Triple-Cut Computer-Aided Design–Computer-Aided Modeling: More Oncologic Safety Added to Precise Mandible Modeling

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Purpose: Computer-aided design–computer-aided modeling (CAD-CAM) has become standard in mandibular reconstruction because it offers better outcomes. Occasionally, the reconstructive plans need to be changed intraoperatively and the custom-made prefabricated devices may become inadequate. We present an efficient adjunct to the standard CAD-CAM technique that resolves this problem.

Materials and Methods: Customized surgical devices with our "triple-cut" concept were used in 5 patients for mandibular reconstruction with free fibula flap (4 after mandibular resection for squamous cell carcinoma and 1 after mandibular osteoradionecrosis). In all patients the mandibular and fibular cutting guides were provided with 3 different cutting levels per side.

Results: Three different cutting levels on the mandible permitted an accurate resection based on the intraoperative needs. The corresponding 3 "cutting levels" on the fibula created perfectly matching segments of vascularized bone. Good contact of bony segments was obtained in all patients.

Conclusions: The prefabricated triple-cut cutting guides make changing the dimensions of bony resection, while still using the prefabricated CAD-CAM reconstructive plate, possible.

Since its introduction by Hidalgo[1] in 1989, mandibular reconstruction with a free fibula flap has seen many important refinements. The most recent refinement, virtual surgical planning (VSP) with computer-aided design–computer-aided modeling (CAD-CAM), shortens the operating time and offers precise bone-to-bone contact and good maxilla-to-mandible occlusion.[2-5]

A search of the current literature shows mainly reports on the advantages of CAD-CAM technology over the classic techniques (manual cutting and modeling of fibula and manual bending and cutting of fixation plate). The problem with CAD-CAM technology, with its prefabricated and customized surgical devices, in relation to an inadvertent intraoperative change in the surgical plan regarding the dimensions

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of mandibular resection, has been addressed by only a few authors.[6-8] The surgeon is faced with such a situation in the case of rapid cancer growth or a long interval between preoperative diagnostic procedures and surgery. In such cases, the preoperative mandibular bone involvement with cancer or osteoradionecrosis (ORN), evidenced by computed tomography (CT) and/or magnetic resonance imaging (MRI) scans, may differ considerably from that found during surgery.[9,10] Reported sensitivity and specificity namely range from 94 to 100% for MRI and from 83% to 100% for CT.[11] The size of planned mandibular resection, at the time of VSP, also depends on the surgeon's skills and experience. However, the final size of mandibular resection is determined during surgery, still by direct inspection of cancer infiltration of the mandible.[12]

Intraoperative histologic techniques, which could be helpful, are currently being investigated.[13,14] Namin et al[13] found that after mandibular resection for cancer, 12% of patients (6 of 51) had cancer-positive results on intraoperative bone marrow cytologic evaluation beyond the margins of the original bone resection because of occult cancellous bone invasion. This would not have been detected if only preoperative imaging and no intraoperative cytologic evaluation had been performed. Further resections of the mandible are required in such patients. ORN is another condition in which resection of the necrotic bone is determined only intraoperatively. Resection stops only after bleeding from the bone of the mandibular stumps is reached.[15] Any intraoperative variation in the size of mandibular resection may render the prototyped and/or prefabricated surgical materials (cutting guides and prebent reconstructive plate) inadequate with consequent loss of money. Additional holes could be added to the prebent plate to better adapt the CAD-CAM device to changes in the intraoperative plans for mandibular resection, which could lead to a suboptimal outcome for the patient.[5,8] In the case that it is still possible to use the prefabricated plate, the surgeon is forced to shape one or both fibular resection stumps by manually adapting them to the medial, distal, or both mandibular stumps, without the help of the cutting guides.

Materials and Methods

Between January and September 2016, five patients—four with squamous cell carcinoma and one with ORN of the mandible—were surgically treated at Cattinara University Hospital, Trieste, Italy. In all 5 patients, CAD-CAM technology with the "triple-cut concept" for tumor-free mandibular margins of resection and reconstruction by a free fibula flap was used. Because of its retrospective nature, this study was granted an exemption in writing by the Azienda Sanitaria Universitaria Integrata di Trieste Ethical Committee Review Board. The study adhered to the Declaration of Helsinki. Written informed consent was obtained from all patients. All patients followed the same preoperative protocol (Table 1).

A CT scan and MRI of the head and neck and an angiography-CT scan of the donor leg were obtained in each patient. The DICOM (Digital Imaging and Communications in Medicine) files of the CT scan of the patient's facial skeleton (64 slice, high resolution) were sent to a biomedical engineering company (Sintac, Trento, Italy) to perform the 3-dimensional rendering of the mandible. The clinical and radiologic characteristics of the mandibular cancer were evaluated during a videoconference attended by the head and neck surgeons, the reconstructive surgeons, and the producer's engineers with the aim of planning the soft tissue surgical margins, as well as the mandibular bone resection and reconstruction. Mandibular involvement by cancer or ORN was discussed. It should be noted that preoperative planning is crucial. It also has to take into consideration situations in which additional mandibular resection into the ramus or symphysis (another closing-wedge osteotomy) would be required and provide adequate solutions. Once the dimensions of mandibular resection were determined at 1 cm or more from the farthest extent of the tumor found by imaging and clinically, the location and configuration of the osteotomies were proposed. These sites were called the "first cutting levels." With it being taken into account that the real and final extent of bone resection can be established only during the operation, additional cutting options were planned farther from the tumor and were therefore called the "second" and "third cutting levels." The third cutting level thus was the outermost, the farthest from the center of the tumor. The distances between different cutting levels can vary (from 5 to 10 mm) depending on different factors (predicted cancer growth rate or intraoperatively determined positive bone margins). The customized mandibular polyamide cutting guides (with the options for several different cutting levels) were then fabricated as shown in Figure 1 (patient 5, Table 1).

Use of 3 cutting levels per side permitted for 9 different intraoperative resection scenarios (3 × 3) compared with the standard, commonly used "single-cut" devices. The same triple-cut concept was reproduced on the donor (fibular) bone, and polyamide cutting guides were manufactured with 3 cutting levels proximally and distally carrying exactly the same angles and inclinations (Fig 2). The 9 different mandibular cuts could be matched perfectly to the corresponding 9 different fibular options (Fig 3 shows

Table 1. PATIENT DATA

Patient No.	Tumor	Boyd Classification of Defect[16]	Flaps	Fibular Bone Segments	Cutting Level	Early Complications	Disease-Free Bone Margins
1	SCC	Symphysis	Right osteocutaneous FFF	3	First, both sides	No	Yes
2	SCC	Right mandibular body	Left FFF and left RFFF	2	First, both sides	No	Yes
3	SCC	Symphysis	Right FFF and left ALT	3	First, both sides	No	Yes
4	SCC	Left mandibular body	Right osteocutaneous FFF	1	Second, both sides	No	Yes
5	ORN	Right mandibular body	Left osteocutaneous FFF	1	Third, both sides	No	NA

Abbreviations: ALT, anterolateral thigh; FFF, free fibula flap; NA, not applicable; ORN, osteoradionecrosis; RFFF, radial forearm free flap; SCC, squamous cell carcinoma.

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examples of 3 possible reconstruction scenarios according to different resections).

A single titanium custom-made mandibular plate was then engineered to fit all different surgical scenarios possible. The holes on the cutting guides for the mandible and the fibula were used to secure the guides to the bone. This permitted controlled osteotomies. The holes were designed to precisely match the holes of the titanium reconstructive plate that would be used to fix all fibular (neo-mandibular) segments to the mandibular stumps (Fig 4). The triple-cut concept also can be applied in the same way when multiple fibular segments are required (Fig 5).

In the operating room, the soft tissue cancer invasion was removed en bloc with the infiltrated bone segment and submitted for histologic examination. Frozen sections of soft tissue margins were analyzed. Currently, at our institution, there is no intraoperative histologic evaluation of bone margins available, so the dimensions of bone excision depend only on the surgeon's experience and clinical judgment.

Results

The data of the 5 patients treated by triple-cut integrated CAD-CAM devices are summarized in Table 1. Mandibular reconstruction by free fibula transfer succeeded in all 5 cases without complications.

In patient 4, an intraoperative change in the planned mandibular resection was necessary because the tumor was larger than estimated at the time of the preoperative CT scan. In this case the second cutting level was chosen on both sides of the resected mandibular segment, and then the same levels were reproduced on the fibular bone.

In patient 5, the bone resection was carried out to obtain visualization of normal-appearing bleeding

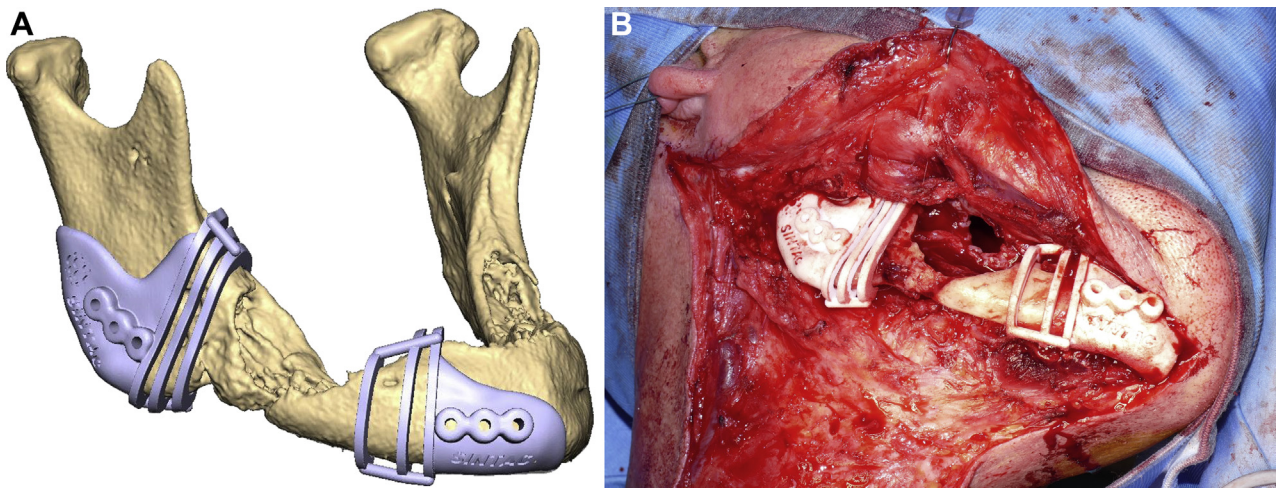

FIGURE 1. Customized cutting guides designed according to planned cutting levels during preoperative planning (*A*) and in intraoperative setting (*B*) in patient 5.

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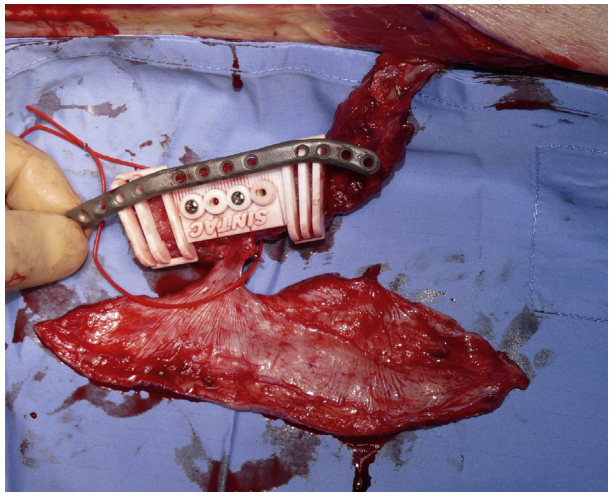

FIGURE 2. Intraoperative view of cutting guides virtually planned in Figure 1 for patient 5. Fibular cutting guides are fixed with screws to the harvested fibular osteocutaneous flap. The surgeon is holding the titanium mandibular plate to show the correspondence of every hole.

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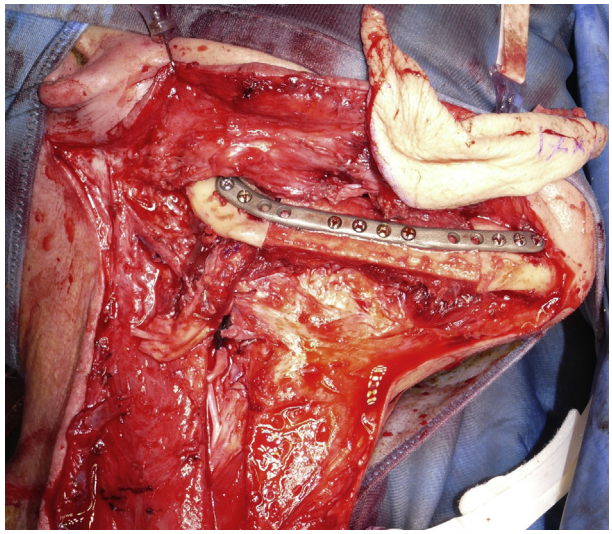

FIGURE 4. Intraoperative view of reconstructed mandible in patient 5 (same patient shown in Figs 1-3). The titanium plate is designed to guarantee a good fit with all the different mandibular stumps and different fibular segments that could be used.

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bone. Resection to the third cutting level on both the mandibular cutting guides was necessary because the necrotic bone extended beyond the limits that were preoperatively presumed by the head and neck surgeon as being involved by ORN based on the CT scan evaluation of the mandible.

In all 5 cases the cutting and assembling procedures were fast and were carried out uneventfully. Stable contact between bone segments and alignment were reached with a good restoration of the mandibular shape. Good results were confirmed by postoperative CT scans (Fig 6).

Discussion

VSP and CAD-CAM are becoming standard in mandibular reconstruction.[2-5] On the basis of on the preoperative workup, they offer precise matching of the mandibular resection stumps with those of the donor fibular flap, thus facilitating perfect bone fixation and fast bone healing. It is true that the triple-cut concept requires larger polyamide cutting guides and thus more freeing of soft tissues from the mandible. However, no periosteal stripping is required, and we have not encountered any bone-healing problems in our patients for the time being. The donor bone or osteocutaneous flap can be harvested, cut, and fixed by a reconstructive plate while still being perfused by its donor vessels. This shortens the ischemia time and favors undisturbed bone healing. After division of the donor vessels, the preshaped (to exact measures of the mandibular defect) and fixed bony flap needs only to be inserted into the mandibular defect and fixed with screws

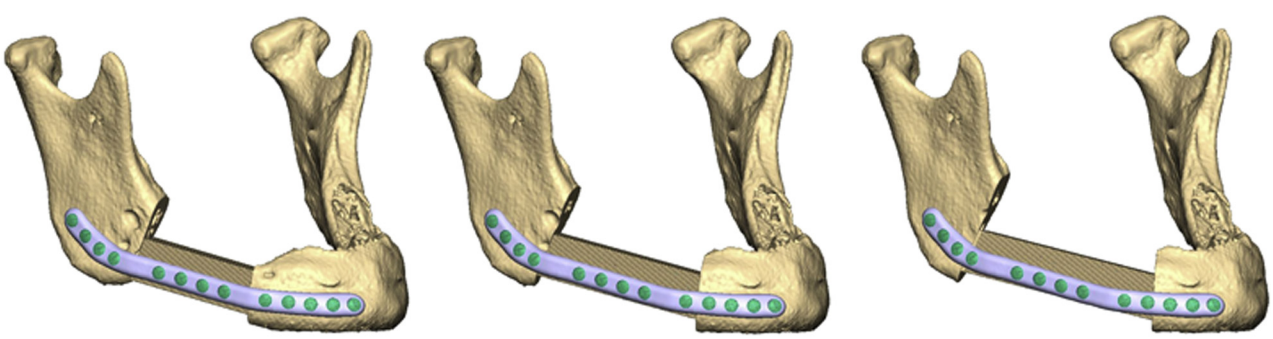

FIGURE 3. Three (of nine) possible reconstructive scenarios are shown in patient 5 (same patient shown in Figs 1 and 2). The first cutting levels (left), second cutting levels (middle), and third cutting levels (right) are simulated.

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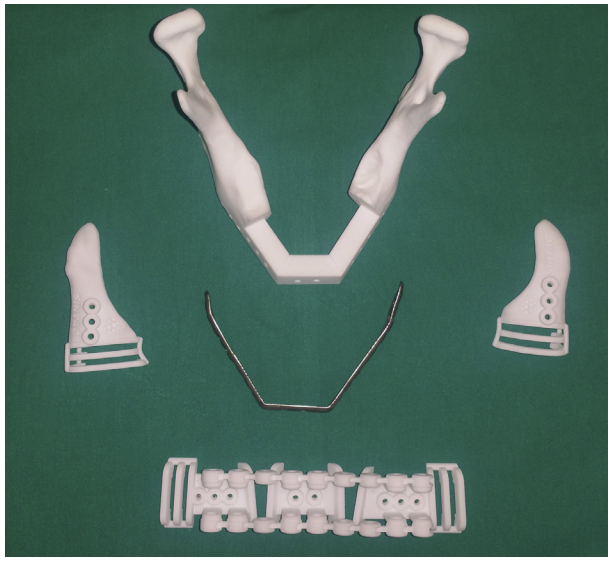

FIGURE 5. The triple-cut concept can be applied in multiple-segment reconstructions. The reconstructive plate and cutting guides for patient 3 are shown.

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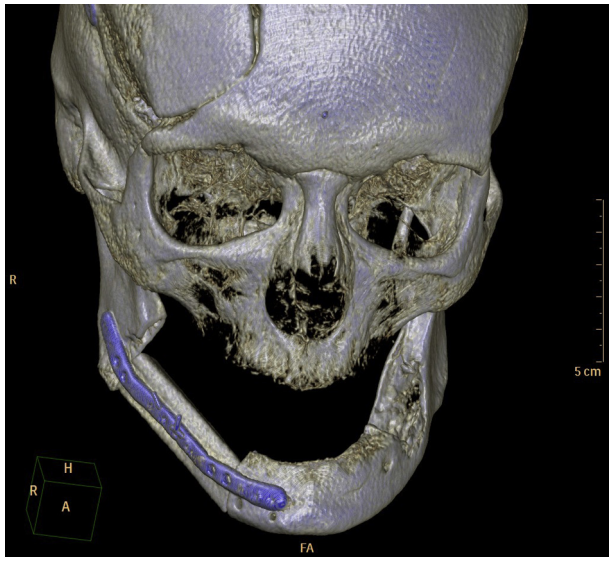

FIGURE 6. Postoperative evaluation with computed tomography scan in patient 5 (same patient shown in Figs 1-4). Good alignment and stable contact between bone segments were reached. A, anterior; FA, foot anterior; H, head; R, right.

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inserted into the predrilled holes of the mandibular stumps, without any remodeling of the bone or plate. This consumes considerably less operating room time than the conventional method of mandibular reconstruction. Furthermore, functional and cosmetic outcomes are much better.[4]

Our article addresses a major problem of the CAD-CAM technique, which occurs when the dimensions of the mandibular resection need to be changed during the operation because of a larger amount of cancer invasion of the mandible than established preoperatively. When this happens, the prefabricated and preshaped reconstructive plate may become too short and thus may be inadequate. Instead of shortening the procedure, the surgeon is faced with the need to return to manual bending of a new fixation plate, which makes the operation longer and increases its costs. On the contrary, CAD-CAM planning and fabrication of 2 additional cutting levels on each side come at no additional cost compared with the traditional "one-cut" devices used previously at our hospital.

The purpose of this article is to present a simple, novel but effective adjunct to the aforementioned CAD-CAM technology that resolves the problem of residual tumor-positive mandibular margins after resection of the mandibular segment, as planned preoperatively. Usually, the CAD-CAM process for mandibular reconstruction takes about 7 to 10 days. During this time, it seems unlikely that the tumor would grow beyond the established safety margins as defined by preoperative CT and nuclear magnetic resonance scans. Tumor-free margins of at least 10 mm are required, according to the guidelines, in cases of erosive bone defects.[17]

At our institution, the head and neck surgeon determines the tumor spread in the mandible beyond the cutting levels by direct inspection. In the literature new intraoperative investigations for evaluation of tumor extension are currently being tested and could become standard practice.[13,14] These methods could lead to additional mandibular resection because of occult bone invasion that had not been detected by preoperative imaging tests.

Triple-cut CAD-CAM planning permits 2 additional mandibular resections (Table 1), from 5 to 10 mm wide, until tumor-free resection margins are obtained. It does not violate the CAD-CAM–based principles and benefits of CAD-CAM planning. In other words, 1 or 2 additional mandibular resections along the prefabricated guides allow for perfect matching and apposition of bone stumps and the use of the same, already delivered reconstructive plate without any need for remodeling.

The triple-cut prefabricated cutting guides seem to obviate, as seen from our small case series, one of the greatest problems of the prefabricated reconstructive plates in mandibular reconstruction, namely, the intraoperative need for further mandibular resection beyond the preoperative plan; thus the surgical team is given the possibility to change the dimensions of bony resection (based on oncologic or other intraoperative needs) and, according to this, the size of the fibular segment used for reconstruction while maintaining the prefabricated CAD-CAM reconstructive plate.

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