INTRODUCTION
Since the introduction of the fibula free flap for mandibular reconstruction in 1989, osteocutaneous microvascular free flap transfer has become the gold standard for repairing segmental mandibular defects when possible. Successful reconstruction of segmental defects is dependent on a variety of factors including anatomic location, microvascular flap choice, and rigid plating techniques. Historically, bone fixation consisted of hand-bent hardware and the characteristics were individually determined at the time of reconstruction.

Recent technological advances have made possible the use of reconstruction plates that no longer require hand bending. Preformed/prebent reconstruction plates with multiple predetermined sizes have been designed to fit most mandibles. In addition, computer-aided design and computer-aided manufacturing (CAD/CAM) now permits more individualized and better-fitted plates based on radiographic osseous morphology.

The aesthetic advantages and reduced operative times of CAD/CAM custom plates have been well documented. However, no study has compared perioperative outcomes of preformed/prebent plates with CAD/CAM custom plates. The aim of this study was to investigate postoperative plate complications and rates of reoperation in these two groups. The authors hypothesized that subjects receiving CAD/CAM custom plates will demonstrate fewer plate-related complications and fewer reoperations in comparison with subjects utilizing preformed/prebent plates.

MATERIALS AND METHODS
A retrospective medical chart review was conducted after institutional review board approval (IRB #140359). All subjects who underwent osteocutaneous microvascular reconstruction of
the mandible between July 2011 and July 2016 at the University of Kansas Medical Center were included. Subjects were stratified into two groups based on the technique of rigid fixation: 1) preformed/prebent reconstruction plates and 2) CAD/CAM custom plates. Demographics were obtained including age, sex, race, and ethnicity. Indication for surgery, area of mandible and length of defect, and type of osteocutaneous free flap used were recorded. Pertinent past medical history such as tobacco use and history of head/neck radiation were also included and recorded as binary data points. Flap complications (defined as hematoma, seroma, fistula formation, partial necrosis, or flap loss) were also tabulated, though for statistical analysis subjects with any one of these complications was recorded as a binary “yes” or “no” function. Subjects with incomplete medical records or less than 6 months of documented follow-up were excluded from statistical analysis. Primary outcome measures for this study were plate-related complications (defined as infection of free flap deep tissue resulting in hardware exposure, bone exposure, or plate exposure) and subsequent therapy/surgery for those complications (conservative medical treatments vs. surgery involving hardware alteration or removal). Among the subjects in both groups who had plate-related complications, we then analyzed the rates of reoperation due to those complications, again recorded as a binary function.

Mandible Plating Technologies

Plating techniques were determined preoperatively as all subjects who undergo CAD/CAM custom plating require preoperative virtual surgical planning based upon preoperative imaging. Virtual surgical planning was used to estimate the intended segmental mandibular defect and the planned mandibular construct with osteotomies when necessary (Fig. 1). CAD/CAM custom plates were manufactured by both Synthes (West Chester, PA) and KLS Martin (Jacksonville, FL) at the surgeon’s discretion (Fig. 2). CAD/CAM plates were manufactured by both selective laser milling and three-dimensional printing techniques during this study period by both manufactures. Preformed/prebent reconstruction plates are presized, shaped implants that are selected at the time of surgery at the surgeon’s discretion. Preformed/prebent plates were utilized from both Synthes and KLS Martin. In all such cases, manufacturer-provided templates are used intraoperatively to help select the appropriate preformed/prebent reconstruction plate. Sizes and shapes of the preformed/prebent reconstruction plates are based on the average normal anatomy of the mandible. Statistical analysis of data derived from more than 2,000 computed tomography scans from various adult populations is used to determine this normal anatomy. There are three plate sizes that can be applied to most patient mandibles, which require minor bending to adjust to each subject’s mandibular contour (Fig. 3). The preformed shape helps drastically reduce the amount of intraoperative bending that was required in traditional (hand bent) plating methods, thereby reducing operative times as well maintaining integrity of the metal plate compared to traditional hand-bending techniques.

Statistical Analysis

Primary statistical analysis for this study was performed using a χ² test for discrete and a t test for continuous variables. A Fisher exact test was utilized due to the small sample size of flap types. A P value of .05 was used to determine statistical significance.

Multivariable logistic regression models were used to model the prediction of plate-related complications and operation. Variables included in the models were basic demographic variables, as well as flap complications, plate type, defect length, smoking status, and neoadjuvant radiation. The final models were determined by a stepwise elimination; the entrance criterion α level was 0.1, and .05 was the α level needed for a variable to stay in the model. All statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC).

RESULTS

In this study, 142 subjects underwent microvascular mandibular reconstruction between July 1, 2011 and July 1, 2016 at the University of Kansas Medical Center. Of these, 89 (62.7%) received a preformed/prebent mandibular plate for their reconstruction, compared to 53 (37.3%) who received CAD/CAM plates. One hundred one subjects (71.1%) were male and 41 (28.9%) were female. Ages ranged from 14 to 92 years, with an average age of 61 years. Mean follow-up time was 16 months, with a range of 6 to 72 months. Of the 142 individuals included in the analysis, 108 (76%) had a history of smoking and 34 (24%) did not. Furthermore, a sizeable portion of our subjects had a previous history of treatment for head and neck tumors, with 51 (36%) having undergone prior radiation therapy. We did not find a significant difference in age, gender, and follow-up time between the comparison groups.

Fig. 1. Virtual surgical planning for computer-aided design/computer-aided manufacturing custom plate fabrication. (A) Three-quarter view. (B) Cephalad view showing anatomic contour and abutment of plate to native mandible. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]
Of all cases, 108 (76%) required mandibular reconstruction due to malignancy, by far the most common indication for surgery. Twenty-two subjects (15.5%) required reconstruction secondary to osteoradionecrosis of the mandible, seven (5%) for trauma, and five subjects (3.5%) required surgery for bisphosphonate-related osteonecrosis of the mandible. Free flap donor site consisted of 84 (59.5%) radial forearm osteocutaneous free flaps, 53 (37%) fibular osteocutaneous free flaps, and five (3.5%) received osteocutaneous free flaps from other sites such as scapula or iliac crest. The indications for reconstruction as well as donor site choice was not significantly different between the groups. For patients receiving preformed/prebent plates, 38% of fibular flaps and 34% of radius flaps experienced plate-related complications ($P = .88$); of these, 21% of fibular flaps required reoperation versus 18% of radius flaps ($P = .83$). For custom CAD/CAM plates, 38% of fibular flaps and 34% of radius flaps had plate-related complications; of these, none of the fibular flaps and three (8.8%) of the radius flaps required reoperation ($P = .62$). The proportion of flap complications was in favor of recipients of custom CAD/CAM plates; of the 39 patients who experienced flap complications, nine were custom CAD/CAM recipients (17% of this plating group) and 30 were preformed plate recipients (34% of this plating group). For mandibular defect length, the average defect size in the preformed/prebent plating group was 7 cm, with a standard deviation of 2.4 cm and a range of 2.5 to 14 cm. In the custom CAD/CAM plating group, this had an average defect length of 8.1 cm, standard deviation of 2.9 cm, and a range of 4 to 16 cm (Table I).

Among the 89 subjects who received preformed plates for their reconstruction, 32 (36%) experienced plate-related complications. In the CAD/CAM group, 11 (21%) of the 53 subjects had complications. The difference in complication rate between groups approached significance ($P = .0566$). Of the patients receiving preformed plates who had perioperative complications, 18 (56%) required reoperation. This comprised 20% of the patients reconstructed with preformed/prebent plates. For the 11 patients with CAD/CAM plates who had plate-related complications, three (27%) required reoperation, or 5.6% of all patients receiving CAD/CAM plates. The overall rate of reoperation was significantly lower in the CAD/CAM group ($P = .0180$) (Table II). There was no statistical difference in perioperative complications or reoperation between our providers, as well as different hardware manufacturers. Patients who did not require reoperation were treated with antibiotics, aggressive wound care, and hyperbaric oxygen.

The findings of the stepwise regression model for plate complications revealed that even though plate type was not a statistically significant predictor, patients with preformed plates were 1.6 times more likely to develop plate-related complications. Adjusted for age and plate...
TABLE I. Patient Demographics

<table>
<thead>
<tr>
<th>Mandibular Rigid Fixation Technique</th>
<th>Osteocutaneous Free Flap Type</th>
<th>Mean Mandibular Defect Length, cm</th>
<th>Prior Radiation, No.</th>
<th>Tobacco Abuse, No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preformed/prebent plates, n = 89</td>
<td>Fibula: 38 (43%), radius: 50 (56%), other: 1 (1%)</td>
<td>7 (SD = 2.4)</td>
<td>28</td>
<td>68</td>
</tr>
<tr>
<td>CAD/CAM custom plates, n = 53</td>
<td>Fibula: 16 (30%), radius: 34 (64%), other: 3 (6%)</td>
<td>8 (SD = 2.9)</td>
<td>23</td>
<td>40</td>
</tr>
</tbody>
</table>

P value = .1255

CAD/CAM = computer-aided design/computer-aided manufacturing; SD = standard deviation.

type, flap complications were the only statistically significant predictors retained by the model. Similarly, in the model for plate removal, plate type was not a significant predictor, but patients with preformed plates were 4.3 times more likely to have plates removed, and adjusted for age and plate type, flap complications were the only significant predictors retained by the model.

There was no significant difference in the prevalence of smoking history between plating groups; smoking history was equally prevalent between groups. We did not find a significant relationship between any history of smoking and plate-related complications overall in our entire sample population (P = .7631). Rates of neoadjuvant radiation were equally prevalent between the two groups; however, previously radiated patients were more likely to return to the operating room for plate-related complications if they received a preformed/prebent plate. Of the patients with neoadjuvant radiation and preformed/prebent plates, 35.7% required subsequent reoperation for plate-related complications as compared to 14.8% with no history of radiation who required reoperation (P = .0250). In patients receiving CAD/CAM plates, 17.4% of patients who received neoadjuvant radiation required reoperation as compared to the 3.3% without neoadjuvant reoperation who required reoperation, which was not statistically significant (P = .0827).

DISCUSSION

Microvascular osteocutaneous free tissue transfer is the preferred method of reconstruction for segmental mandibular defects at many institutions. Currently, head and neck surgeons have many decisions to make to perform the ideal reconstruction. These include microvascular flap selection, location and number of microvascular vessel coaptation, as well as choice of fixation techniques to secure the osseous construct. Success rates of flap reconstructions at most institutions are in the 90th percentiles.7,8 Despite these high rates of success, most reconstructive surgeons strive to decrease complication and failure rates.

Technologic advancements have contributed to improved successes. These include but are not limited to advances in preoperative imaging and presurgical planning, improved intraoperative microscopy and magnification, and better instrumentation. Most recently, advances in rigid fixation manufacturing have created next generation mandibular reconstruction plates that have replaced traditional hand-bent techniques at many institutions. This next generation mandibular hardware comes in two varieties. One variety is the preformed/prebent standardized reconstruction plate, which comes in a variety of manufactured shapes and sizes, and allows for the selection of near anatomic hardware. The second variety is the CAD/CAM custom plate, which offers anatomic coaptation of the mandible. These custom reconstruction plates are based on stereolithic modeling derived from analysis of patient-specific preoperative radiographic imaging, which has proven advantageous for complex pathologies and increasingly complex procedures.9,10

CAD/CAM custom plates offer advantages over conventional hardware and even preformed/prebent plates. One advantage is decreased surgical time, as the surgeon no longer needs to hand bend the plate to match the desired contour; this is due to precise modifications to both the plate as well as osteotomy guides in both the donor and recipient sites.3,4,11,12 Although the up-front cost of patient-specific planning and manufacturing can be significant, it must be taken in context of decreased operative time as well as decreased postoperative complications. Based on previously estimated price per minute of time in the operative theater, Tarsitano et al. have reported that the average time saved by using CAD/CAM technologies (~115 minutes) was enough to offset the costs of the plates in their cases.8 Based on the data presented in this article, we argue that CAD/CAM plates are economically viable when compared to preformed/prebent plates, as patients receiving preformed/prebent plates were more likely to return to the operating room, thus extending and increasing the cost of treatment for their original pathology.

Another advantage of CAD/CAM plating is in the physical characteristics of the plate itself. Accurate contour, reduced profile, and increased surface area of the bone-plate interface are ideal characteristics of mandibular reconstruction plates. The overlying skin and soft tissues tend to contract around the plate, and it is important to minimize and space between the plate and underlying

<table>
<thead>
<tr>
<th>Subjects (%)</th>
<th>Perioperative Complications, No. (%)</th>
<th>Reoperation for Hardware Failure/Explantation, No. (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preformed/ prebent plates</td>
<td>89 (62.7%)</td>
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CAD/CAM = computer-aided design/computer-aided manufacturing.
bony structures to prevent plate and bone exposure. As intraoperative bending is not needed with patient-specific plating models, integrity of the material is still preserved even with thinner profile plates. With an increased bone-plate interface there is also less dependency on the screw to provide rigid fixation as is necessitated when there is a gap between the hardware and the mandibular construct. The enhanced coaptation of the plate to the native mandible in patient-specific planning and fixation such as CAD/CAM has been well documented, leading to improved morphologic and functional outcomes.6,13–15

The impact that these new technologies have on improved patient outcomes remains relatively unknown. Some data exist to suggest an advantage of CAD/CAM plates over more conventional fixation techniques. When comparing CAD/CAM technologies versus preformed/prebent mandibular plates, Sieira Gil et al. demonstrated a significantly lower rate of plate exposure in favor of the CAD/CAM plates, though the treatment for these complications was not mentioned.4 Although our results approached statistical significance, there was certainly a noticeably lower rate of plate-related complications in patients receiving CAD/CAM plates. In our study, the severity of perioperative complications in the CAD/CAM group was significantly lower. Fifty-six percent of patients with complications after receiving preformed plates required reoperation involving alteration or removal of mandibular hardware; this was over double the rate in patients with complications after receiving CAD/CAM plates. Patients who did not undergo reoperation were treated typically with a combination of hyperbaric oxygen therapy, antibiotics, and aggressive wound management. Our data suggest that although plate-related complications occur with patient-specific plating techniques, the likelihood of these complications requiring surgery is much lower, and therefore longitudinal morbidity and cost of therapy are reduced for these patients.

Though data exist to suggest that donor site choice for free flap tissue can be a risk factor for plate-related complications,16,17 no comparison of this variable in the context of mandibular fixation technologies has been performed. In this study, there was no significant difference in complication rate or reoperation rate between reconstructive flap type. Additionally, data exist to suggest that the size of the reconstructed mandibular defect correlates with an increasing complication rate; this may be another independent risk factor for plate-related complications.16,18 Arganbright et al. demonstrated that patients are 1.3 times more likely to have plate exposure for every 1-cm increase of bone harvest length in patients receiving radial forearm free flaps.17 Although we did record graft length for each patient, we did not stratify plate-related complications and reoperation in the context of graft length. Following multivariable analysis, we found that the presence of any type of flap complication (as defined above) was an independent risk factor for both plate complications and plate-related reoperation in both plating groups; however, recipients of preformed plates experienced nearly twice the rate of flap complications when compared to the custom CAD/CAM plate recipients. Although this may indirectly suggest an advantage in selecting custom CAD/CAM plates for reconstruction, the form and severity of flap-related complications are diverse and would need further investigation on the strength of the association between these complications and plate-related outcomes.

In contrast to other studies, any smoking history was not found to be associated with an increased risk of hardware complication.19 Regarding history of prior radiotherapy, we found that previously radiated patients reconstructed with preformed plates were significantly more likely to require reoperation due to plate-related complications as compared to those without prior radiation. This contrasts with previously radiated patients reconstructed with CAD/CAM plates who did not exhibit a significant increase in complication and reoperation rates, suggesting that custom plates may be better suited for patients with prior head and neck radiation.

There are several limitations to this study. First, this study was conducted retrospectively. Patients reviewed were subject to a possible selection bias, as rigid fixation techniques were not determined randomly. Factors such as intraoperative technique and postoperative care were not standardized between the four surgeon providers. In addition, the size and the location of the reconstruction may have also determined outcomes which were beyond the scope of this study.

CONCLUSION

CAD/CAM mandibular plating is associated with lower rates of plate-related complications and significantly lower rates of reoperation secondary to these complications when compared to preformed/prebent models. This should be considered in the context of perioperative outcomes and cost of care in patients undergoing mandibular microvascular reconstruction. Furthermore, more in-depth analysis of resection and donor site characteristics as well as prospective studies are needed to further build upon the evidence presented in this article.

BIBLIOGRAPHY


