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Costs incurred by applying computer-aided design/computer-aided manufacturing techniques for the reconstruction of maxillofacial defects

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ABSTRACT

This study aims to evaluate the additional costs incurred by using a computer-aided design/computer-aided manufacturing (CAD/CAM) technique for reconstructing maxillofacial defects by analyzing typical cases. The medical charts of 11 consecutive patients who were subjected to the CAD/CAM technique were considered, and invoices from the companies providing the CAD/CAM devices were reviewed for every case. The number of devices used was significantly correlated with cost ($r = 0.880$; $p < 0.001$). Significant differences in mean costs were found between cases in which prebent reconstruction plates were used (€3346.00 ± €29.00) and cases in which they were not (€2534.22 ± €264.48; $p < 0.001$). Significant differences were also obtained between the costs of two, three and four devices, even when ignoring the cost of reconstruction plates. Additional fees provided by statutory health insurance covered a mean of 171.5% ± 25.6% of the cost of the CAD/CAM devices. Since the additional fees provide financial compensation, we believe that the CAD/CAM technique is suited for wide application and not restricted to complex cases. Where additional fees/funds are not available, the CAD/CAM technique might be unprofitable, so the decision whether or not to use it remains a case-to-case decision with respect to cost versus benefit.

1. Introduction

Over the past few years, virtual surgical planning and computer-aided design/computer-aided manufacturing (CAD/CAM) techniques, including stereolithographic modeling and cutting guide-directed resection, have been increasingly used for reconstructing maxillofacial osseous defects. Proposed clinical indications for the use of virtual surgical planning comprise the need for multiple, simultaneous, free tissue transfers; defects involving multiple parts of the mandible or midface; the need for multiple osteotomies in reconstructive flaps; the possibility of osteoradionecrosis or irradiated tissue; and a history of high-velocity ballistic injury (Saad et al., 2013).

In the past, the main issue in performing conventional osseous reconstructive surgery was that the precise margins of resection and the anatomy of the graft recipient site could only be revealed in the operating room. This often resulted in a prolonged intraoperative time and suboptimal reconstruction of a region requiring a high degree of precision for optimal orthognathic and esthetic outcome (Hirsch et al., 2009). Today, CAD/CAM technology offers a reduction in the learning curve associated with osseous contouring, enhanced levels of accuracy, acceleration of the time-consuming intraoperative steps, improved esthetic contour, and improved functional outcome (Hou et al., 2011; Lethaus et al., 2011; Hayden et al., 2012; Levine et al., 2012; Foley et al., 2013). Various studies have revealed that application of the CAD/CAM technique eliminates the need for intraoperative measurement and yields bony segments with excellent apposition, achieves faithful duplication of the preoperative plan, and requires only minimal adjustments when the osseous transplant is inset (Marchetti et al., 2006; Hirsch et al., 2009; Antony et al., 2011). Furthermore, dental implant loading is possible at the time of osseous flap harvesting with a higher degree of accuracy than conventional techniques can provide. Even if not placed intraoperatively, the placement of dental implants and prosthetic dental reconstruction is facilitated by the precise alignment and positioning of the osseous transplant obtained by virtual planning (Levine et al., 2013; Hanasono and Chang, 2013).

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In general, computer-aided osseous reconstruction in maxillofacial surgery involves three steps: (1) virtual planning of the surgical treatment, (2) CAD/CAM and rapid prototyping procedures of the customized surgical devices, and (3) the surgery itself (Mazzoni et al., 2013). Since for every new technique a cost-benefit analysis is recommended to justify possible additional costs – even though the clinical benefits are undisputable – an evaluation is warranted to determine whether additional costs arise, especially within steps 1 and 2 of the CAD/CAM procedure. Hence, this study was focused on evaluating the additional cost of using the CAD/CAM technique to analyze typical cases. Furthermore, we drew a comparison between these costs and the reimbursement available from statutory health insurance coverage.

2. Material and methods

2.1. Subjects

Records from 11 consecutive patients who underwent maxillofacial osseous reconstruction with the CAD/CAM technique between September 2012 and June 2014 were reviewed. All patients gave written informed consent to publish their medical records and accompanying images.

The patients' osseous defects in the maxillofacial region were described using international classification systems. The applied classification of mandibular defects refers to the HLC classification described by Boyd et al. (1993). The H represents a defect compromising a lateral segment of any length containing a condyle and not substantially crossing the midline, L stands for the same defect but without a condyle, and C represents the anterior segment between the incisor foramina. The classification of maxillopalatine defects refers to the classification given by Okay et al. (2001). Class Ia summarizes defects with no involvement of the tooth-bearing alveolus; Class Ib, preservation of both canines; Class II, resection of one canine or less than 50% of the hard palate; Class III, resection of both canines or greater than 50% of the hard palate.

2.2. Application of CAD/CAM technology

Digital imaging and communications in medical formats were generated from high-resolution, helical computed tomographic (CT) scans (0.5 mm fine cuts) of the maxillofacial skeleton and the respective donor site. The data were transmitted to one of the CAD/CAM device-providing companies (Xilloc, Maastricht, Netherlands; Materialise, Leuven, Belgium). Virtual planning started with interactions using Web meetings or e-mail services between the biomedical engineers from the modeling company and the surgical team. The biomedical engineers use the geometry of the virtually resected mandible or maxilla, or they mirror the contralateral disease-free bone to create ideal orthognathic relationships. The mirroring protocol is not possible in defects involving both sides of the mandible or maxilla. Therefore, the solution is to have a database with segmented atraumatic mandibles and maxillae from other patients that can be imported as a reference. The reconstructive surgeon then directed virtual reconstruction by superimposing the patient's own three-dimensional (3D) reconstructed fibula or iliac crest onto the mandibular or maxillary defect and placing osteotomies to recreate the native mandibular or maxillary contour through a trial and error process, optimizing the number and cutting plane of the osteotomies, bone-to-bone contact, and segment lengths. A patient-specific, linearized cutting guide was designed from the cut pieces of the virtual fibula or iliac crest with cutting slots or flanges located at the appropriate lengths along the osseous transplant and at the proper angles to recreate the desired shape without any intraoperative measuring. If applicable, additional cutting guides for definite resection borders of the mandibular or maxillary region were created as well. Virtual cutting guides were converted to hardware by using a laser-sintering 3D printer. Stereolithographic models of the area of the craniomaxillofacial skeleton of interest were manufactured in the same way. This also allowed for the manufacturing of a reconstruction plate or a 3D bending template.

At surgery, the cutting guides were secured to the bone with lateral unicortical screws and the osteotomies were performed with an oscillating saw guided by the cutting slots or flanges, effectively replicating the virtually planned osteotomies at the recipient and the harvesting sites. If a vascularized flap was planned, then the osseous transplant was concurrently dissected and isolated on the vascular pedicle. The osseous segments were either fixed to a prebent reconstruction plate (2.5 mm system, Synthes Corp, Umkirch, Germany) or fixed with miniplates (2.0 mm system, Medicon Corp, Tuttlingen, Germany). Using a sterilized defect model during surgery, it was also possible to partially bend and fix the osteosynthesis plates to the transplant before transection of the pedicle and to check the overall accuracy of osseous modeling. The osseous reconstruction was transferred as a composite unit and secured to the mandibular or maxillary remnant at its predetermined optimal position. The microvascular anastomoses, soft tissue inset, and wound closure were completed in a standard fashion. Fig. 1 illustrates the use of the CAD/CAM technique in an exemplary case.

2.3. Assessment of additional costs for CAD/CAM technology

Invoices from the companies providing CAD/CAM devices were reviewed for every case. Cutting guides and anatomic or defect models were charged as one amount. Costs for prebent reconstruction plates were charged separately, since these plates were provided by cooperating companies and delivered together with the CAD/CAM devices. Hence, it was possible to separate the costs of the devices and the reconstruction plates. Two cases in which prebent reconstruction plates were applied within CAD/CAM technique usage were cases in which they would have been necessary even with conventional surgery. Therefore, the costs of the unbent reconstruction plates (€303 and €232, respectively) were subtracted from those of the prebent plates provided, thus obtaining the pure costs of the bending procedures. These costs were included in the CAD/CAM cost accounting. In all invoices, virtual planning and shipping costs were included without further charges.

In many European countries, adoption of the international classification of procedures in medicine – the operation and procedure key (OPS) – defines the proceeds of each case within the diagnosis-related group (DRG) system. In general, the proceeds involving the CAD/CAM technique of osseous reconstruction do not differ from those of the conventional technique. However, every clinic center has been able to freely negotiate additional fees with the statutory health insurance companies every year for distinctive DRGs, which were in turn triggered by OPS explicitly covering the application of the CAD/CAM technique. These additional fees were set in relation to the additional cost of the CAD/CAM technique.

2.4. Statistics

The collected data were subjected to statistical analysis using the SPSS statistical software package, version 20.0 (SPSS, Chicago, IL, USA). The Kolmogorov–Smirnov test revealed a normal distribution of the datasets. Differences in costs between cases with and without prebent reconstruction plates were evaluated using the two-tailed *t* test, whereas differences between costs and cases with various numbers of CAD/CAM devices or osseous segments were evaluated using the multivariate analysis of variance (ANOVA).