Journal of Cranio-Maxillo-Facial Surgery 44 (2016) 795–799

Contents lists available at ScienceDirect

Journal of Cranio-Maxillo-Facial Surgery

journal homepage: www.jcmfs.com

Is a computer-assisted design and computer-assisted manufacturing method for mandibular reconstruction economically viable?

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ARTICLE INFO

Article history:
Paper received 27 December 2015
Accepted 5 April 2016
Available online 13 April 2016

Keywords:
Computer-aided design
Computer-aided manufacturing
Mandibular reconstruction
Reconstructive surgery
Cost
Surgical time

ABSTRACT

The design and manufacture of patient-specific mandibular reconstruction plates, particularly in combination with cutting guides, has created many new opportunities for the planning and implementation of mandibular reconstruction. Although this surgical method is being used more widely and the outcomes appear to be improved, the question of the additional cost has to be discussed. To evaluate the cost generated by the management of this technology, we studied a cohort of patients treated for mandibular neoplasms. The population was divided into two groups of 20 patients each who were undergoing a 'traditional' freehand mandibular reconstruction or a computer-aided design/computer-aided manufacturing (CAD-CAM) mandibular reconstruction. Data concerning operation time, complications, and days of hospitalisation were used to evaluate costs related to the management of these patients.

The mean operating time for the CAD-CAM group was 435 min, whereas that for the freehand group was 550.5 min. The total difference in terms of average time gain was 115.5 min. No microvascular complication occurred in the CAD-CAM group; two complications (10%) were observed in patients undergoing freehand reconstructions. The mean overall lengths of hospital stay were 13.8 days for the CAD-CAM group and 17 days for the freehand group. Finally, considering that the institutional cost per minute of theatre time is €30, the money saved as a result of the time gained was €3,450. This cost corresponds approximately to the total price of the CAD-CAM surgery. In conclusion, we believe that CAD-CAM technology for mandibular reconstruction will become a widely used reconstructive method and that its cost will be covered by gains in terms of surgical time, quality of reconstruction, and reduced complications.

1. Introduction

Modern planning techniques, including computer-aided design/computer-aided manufacturing (CAD-CAM), offer new ways by which to plan reconstructive surgery, optimising aesthetic outcomes and functional rehabilitation (Wilde et al., 2014; Antony et al., 2011). In particular, mandibular reconstructions with fibular free flaps using cutting guides and customised titanium plates are becoming more common (Tarsitano et al., 2015). The design and manufacture of patient-specific mandibular reconstruction plates, particularly in combination with cutting guides, has created many new opportunities for the planning and implementation of mandibular reconstruction (Hou et al., 2012). Although this surgical method is being used more widely and the outcomes appear to be improved (Mazzoni et al., 2013), the question of the additional cost of planning and manufacturing (cutting guides and customised plate) has to be discussed.

The hypothesis of our study was that the price for CAD-CAM mandibular reconstructions would not exceed the total cost of freehand reconstructions when all aspects related to the quality of

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http://dx.doi.org/10.1016/j.jcms.2016.04.003
1010-5182/

the results and the time of recovery for the patient were considered. In particular, the present study was designed to answer two main questions. First, we sought to determine whether there would be an intraoperative time gain compared with freehand plate bending and osteotomies as a result of preoperatively virtually planning the mandibular reconstruction using microvascular fibular flaps with guided surgery using cutting guides and customised plates. Second, we aimed to determine whether the CAD-CAM surgery would translate into a reduction of costs in terms of a lower rate of complications, reoperations, and days of hospitalisation. These parameters can be used to discuss whether this new surgical option can be considered economically viable.

2. Material and methods

This prospective study was based on data from 20 consecutive patients undergoing mandibular reconstruction using CAD-CAM technologies in the Maxillofacial Surgery Unit of S. Orsola Hospital, Bologna University, between 2011 and 2015. The study was approved by the S. Orsola Hospital Ethics Committee in September 2011 (approval no. 57/2011/O/Disp). Patients with oral tumours involving the mandibular bone were recruited for the present study. Patients with vascular problems in the neck and/or donor site region were excluded. The second cohort for the study consisted of an equal number of consecutive patients ($n = 20$) undergoing a 'traditional' freehand mandibular reconstruction who were selected retrospectively as a control group. The enrolled patients were divided into two groups: the CAD-CAM mandibular-reconstructed patients and the freehand mandibular-reconstructed patients.

2.1. CAD-CAM technique

Virtual planning began with the acquisition of a high-resolution computed tomography (CT) scan of the craniofacial region and of the lower leg as a donor site. CT scans were performed with a 64-channel helical CT system (Lightspeed VCT LS Advantage 64 slices, General Electric Medical System) according to the following protocol parameters: 120 kV, 225 mA, 0.5 pitch, 1-second rotation time, 0.6-mm slice thickness, 0.6-mm collimation, and 512 × 512 matrix size. An iodine-based intravenous contrast agent was administered in all cases. Preoperative planning was performed with Sintac Company (Trento, Italy) using the Rhino 4.0 software (Robert McNeel & Associates, Seattle, WA, USA) via a Web meeting in which the surgeon (A.T.) and a trained technician virtually simulated the osteotomies in both the mandible and the selected donor site.

Reconstructive plates were manufactured by a direct metal laser sintering method (DMLS), as described previously: metal powder was fused into a solid component and melted locally using a focused laser beam (Leiggener et al., 2009). The solid-to-layer files of the guide and plate were then manufactured by DMLS using an EOSINT M270 system (Electro-Optical Systems, GmbH, Munich, Germany). DMLS was used to fuse the titanium powder into a solid form and then melt it locally with a focused laser beam. As with other additive manufacturing technologies, the components were built up additively, in layers.

The customised reconstructive titanium plate was 2.5 mm thick. It was designed by thickening the outer surface of the healthy side of the mandible to obtain an ideal aesthetic contour and to avoid bone deformities on the side affected by the tumour. It was fixed to the native mandible using a locking system. When the anatomical position of the reconstructed mandible contrasted with the optimal prosthetic position of the fibular bone segments (in particular, for the chin region), we did a set-back of the bony segment to achieve a good intermaxillary relationship.

Next, a customised cutting guide for bony free-flap was designed to allow the surgeon to precisely segment the osseous free flap. Cutting guides were manufactured in polyamide using a three-dimensional (3D) printer. The guides were designed to fit the patient's anatomy. When a stable position for the guide was obtained, it was fixed to the bone. The number of reconstructive bony segments was identified in relation to the site of the defect according to our recently published reconstructive algorithm (Tarsitano et al., 2015).

Two holes for each bone segment were made. Because the holes for the fixing screws of the guides were the same as those in the bone plate, it was easy to insert all fibular segments in the final planned position, anchored to the reconstructive plate. The straight fibular flap was contoured to resemble a neo-mandible using a surgical cutting guide that was virtually planned to guide the osteotomy site and orientation of the fibular fragment.

2.2. Control group

The control group consisted of 20 consecutive patients who underwent reconstruction by a freehand technique. For these patients, the osteotomies of the fibula were performed freehand to obtain maximum proximity to the bone cuts: a standard osteosynthesis using 2.7-mm reconstructive plates that were bent manually using a pre-plating technique (Marchetti et al., 2006). The native mandible was used as a template while moulding the titanium plate. In particular, when the external cortical bone of the mandible was not affected by the tumour, the plate was moulded on the vestibular surface of the mandible. The plate was placed across the entire defect and was secured to the bone on each side of the resection line with at least three locking screws. Then the plate was removed and a segmental resection was performed. The plate was then replaced and fixed with the holes and screws used previously.

The start time point was defined as the moment when reconstruction could begin (i.e., when the osteotomies were performed on the raised fibula). The endpoint was when the reconstruction plate was screwed to the proximal segments of the mandible and the fibular segments were in place. For the freehand cases, the prebending of the reconstruction plate was added to the respective times.

The costs of the CAD-CAM technique (planning, cutting guides, and customised plate), as well as of regular reconstruction plates, were derived from patient dossiers. Data related to microvascular complications, days of hospitalisation, and reoperations were recorded for both the test and control groups.

3. Results

We performed 20 cases of mandibular free-flap reconstruction using a CAD-CAM technique and 20 cases of traditional mandibular reconstruction using a freehand bent plate to fix the fibula flap. All patients were operated on by the same two surgeons (A.T., C.M.) working as a team.

The raw results are presented in Table 1. The mean age of the patients was 48 years in the test group and 59 years in the control group.

Complications were divided into flap and systemic complications using Classen and Ward's classification (Classen and Ward, 2006). The number of patients who developed complications in each group was compared (Tables 2 and 3), and comorbidities were assessed to stratify the risk of complications for both groups (Tables 2 and 3).

Because the difference between groups in regard to mean age could potentially influence the complication rates and surgery