Evaluation of Hardware-Related Complications in Vascularized Bone Grafts With Locking Mandibular Reconstruction Plate Fixation

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**Objective:** To identify the incidence of hardware and bone-healing complications in patients who underwent locking mandibular reconstruction plate (LMRP) fixation of vascularized bone grafts for reconstruction of segmental mandibular defects.

**Design:** Case series.

**Setting:** Academic tertiary care medical center.

**Patients:** One hundred one patients who had undergone LMRP fixation of vascularized bone grafts for reconstruction of segmental mandibular defects with a minimum follow-up of 6 months.

**Main Outcome Measures:** Association of patient- and defect-related characteristics with the incidence of loose screws, osteosynthesis nonunion, and complications necessitating hardware removal.

**Results:** The incidence of loose screws was 0.8% in 984 locking screws implanted. The incidence of nonunion was 0.7% in 290 osteosyntheses. Overall, 15 of 101 LMRPs (14.8%) were removed because of hardware-related complications, with plate extrusion (n=10) the most common complication necessitating hardware removal. Pathologic diagnosis (P=.002), previous treatment with hyperbaric oxygen (P<.001), radiation therapy (P<.001), and cancer recurrence (P=.03) were statistically significant predictors of LMRP-related complications at univariate analysis. At multivariate analysis, previous treatment with hyperbaric oxygen (P=.046) remained a statistically significant predictor of LMRP-related complications.

**Conclusions:** In patients undergoing mandibular reconstruction, LMRPs are highly effective for fixation of vascularized bone grafts, with a high incidence of bone-graft healing and a low incidence of complications related to loose screws. Nevertheless, there remains a 15% incidence of hardware-related complications, most related to hardware extrusion. Previous treatment with hyperbaric oxygen is a statistically significant predictor of LMRP-related complications.

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**CONCEPTS AND CONVENTIONS associated with mandibular reconstruction have benefited from continuous improvements in both surgical techniques and hardware technology.** The evolution in the standard of care for the treatment of segmental mandibular defects has progressed from the use of bridging plates with local flaps to the use of soft-tissue free flaps and bridging plates to the current use of plates coupled with a variety of microvascular flaps employing vascularized bone and soft tissue. In each instance, the advances have been generated by the recognition of the limitations and complications associated with previously accepted techniques. Paralleling the improvements in surgical technique has been a concomitant improvement in hardware technology. Titanium plates have replaced stainless steel, plate profiles have been reduced, and the use of locking screws has greatly facilitated osseous reconstruction. Therefore, with the exception of selected patients who may not benefit from restoration of osseous integrity because of medical comorbidity or dismal prognosis, the use of vascularized bone grafts with a locking reconstruction plate may be considered the standard of care for mandible reconstruction after segmental resection.

While there is considerable consensus about the need for vascularized bone for optimal reconstruction, there remains some controversy about the optimal hardware system. All current systems provide for fixation of the osteotomized segments for the reestablishment of osseous union, and comparable complication rates...
have been reported for many of the most commonly used systems.6,7 Nevertheless, recent reports have advocated the use of miniplates or reconstruction plates with lower profiles and smaller screw diameters.8-10 The locking mandibular reconstruction plate (LMRP) offers several theoretical advantages over preexisting systems, including the need for fewer osteosyntheses and fewer screws. Ultimately, the decision as to the choice of the optimal reconstructive system will be provided by data demonstrating the highest success rate with the lowest incidence of complications. The objective of this study, therefore, was to evaluate the hardware- and osteosynthesis-related complications associated with the use of a current-generation LMRP system.

METHODS

A retrospective review of medical records was performed for all patients who underwent reconstruction of segmental mandibular defects using vascularized bone grafts fixed with LMRPs between September 16, 2002, and March 6, 2006, at the University of California, Los Angeles Medical Center. One hundred one patients who underwent 105 procedures were included in the study. A minimum of 6 months of postoperative follow-up was necessary for study inclusion, with follow-up ranging from 6 to 46 months (mean, 14.6 months). Data were collected prospectively using a personal computer–based database and included patient age and sex; American Society of Anesthesiology preoperative comorbidity classification; previous surgery; treatment with radiation therapy, chemotherapy, or both; previous treatment with hyperbaric oxygen; TNM classification; recurrence of carcinoma; defect classification; free flap selection; occurrence of complications; duration of follow-up; number of screws used and screw diameters; length of the defect; and number of osteosyntheses. A current-generation LMRP (2.8-mm profile height LMRP; Leibinger Universal Mandibular System; Stryker-Craniomaxillofacial, Portage, Michigan) was used in all procedures. The standard of choice for size of screws used in this series was 2.3 mm; 2.0-mm screws were used when the native mandible or fibula bone stock was poor and there was concern that the use of the larger diameter 2.3-mm screw holes could contribute to a pathologic fracture. Screws were placed bicortically in native mandible, bicortically in rib grafts, and monocortically in fibula bone grafts to avoid drill injury to the vascular pedicle, which generally courses along the inner cortex of the bone graft. Complications such as screw loosening or nonunion were determined on the basis of clinical criteria (symptoms such as infection, extrusion, or pain) and confirmed at surgical exploration.

Statistical analysis was performed using commercially available statistical software (SPSS for Windows, version 11.0.1; SPSS Inc, Chicago, Illinois). Univariate statistical analysis was performed using the χ² method. Multivariate analysis using logistical regression was then undertaken for those factors showing statistical significance at univariate analysis. Statistical significance was set at P < .05.

RESULTS

The study included 66 men and 35 women. Diagnoses are given in Table 1. The incidence of previous surgery and treatment with radiation therapy, chemotherapy, or both is given in Table 2. Defect length ranged from 4 to 23 cm (mean, 8.1 cm), measured along post-
Because they offer superior flexibility, ease of application, and multiple miniplates has been investigated by several authors. While the surgical conventions have focused on large mandibular arch with restoration of oral function. Large clinical studies that used many of the commercial plating systems have demonstrated excellent restoration of the osseous continuity and restoration of oral function while achieving a return to a usual diet. Optimal fixation of the vascularized bone grafts. The mandibular reconstruction system is, therefore, critical, and options for rigid fixation have increased in recent years. Nevertheless, the goals of ideal reconstruction remain unchanged: reestablishment of osseous continuity and restoration of oral function while providing optimal cosmesis with minimal complications.

Many aspects of this ideal reconstructive paradigm have largely been attained with the available plating systems. Large clinical studies that used many of the commercial plating systems demonstrate excellent restoration of the osseous mandibular arch with restoration of oral function. While the surgical conventions have focused on large-plate reconstruction, other options exist. The use of multiple miniplates has been investigated by several authors because they offer superior flexibility, ease of application, and smaller plate profile. While these factors are certainly desirable, there remains concern about reportedly increased rates of nonunion and plate extrusion associated with their use. Distraction osteogenesis is another option that has been explored experimentally for restoration of segmental mandibular defects. While several animal models exist and designs have been developed, distraction osteogenesis is not a viable clinical option for primary segmental mandible reconstruction.

Locking hardware is one of the most important recent technological advances in mandibular fixation. While initially developed for use with the titanium hollow-screw osseointegrating reconstruction plate (THORP), this system was eventually supplanted by modern LMRPs secondary to concerns about the THORP large screw diameter, plate profile height, and characteristics of the osteointegrated locking screws that made hardware removal difficult. The locking system enables the screw to achieve rigid fixation of the bone graft to the plate without a need for compression of the bone graft. The LMRP acts much like an internal-external fixator. Therefore, LMRPs have many advantages. Primarily, the screws are locked to the plate, thereby reducing the risk of hardware-related complications caused by loose screws. Use of LMRPs may require fewer screws; only 2 monocortical screws per bone graft segment are needed. In addition, LMRPs reduce the theoretical risk of ischemic bone graft loss because monocortical noncompression screws limit periosteal injury and likely cause less endosteal injury as well. In a previous series of patients undergoing internal fixation of mandibular osteosyntheses, we demonstrated a lower incidence of hardware-related complications with the use of LMRPs compared with nonlocking mandibular fracture plates.

Complication rates associated with segmental mandibular reconstruction using different plate designs have been studied in the past. Klotch et al found comparable complication rates associated with mandibular reconstruction with miniplates, reconstruction plates, THORPs, and LMRPs, although the incidence of plate fracture decreased with the more contemporary plate designs. Furthermore, they noted that tumor recurrence was associated with an increase in plate-related complications. Similarly, Nicholson et al studied factors involved in plate exposure and found no statistically significant association with the various plating systems, although LMRPs were not studied and osteocutaneous free flaps were used in less than 25% of cases. Size and site of the defect were the only significant predictors of plate exposure, and radiation therapy was not associated with an increased risk of plate-related complications. Putran et al examined the complication rates of 3 different reconstruction plates (including stainless steel, titanium [Arbeitsgemeinschaft fur Osteosynthesefragen, Bochum, Germany], and THORP). They found higher complication rates with the stainless steel plates and noted that radiation therapy was not associated with higher complication rates.

It is interesting to compare our methods and complications with the recently published series by Farwell et al, which focused on the utility of a 1.5-mm low-profile LMRP made by another hardware manufacturer (Synthes Inc, Paoli, Pennsylvania) for fixation of vascularized bone grafts. The mandibular reconstruction system

| Table 3. Univariate and Multivariate Analysis of Factor vs Plate Complication |
|---------------------------------|---------|-------------------------------|
| Factor                         | Univariate Analysis | Multivariate Analysis |
| Length of bone resection       | .18     |                               |
| No. of osteosyntheses          | .002    |                               |
| Screw diameter                 | .002    |                               |
| Flap type                      | .016    |                               |
| No. of screws                   | .016    |                               |
| Patient age                    | .20     |                               |
| Patient sex                    | .57     |                               |
| American Society of Anesthesiology status | .37 |                               |
| T stage                        | .42     |                               |
| N stage                        | .81     |                               |
| Pathologic diagnosis           | .03     |                               |
| Radiation therapy              | .001    |                               |
| Previous surgical treatment    | .29     |                               |
| Chemotherapy                   | .19     |                               |
| Cancer recurrence              | .03     |                               |
| Previous hyperbaric oxygen     | <.001   |                               |

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used in our series and in the series reported by Farwell et al,\(^9\) are the 2 most commonly used mandibular reconstruction systems in the United States, having roughly equal market shares and together accounting for about 70% of all cases. Unlike the low-profile plates used by Farwell et al,\(^9\), all reconstructions in our series were carried out using an LRMP with a relatively high profile height of 2.8 mm. The plating system used in our series (Leibinger Universal Mandibular System, Stryker-Craniomaxillofacial) also includes a low-profile LRMP with a profile height of 1.5 mm. However, it has been our preference to use high-profile LMRPs for vascularized bone graft fixation because they are more rigid and less prone to deformation during insetting of precisely contoured, tightly fitting bone grafts into segmental mandibular defects, thereby reducing the risk that small changes in plate contour could result in major misalignment of dental occlusion. The higher profile 2.8-mm plates (Stryker-Craniomaxillofacial) have a higher bending moment amplitude on dynamic system testing compared with the 1.5-mm plates (Stryker-Craniomaxillofacial) (2.64 Nm vs 1.01 Nm), which corresponds with clinical experience.\(^18\) A theoretical disadvantage of high-profile LMRPs is associated with the possibility that high plate profile may contribute to an increased risk of plate extrusion. However, the 9.9% incidence of plate extrusion in our series was similar to the 10.5% incidence of plate extrusion reported by Farwell et al\(^9\) using low-profile LRMPs. The 14.8% overall incidence of hardware-related complications observed in our series was similar to the 14.3% overall incidence of hardware-related complications reported by Farwell et al\(^9\),\(^\) indicating that both mandibular reconstruction systems are associated with a similar pattern and incidence of hardware-related complications. Another disadvantage of high-profile LRMPs is that they are more prone to be visible or palpable after implantation than are low-profile LMRPs. However, no patient in our series requested that an LRMP be removed because it was visible or palpable.

The presence of a low but persistent rate of hardware-related complications highlights a number of contributory factors. In the present study, clinically apparent screw loosening occurred at a rate of 0.8%. This low rate underscores one of the advantages of the locking plate, that is, that screw loosening is a rare clinical event. Some patients experienced a foreign-body reaction to the plates and screws, either leading to eventual plate extrusion or removal before extrusion, although titanium alloy plates have reduced the incidence of this complication. The titanium alloy rapidly develops an oxidized capsule surrounding the plates and screws that seems to serve as a protective barrier against foreign-body reaction.

Hyperbaric oxygen therapy has an interesting role in the overall treatment paradigm for mandible osteonecrosis. It is an efficacious option for early- as well as late-stage mandibular osteonecrosis and may obviate the necessity of vascularized bone graft reconstruction in a subset of patients.\(^19\) Nevertheless, previous use of hyperbaric oxygen therapy is associated with a significantly increased incidence of complications in patients undergoing microvascular mandibular reconstruction. Chang et al\(^20\) reported a complication rate of 21%, with 4 patients subsequently requiring microvascular reconstruction. Gal et al\(^21\) cited a complication rate of 43%, although no free flaps were lost in their series.\(^21\) In the present study, osteoradionecrosis alone was not associated with a statistically significant increase in complication rates. However, patients with a history of hyperbaric oxygen therapy had a statistically significant increase in complications at multivariate analysis. While the specific mechanism of injury of hyperbaric oxygen therapy is uncertain, it seems that this phenomenon represents selection bias because patients whose mandibular disease is refractory to hyperbaric oxygen therapy have particularly severe underlying bone and soft-tissue microcirculatory ischemia.

Radiation therapy remains a controversial risk factor for plate-related complications. It is well known that radiation therapy is associated with small-vessel damage, diminished smooth-muscle density, and small-vessel fibrosis.\(^22\) Large clinical series that explored the association of radiation therapy with free flap complication rates reached different conclusions.\(^3,9,17,21,24,26\) Choi et al\(^23\) in a study of 100 consecutive patients undergoing fibula free flap reconstruction of the mandible, did not find that radiation therapy was associated with an increase in complication rates. Conversely, in a similar study of 140 patients undergoing fibula free flap mandible reconstruction, Deutsch et al\(^24\) found that administration of radiation therapy increased complication rates regardless of the timing of the dose. Shaw et al\(^,9\) in a study of 143 mandible reconstructions, also found that complication rates in patients who received postoperative radiation therapy were 23% higher than in those not receiving radiation therapy, a level reaching statistical significance. Farwell et al\(^9\) reported that, while radiation therapy per se was not a significant predictor of hardware-related complications, the diagnosis of osteoradionecrosis was.

The results of our study demonstrate the effectiveness of LMRPs used for mandible reconstruction using vascularized bone grafts. This latest-generation system eliminated plate fracture, minimized screw loosening and nonunion, and was associated with a need for hardware removal, which is comparable with other commercially available systems reported in the literature. There remains a 15% incidence of hardware-related complications, most often related to hardware extrusion. This complication was effectively managed by hardware removal and usually did not result in compromise of maintenance of mandibular continuity or dental occlusion. While radiation therapy, previous hyperbaric oxygen therapy, pathologic diagnosis, and cancer recurrence were significantly associated with LMRP-related complications at univariate analysis, only previous hyperbaric oxygen therapy remained a statistically significant predictor of LMRP-related complications at multivariate analysis.

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**Author Contributions:** Dr Blackwell had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. **Study concept and design:** Knott, Head, Abemayor, and Blackwell. **Acquisition of data:** Sercarz, Head, and Blackwell. **Analysis and interpretation of data:** Knott, Suh, Nabil, Head, and Blackwell. **Drafting of the manuscript:** Knott and Head. **Critical revision of the manuscript for important intellectual content:** Nabil, Sercarz, Head, Abemayor, and Blackwell. **Statistical analysis:** Suh. **Administrative, technical, and material support:** Knott, Sercarz, and Head. **Study supervision:** Sercarz, Abemayor, and Blackwell.

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