported that 12 of 51 titanium hollow screw reconstruction plates (THORP) failed (24%) during a 4-year period owing to fracture, exposure, or osteoradionecrosis. A retrospective study performed by Blackwell and Lacombe10 showed a similar 29% incidence of hardware-related reconstructive failure in 14 patients treated with THORPs. Blackwell et al1 demonstrated a lower failure rate of 11% in 27 patients when second-generation lower-profile reconstruction plates were used. These reports indicate that plate fracture due to fatigue loading is an important mode of failure with reconstruction plate stabilization of mandibular defects. These reports also validate our test method and support the results shown.

Our preliminary incisal edge loading resulted in synthetic mandible fracture before irreversible plate deformation or plate fracture consistently. These results support similar findings by Haug et al,7 who concluded that existing plating systems (including reconstructive plates) in the setting of mandibular angle fractures meet functional requirements for incisal edge loading but fall short with respect to contralateral molar loading. Torsional forces appear to have the greatest impact on plate deformation and eventual fracture due to plate geometry. These torsional forces include the pull of the pterygoid muscles on the subcondylar remnant, generating a superomedial vector of force, and the pull of the contralateral diastegus muscle on the inferior mandible, producing an inferolateral vector. Horizontal deformation is more easily achieved than vertical deformation, because the plate height is greater than its thickness (profile) in all current designs. Higher profile plates (for example, the THORP with a 3.5-mm profile) in theory better resist horizontal deformation secondary to torsional forces but may be associated with increased exposure rates.5,10 This study demonstrated a trend toward better fatigue performance in a 3.0-mm profile plate compared with 2 other 2.4-mm profile plating constructs. The plate profile must be tailored to allow for the best fatigue performance relative to torsional force, while limiting the extrusion rate. Although vertical forces from incisal edge loading are significant, it appears that contralateral molar loading exerts a torsional force that is more likely to cause plate fracture.

Clinically relevant postoperative bite force information in the setting of reconstruction of mandibular defects is limited. On the basis of studies by Harada et al17 and Ellis et al18 that dealt with fracture repair and orthognathics, one can conclude that a 0- to 200-N load range should provide meaningful information, and these values support the clinical relevance of the 8- to 88-N load amplitudes used in the present study.7 Greater bite forces will be generated with increasing time after surgery. In many cases of oral cavity malignancy, patients are edentulous in anticipation of preoperative or postoperative radiation therapy. This will no doubt limit their ability to generate significant bite forces. On the other hand, significant placement of stress on the mandible has been demonstrated during swallowing alone.19,20 Plate failure occurred after a minimum of 2347 cycles (one locking-screw construct failed at 1048 cycles because of synthetic mandible fracture), a number that could certainly be attained given the number of bites taken during the average week. Plate fracture rates are limited clinically partly because these patients are often using feeding tubes or are receiving liquid or soft diets.

As one would expect, there were significant differences in the mean yield load, stiffness, and cycles to failure between the control and plated groups. This represents the differences in rigidity between the polyurethane mandibles and the mandibles augmented with titanium plating systems. Although all 3 designs tested offer comparable biomechanical performance in static testing, there was a trend of better fatigue performance from the higher-profile locking-screw plate designs. The higher-profile plates had a higher number of cycles to construct failure, but this did not meet statistical significance.

Both static and cyclic contralateral molar loading demonstrated no significant differences between the 3 plating systems examined with respect to mean yield load, stiffness, and fatigue life. In addition, failure at the screw-substance interface was not encountered in this study. Because the biomechanical properties were similar among the tested mandibular reconstruction plate systems, factors such as ease of use, familiarity with the plating system, and cost can be expected to be more influential in the surgeon’s choice of mandibular reconstruction implant.

Submitted for Publication: July 7, 2003; final revision received January 26, 2004; accepted August 12, 2004.
Correspondence: Oneida A. Arosarena, MD, Division of Otolaryngology, Department of Surgery, University of Kentucky Medical Center, 800 Rose St, Room C236, Lexington, KY 40536-0293 (oaaros2@pop.uky.edu).

Funding/Support: Synthes Maxillofacial and Stryker Corp provided the implants and instruments used to complete this project. We also acknowledge support from the University of Kentucky's Medical Center Research Fund, the Center for Biomedical Engineering, and the Division of Otolaryngology.

Acknowledgment: We thank John Foust of Stryker-Leibinger and Jason Gerwe of Synthes Maxillofacial.

REFERENCES


