"One-Piece" Patient-Specific Reconstruction Plate for "Double-Barrel" Fibula-Based Mandibular Reconstruction

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Competing interests

The authors declared no competing interests regarding this manuscript.

Ethical approval

The study has been approved by the Institutional Review Board of the University of Hong Kong (UW 16-315). The study protocol has been registered at ClinicalTrials.gov (NCT03057223). All procedures were executed strictly following the tenets of the Declaration of Helsinki.

Patient consent

Not required.

Abstract

Segmental mandibular defects require reconstruction and the fibula flap serves as a versatile flap in restoring mandibular contour and bony height. With the advance of computer-aided designing and additive manufacturing technology, the present study describes an innovative "one-piece" patient specific reconstruction plate to facilitate "double-barrel" fibula flap shaping and bone securing. The "one-piece" plate is fabricated with individualized specifications and mainly composed of three components: the long-bar reconstruction plate, short-bar plate and connecting bars. Our initial experiences showed mandibular reconstructive surgery has been greatly facilitated by the "one-piece" reconstruction plate for "double-barrel" fibula flap and achieved satisfactory reconstruction outcomes. A well-designed clinical trial is necessitated to confirm the superiority of the "one-piece" reconstruction plate in future.

ClinicalTrials.gov registration: NCT03057223.

Keywords:

Mandibular reconstruction; head and neck reconstruction; patient-specific surgical plate; reconstruction plate; bone plates; titanium; three-dimensional printing; fibula; vascularized flap; double-barrel; computer-assisted surgery; computer-aided surgery; virtual surgery

Introduction

The mandibular defect after tumor resection should be repaired to prevent violating the aesthetic and physiological functions. The vascularized free fibular flap is the workhorse in mandibular reconstruction with good blood supply and flexibility.[1] However, the thickness of the fibula is not enough to fully restore the normal height of the mandible. To address the problem of bone height, the distal fibular segment can be folded back onto the proximal portion to form a "double-barrel" complex.[2] As the lower fibula is aligned to restore the lower jaw line, the upper fibula is fine-tuned to approximate the normal dentition. In the "double-barrel" fibula-based mandibular reconstruction, multiple pieces of surgical plates are generally used for the fixation of bone segments, which is hard to manipulate and mainly based on the surgeon's experience.[2] In addition, it is difficult to determine the optimal position of multiple bone segments and plates simultaneously, thereby rendering the reconstruction outcomes unpredictable.[2]

In recent years, the additive manufacturing technology has been widely used to develop patient-specific medical devices. A large number of medical implants have emerged in the repair of skull, zygoma, vertebra, finger and pelvic bone defects.[3] Meanwhile, patient-specific surgical plates have been developed to facilitate head and neck reconstruction.[4] The patient-specific plate can precisely

fit the bone without the need of bending and guide the alignment and fixation of bone segments.[4] In an effort to deal with the "double-barrel" fibula-based mandibular reconstruction, we developed the "one-piece" patient-specific reconstruction plate that greatly simplifies the surgical procedure and improves reconstruction outcomes. This article describes the basic features of the "one-piece" reconstruction plate and its advantages in the "double-barrel" mandibular reconstruction.

Patients and Methods

The study has been approved by the Institutional Review Board of the University of Hong Kong (UW 16-315). Detailed procedures for computer-assisted mandibular reconstruction and additive manufacturing have been previously described.[4, 5] A total of 24 patients underwent mandibular reconstruction using patient-specific surgical plates in our unit, and five of them received the "one-piece" reconstruction plate for "double-barrel" fibula-based mandibular reconstruction. **(Table S1)** The accuracy of reconstruction and clinical outcomes are reported in our previous articles,[4, 5] while the current article focuses on the features and benefits of the "one-piece" reconstruction plate.

Results

The "one-piece" reconstruction plate comprises the lower long-bar reconstruction plate, the upper short-bar plate, and two vertical connecting rods, which are designed in a "double-layer" structure. The "one-piece" reconstruction plate was developed based upon the patient's CT imaging data and adapted to the reconstructed mandible accurately. ***(Figure 1)*** The plate was designed with customized dimensions and screw hole spacing was varied in each case. In the shown case, the thickness and width of the load-sharing long-bar reconstruction plate were 1.8mm and 4mm,

whereas for the non-load-sharing short-bar plate, the thickness and width were 1.5mm and 3.6mm respectively. ***(Figure 1)*** The screw hole positions were defined individually to prevent interrupting key anatomical structures or dental implants. Screw holes were also spared from the positions that bridged the osteotomies, where stress concentration occurred and enhanced fatigue strength was needed. In connecting the two horizontal long-bar and short-bar plates, two vertical rods were designed to ensure the stability of the fibular segments, which assured the vertical height of reconstructed mandible for both esthetic and functional considerations. There was no flap failure in this case series. No plate or screw exposure was observed during the follow-up.

Case Report

A 54-year-old female patient presented with a left mandibular alveolar squamous cell carcinoma (pT4aN0M0). ***(Figure 2)*** Mandibulectomy was performed with the aid of pre-fabricated cutting guides as previously reported.[4-9] Briefly, the skin flap was elevated and the mandibular lesion exposed. The surgical cutting guides were fixed on the mandible by screws in accordance with the anatomical landmarks. After the lesion excised, the cutting guides were removed while the drilled screw holes were left in the mandibular stumps for the accurate positioning of the patient-specific surgical plate. At the same time, the vascularized fibula flap was harvested using the standard lateral approach. The fibular osteotomies were guided by the cutting guide before dividing the pedicle. The cutting guide was released and the screw holes left in the fibular segments matched those of the patient-specific surgical plate. Then the fibular segments were folded in line with the patient-specific plate by registering the screw holes and securing the screws. To reconstruct the mandibular defect, the fibular pedicle was ligated and the fibula-plate complex was transferred to the defect site. The

positioning of the fibula-plate complex was guided by the pre-drilled screw holes in the mandibular stumps. The plate was fixed using monocortical screws. Surgery went smoothly as planned and the plate fitted to the surface of the bones precisely. No plate bending was needed in the surgery. No major postoperative complications occurred and facial appearance was satisfactory. Post-operative panorex film showed the contour of reconstructed mandible was satisfactory. ***(Figure 2)*** Another patient with mandible ameloblastoma undergone double-barrel fibula flap reconstruction and denture rehabilitation is shown in ***Figure S1***.

Discussion

Although the cross-sectional anatomy of the fibular shaft is generally not sufficient for restoring the bony height of mandible, the "double-barrel" design skillfully solves this problem and henceforth plays an important role in reconstructing complicated defects.[2, 10] However, the "double-barrel" fibula flap usually involves multiple bone segments that should be precisely located in restoring mandibular contour and occlusal relationship simultaneously, which is hard to be managed even in experienced hands. In the present study, we fabricated the "one-piece" reconstruction plate specifically for "double-barrel" fibula-based mandibular reconstruction. The specific configurations of the "one-piece" place could be customized in each case to not violate the vascular supply, bone stabilization and healing, and potential dental implantation. ***(Figure S2)***

The patient-specific 3D architecture derived from CT images enables surgeons/engineers to design the "one-piece" plate to guide the folding and fixation of fibular segments.[5] No more plate bending is needed since the plate adapts to the reconstructed mandible precisely.[4] As a result, the patient-

specific “one-piece” plate greatly simplifies the surgical procedure and can reduce operation time and enhance surgical outcomes at the same time.[4] Nevertheless, the benefits of “one-piece” surgical plate in complex mandibular reconstruction should be further confirmed in high-quality clinical trials by comparing to the conventional titanium plates. It is anticipated the accumulating evidence will finally lead to the large-scale production and application of the “one-piece” patient-specific surgical plate, which will contribute to the benefit of patients.

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Figure Legends

Figure 1. (A) The "double-layer" architecture of the "one-piece" patient-specific reconstruction plate in the case report, which adapts to the reconstructed mandible well. The achieved occlusal relationship and mandibular contour are satisfactory. (B) The 3D architecture and profile parameters of the "one-piece" plate were customized in each case.

Figure 2. (A) The "double-barrel" fibula-based mandibular reconstruction was greatly facilitated by the "one-piece" patient-specific reconstruction plate. (B) The postoperative panorex film showed the optimal placement of bone segments guided by the "one-piece" reconstruction plate.

Figure S1. A 22-year old patient was diagnosed with ameloblastoma and underwent surgery. (A) In the virtual surgery, the mandibular defect was restored using the "double-barrel" vascularized fibular flap. (B) The surgery was operated as virtually planned with the aid of the "one-piece" plate. (C) The intraoral wound healed smoothly after surgery, with the alveolar ridge in satisfactory shape and position. (D) A partial denture with a guide flange was fabricated to restore the normal chewing function. (E) The panorex film showed the optimal reconstruction and bone healing. (F) The frontal

view showed the optimal appearance after reconstruction.

Figure S2. The alternative forms of the “one-piece” plate showing the (A) “three-hole” or (B) “two-hole” configurations for the upper short-bar plate. The specific configurations of the “one-piece” place could be customized in each case.

Figure1

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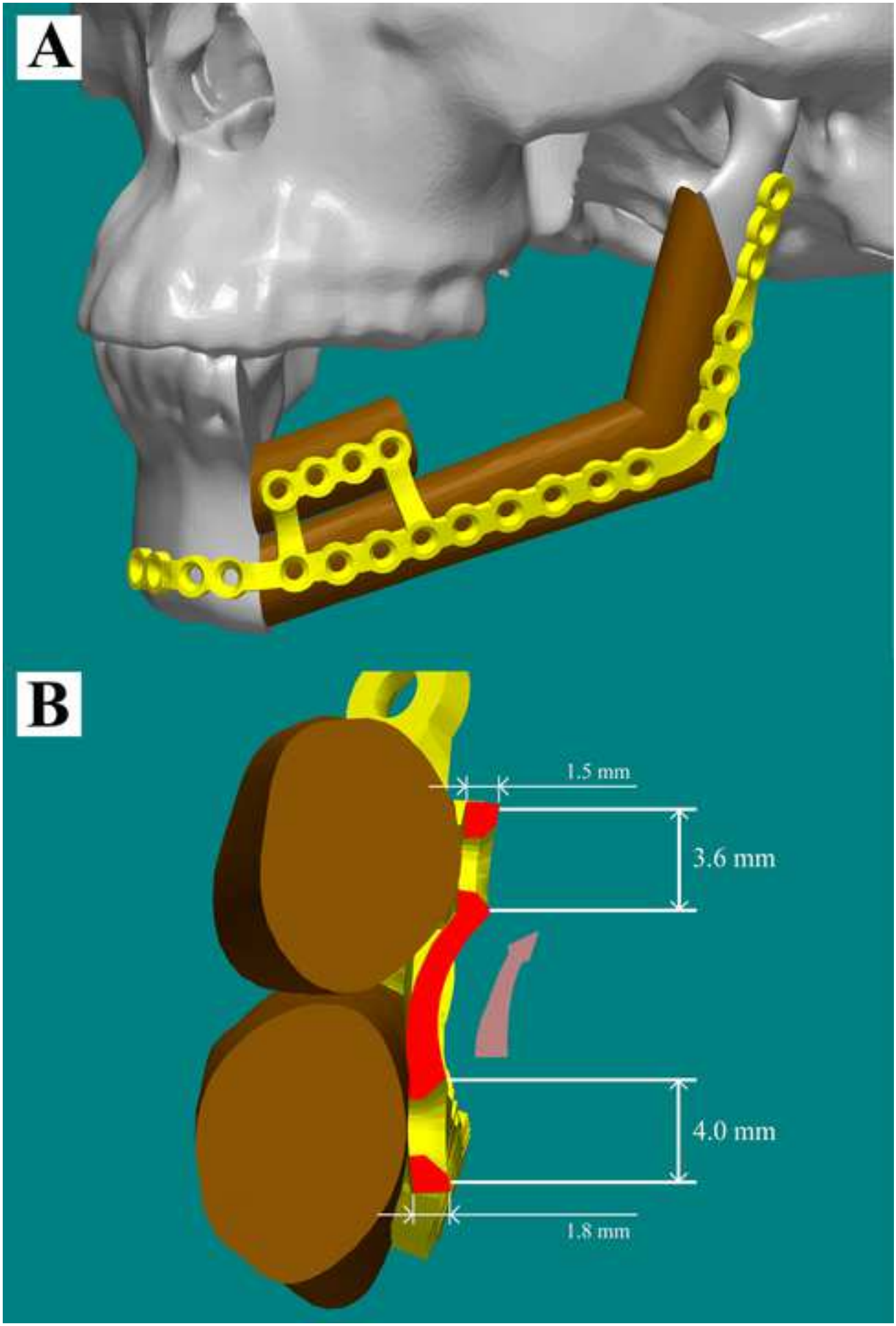

Figure2

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