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ScienceDirect

British Journal of Oral and Maxillofacial Surgery xxx (2022) xxx–xxx

BRITISH Journal of Oral and Maxillofacial Surgery

www.bjoms.com

The 3D-printed miniplate-jig system: a new, rapid, precise, and user-friendly approach to miniplate fixation of free-tissue mandibular reconstructions

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Accepted 7 May 2022

Abstract

Patient-specific, additively manufactured (printed) titanium reconstruction plates have been widely used to improve accuracy and efficiency of fibular flap reconstruction of the mandible. Miniplates possess some potential advantages over single-piece reconstruction plates, however multiple-miniplate fixation can be more technically demanding and may lengthen the duration of surgery. Furthermore, incremental angulation errors in screw placement for each miniplate could compromise overall dimensional accuracy of the neomandibular reconstruction. This preliminary article reports the first clinical use of a new patient-specific, printed titanium miniplate-jig system in a patient undergoing hemimandibulectomy for osteoradionecrosis of the mandible with fibular flap reconstruction. Our initial experience with the new device and technique demonstrates a quick, user friendly, and precise method for the placement and fixation of multiple miniplates in fibular-flap reconstruction of the mandible.

Keywords: Miniplate jig system; 3D printing; Additive manufacture; Fixation; Reconstruction

Introduction

Fibular free flap reconstruction of the mandible traditionally involves the placement of the fibular bone segment(s) into a mandibular continuity defect, supported by a single titanium osteosynthesis reconstruction plate. Some clinical researchers have demonstrated that in the context of surgical complication rates, miniplate fixation is equally effective as a load bearing, more rigid reconstruction plate1 and this has been backed up by others since.[1,2] There are some additional gains from miniplate fixation in fibular free flap reconstruction of the mandible. Firstly, in the event of focal infection or need to place osseointegrated dental implants at the site of a plate/screw necessitating plate removal, only fixation of a single miniplate site may need be compromised (the remainder of the neomandibular benefits from continued fixation by other miniplates/screws at other osteotomy sites). Secondly, removal of metalwork can be less traumatic with removal through small transoral or transcutaneous incisions (as opposed to needing more extensive incisions for removal of a larger one-piece reconstruction plate).[3] In parallel to changes in fixation techniques from thicker-profile reconstruction plates to a more load-sharing miniplate approach, advances in metal 3D-printing technology has facilitated the development of patient-specific, additively manufactured titanium-alloy osteosynthesis plates. These been popularised internationally because of widely-reported benefits relating to surgical accuracy, efficiency and biomechanical performance.[4]

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https://doi.org/10.1016/j.bjoms.2022.05.006

Placement of multiple miniplates could be considered to be technically cumbersome and even with patient-specific (such as printed) miniplates, sequential fixation of individual miniplates, with minor cumulative errors in screw angulation may lead to an overall error along the length of the neomandibular reconstruction, perhaps less likely when using a single-piece patient-specific reconstruction plate.

This study reports the first clinical use of a new, 3D-printed, miniplating device with an integral patient-specific and detachable positioning jig to facilitate rapid, user friendly, and precise, miniplate fixation in fibular flap reconstruction of the mandible.

Virtual surgical planning

This study follows the management of 58-year-old man suffering from Notani grade 3 osteoradionecrosis of the mandible. Bony anatomy of the diseased mandible and patency of the external carotid arteries and internal jugular veins (for subsequent microvascular anastomosis) was assessed using fine-cut (0.625 mm slice) contrast-enhanced computed tomography (CT). CT angiography was used to assess both lower limbs for adequate three-vessel run off, aiming to preclude distal ischaemia following harvest of the peroneal artery with the fibular free flap. A right Brown type IIc hemimandibulectomy defect and left fibular free flap reconstruction was planned by the patient's surgeon and in-house technician. The novel patient-specific miniplating device, also printed using titanium alloy was designed in collaboration with the device inventors (AG & MW), incorporating 2.0 mm profile miniplates for use with 2.0 mm diameter non-locking bone screws. Manufacturing of cutting/drill guides and the mini-plating device was undertaken by Renishaw plc, Wotton-under-Edge, UK (Fig. 1).

Surgery

Following mandibulectomy, bleeding bone was confirmed at the planned lower right canine osteotomy site (suggesting potential for bony union) before proceeding with harvest of the fibular flap according to the planned design.

Except for the remaining peroneal artery (and venae comitantes) attachment to the donor left leg, the flap was mobilised from the leg to allow flap preparation (pre-drilling of fixation screw holes and cutting of osteotomies using the patient-specific guide, whilst still maintaining vascular perfusion and avoiding flap ischaemia during this period). Planned fibular osteotomies and screw fixation holes were

Fig. 1. Stereolithographic model of the planned Brown type IIc hemimandibulectomy defect reconstructed with a two-segment fibular free-flap and fixation using a printed titanium alloy miniplating device with detachable patient-specific plate positioning jig.

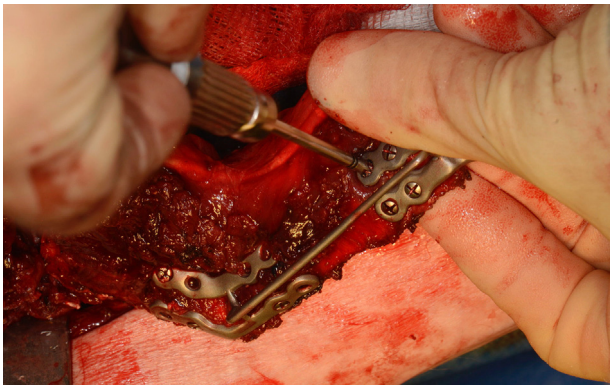

Fig. 2. Placement of screws into all fibula drill holes, enabling synchronous fixation of all miniplate implants within the device and rapid assembly of the neomandibular reconstruction.

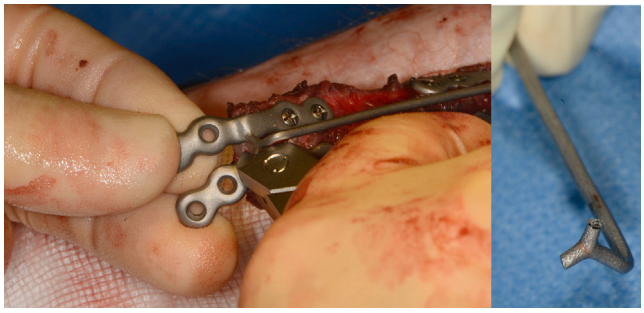

Fig. 3. Detachment of the patient-specific miniplate positioning jig from the fixation device with cutting pliers before transfer of the flap to the neck.

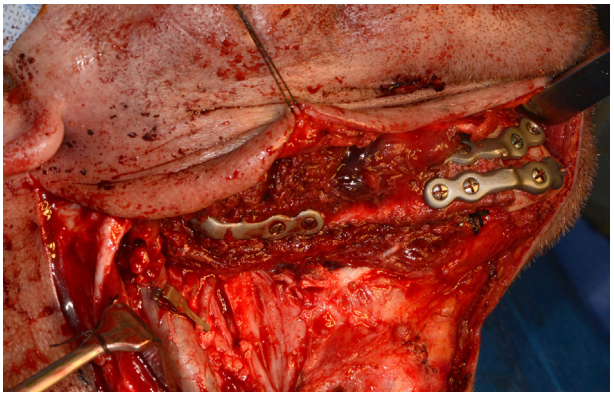

Fig. 4. Appearance of the fibular free-flap reconstruction after positioning and screw fixation into the native mandibular defect.

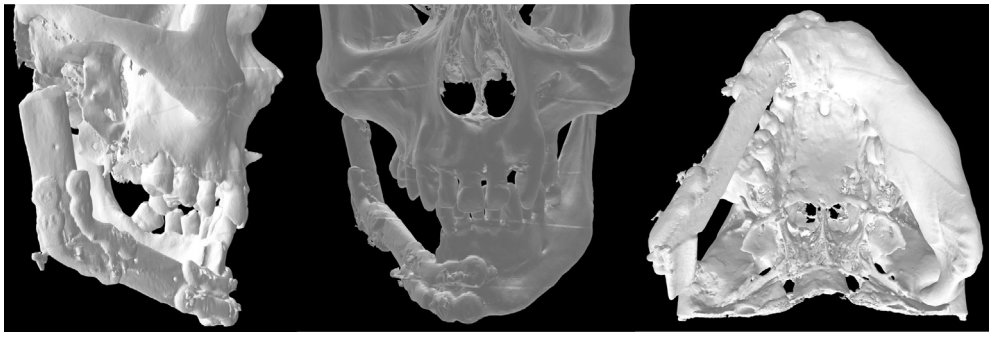

Fig. 5. Three-dimensional reconstruction of post-operative CT scan images.

made using CAD-CAM titanium cutting/drill guides. Within 8 min, the multiple-miniplate fixation device was attached to the two segments of fibula, with screws placed at all fibular-miniplate drill holes synchronously (Fig. 2). Within 1 min, the patient-specific miniplate positioning jig (frame) was detached from the miniplate implants and disposed of, allowing each miniplate to function as individual unit of fixation (Fig. 3). The flap was then transferred to the neck. Positioning of the assembled flap and pedicle into the mandibular defect and fixation to the residual mandible was completed within a further 2 min 30 s (Fig. 4).

Subjectively, the surgeon felt the device was efficient, with timings of surgical steps within acceptable clinical limits and comparable with time taken to place a 3D-printed single-piece reconstruction plate. Furthermore, fixation of the miniplates and division of the jig frame was felt to be technically easier than placing multiple pre-bent miniplates individually.

The patient's recovery was uneventful with no inpatient complications postoperatively; discharged from hospital on day 9 with no intraoral or extraoral wound issues and feeding per orally. At 6 weeks postoperatively, CT scanning demonstrated no fluid collections or evidence of surgical site complications such as osteomyelitis, periprosthetic lucency (screw loosening), or plate fracture (Fig. 5).

Discussion

This miniplate-jig system was designed and manufactured within the 2016 medical device regulations; ISO 13485:2016. The relative design freedom of additively-manufactured patient-specific titanium implants means that the miniplate jig system and other novel 3D-printed patient-specific craniomaxillofacial implants can be developed by end-users themselves. This novel device benefits from the manufacturing and associated surgical precision of 3D-printed patient-specific osteosynthesis as well as the fail-safe approach (in the event of localised metalwork infection) of using miniplates over single-piece reconstruction plates for free flap mandibular reconstruction. This approach is therefore well-suited to mandibular reconstructions where there is particular concern regarding the risk of subsequent plate/screw-related complications, such as osteoradionecrosis. To maintain submillimetre precision and practical ease of miniplate fixation of multiple fibular flap segments, the key feature of the design involves an integral but detachable patient-specific miniplate positioning jig. Intraoperative, in situ, removable components such as plate-holding tabs for easy grasping are currently used in commercially available stock miniplates such as the Arnett miniplates produced by KLS Martin Group. Furthermore, intraoperative in situ sectioning of titanium alloy, as long as undertaken carefully, is an established and accepted surgical technique for the removal of longstanding osseointegrated metalwork.[5,6] With our device, the principles of use remain within the remit of standard practice, even though the overall concept as a potentially commercial product is entirely novel and unique. Accordingly, the intellectual property behind this device has been registered through publication of both UK and international (PCT) patent applications, with a UK patent granted in January 2022.[7]

Conclusion

This first case of using the miniplate jig system in fibular free flap reconstruction of the mandible for osteoradionecrosis has been technically successful, providing an entirely new, high-precision, and user-friendly approach to miniplate fixation of free flap mandibular reconstructions, with potential for application in other areas of oral and maxillofacial surgery. A detailed description of the device's development will be published separately. Following this first clinical use and recent attainment of UK patent status, a UK multi-centre product and service evaluation study is planned in the first instance, with a view to achieving availability internationally.

Funding

This study is funded externally through KESS, in partnership with Renishaw plc and the University of South Wales, UK. Knowledge Economy Skills Scholarships (KESS) is a pan-Wales higher level skills initiative led by Bangor University on behalf of the HE sector in Wales. It is part funded by the Welsh Government's European Social Fund (ESF) convergence programme for West Wales and the Valleys.

Ethics statement/confirmation of patients permission

Ethics approval not required. We have permission from the patient to use clinical images for journal publication.

Conflict of Interest

The lead and senior author, as co-researchers and inventors have declared the funding source and UK-registered patent.

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