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Maxillo facial surgery

Factors influencing CAD/CAM accuracy in fibula free flap mandibular reconstruction

I fattori che influenzano l'accuratezza del CAD/CAM nella ricostruzione mandibolare del lembo libero di fibula

Ahmed Hassan Sweed[1,3], Alessandro Remigio Bolzoni[1,2], Aleksandra Kadubiec[1], Giada Anna Beltramini[1], Alessandro Cherchi[1], Alessandro Baj[1,2]

[1] Dental and Maxillo-Facial Surgery Unit, IRCCS Ca' Granda Ospedale Maggiore Policlinico di Milano, Milan, Italy; [2] Department of Biomedical, Surgical and Dental Sciences, University of Milan; [3] Assistant Lecturer of ORL-HNS, Zagazig University, Faculty of Medicine, Egypt

SUMMARY

Computer-aided design/computer-aided manufacturing (CAD/CAM) technology has improved the functional and morphological results of mandibular reconstructive surgery. The purpose of this study was to objectively assess this technology and factors affecting its accuracy. Fibula free flap mandibular reconstruction was performed in 26 cases using CAD/CAM technology at the Maxillofacial Unit of Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, between June 2014 and February 2018. We evaluated the technology's accuracy by comparing the virtual surgical planning STL file (planned-target mesh) with the STL file from an early postoperative CT scan (postoperative-achievement mesh) in each case. The STL files were imported into Geomagic Studio 2016 (Geomagic GmbH). According to the position of the reconstruction plate (fixed reference point), we assessed deviations at the right condyle, right gonion, gnathion, left gonion and left condyle, calculating mean, minimum and maximum error values. Mean error values ranged from 0.6 to 2.2 mm; they were ≥ 2 mm in only 2 (7.7%) cases. The midline area (symphysis-gnathion) showed the least variation (1.05 ± 0.92 mm), and the gonion area showed the greatest variation (right and left means of 1.6 and 1.46 mm, respectively). Among all possible factors that could affect CAD\CAM accuracy, nothing showed significant influence, including the timing of reconstruction, site and size of the defect and malignancy status. CAD/CAM technology has a high degree of accuracy and reproducibility for microvascular reconstruction of mandibular defects using fibula free flaps, regardless of the defect site and length, use of a single- or double-barrel graft or timing of reconstruction.

KEYWORDS: fibula free flap, CAD/CAM, mandibular reconstruction

RIASSUNTO

La tecnologia CAD/CAM (Computer-Aided Design/Computer-Aided Manufacturing) ha migliorato sia i risultati funzionali che morfologici nella chirurgia ricostruttiva mandibolare. L'obiettivo del nostro studio è stato quello di valutare questo tipo di tecnologia ed i fattori che possono influenzare la sua precisione. Un totale di 26 casi di ricostruzione mandibolare con lembo libero di fibula, utilizzando tecnologia CAD/CAM sono stati operati presso l'Unità Maxillofacciale della Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico di Milano, da giugno 2014 a febbraio 2018. Abbiamo valutato l'accuratezza confrontando i files STL di pianificazione chirurgica virtuale (obiettivo pianificato) con il file STL di una scansione TC postoperatoria precoce (risultato postoperatorio ottenuto). Entrambi i file STL sono stati importati su Geomagic Studio 2016 (Geomagic Gmbh). In base alla posizione della placca di ricostruzione (punto di riferimento fisso), abbiamo confrontato la deviazione sul condilo sinistro, gonion sinistro, gnathion, gonion destro e condilo destro, per calcolare l'errore medio di deviazione. L'errore medio di deviazione varia da 0,6 mm a 2,2 mm. Solo 2 dei 26 casi analizzati avevano un errore medio uguale o superiore a 2 mm (7,7%). L'area mediana (symphysis-gnathion) ha mostrato una variazione più

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Correspondence
Ahmed Hassan Sweed
Otorhinolaryngology, Head and Neck Surgery Department, Faculty of Medicine, Zagazig University, Egypt
Tel. 00201066118764
E-mail: dr.orl.sweed@gmail.com

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bassa (1,05 ± 0,92 mm) mentre l'area di gonion ha mostrato maggiore variazione (la variazione media del gonion destro e sinistro era rispettivamente di 1,6 mm e 1,46 mm). Nessuno dei possibili fattori (tempi di ricostruzione, malignità o benignità, sito o dimensione del difetto) che potrebbero influenzare la precisione del CAD/CAM, ha mostrato un'influenza significativa. La tecnologia CAD/CAM nella ricostruzione microvascolare dei difetti mandibolari mediante lembo libero di fibula minimizza gli errori umani ed è considerato come un intervento chirurgico indipendente dall'operatore con alto grado di accuratezza e riproducibilità.

PAROLE CHIAVE: *limbo libero di perone, CAD/CAM, ricostruzione mandibolare*

Introduction

The fibula free flap (FFF) has become the gold standard for surgical reconstruction of mandibular bony defects since Hidalgo first used it in 1989 [1]. Use of the FFF has several advantages, including harvest from the longest (up to 25 cm) dense bicortical bone, the ability to employ a simultaneous two-team approach, adequate length and diameter of peroneal vessels, least donor-site morbidity and dual blood supplies from the contemporary intraosseous and segmental periosteal arterial systems, which permits the performance of multiple osteotomies (separated by as little as 2 cm) [2] and thereby optimal bone shaping without concern for bone viability [3].

Since Hirsch's description of the pioneering technique in 2009 [4], computer-assisted surgery (CAS) or computer-aided design/computer-aided manufacturing (CAD/CAM) for mandibular reconstruction has gained popularity due to its reproducibility, its role in improving surgeons' performance and patient satisfaction (aesthetic and functional), and its cost burden, which is comparable to those of traditional freehand reconstructive techniques [5,6]. CAD/CAM technology has been applied successfully even for secondary mandibular reconstruction, which is considered to be a reconstructive challenge [7].

CAS for mandibular reconstruction involves four phases: 1) preoperative planning and virtual surgery, 2) manufacturing of patient-specific devices, 3) surgical intervention and 4) postoperative evaluation. The last phase was not performed in previously reported studies [8].

van Baar et al. performed a systematic review which revealed that three methods are used for CAD/CAM evaluation: comparison of 1) preoperative and postoperative DICOM images, 2) preoperative (unrevised to the virtual plan, without segmentation or neomandible) and postoperative STL models and 3) preoperative (revised to the virtual plan, including the neomandible) and postoperative STL models [9].

Despite the widespread utilisation and proven accuracy of this technology, studies comparing it with traditional reconstructive techniques, with the analysis of variables affecting computer-aided reconstruction, are lacking [5,6]. In this study, we aimed to objectively assess the accuracy and reproducibility of CAD/CAM technology in mandibular reconstruction with vascularised FFFs, using superimposition software to assess average linear deviations and to evaluate the potential effects of various factors on the outcomes of these procedures.

Patients and methods

Study design

This retrospective study was conducted at the Maxillofacial Unit of Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy, between June 2014 and February 2018. This study was approved by the facility's ethics committee and was conducted according to the ethical guidelines outlined in the Declaration of Helsinki.

Subjects

All adult patients who underwent mandibular reconstruction with FFFs using CAD/CAM technology were included, regardless of pathological aetiology, timing of reconstruction (primary vs secondary reconstruction), number of fibular segments or type and size of the mandibular defect.

After virtual surgery and preoperative planning using the Proplan CMF (Materialise, Leuven, Belgium) software programme, a patient-specific cutting guide, STL model and patient-specific plate were manufactured to guide the reconstructive surgery in each case.

Surgical procedure

A simultaneous two-team approach was employed for reconstructive and extirpative surgery. First, the FFF was harvested using the traditional[1] or minimally invasive approach [10], with or without a skin paddle according to the aetiology of the defect (benign or malignant), followed by flap reshaping using the fibula cutting guide. Next, the team performed surgical ablation of the mandibular defect using the mandibular cutting guide, as well as preparation for microanastomosis with or without neck dissection according to the defect's aetiology. The mandibular reconstruction was completed by fixing the reconstructed unit of fibula segments onto the bone defect with the aid of the patient-specific plate, and performing microvascular anastomoses between the donor and recipient vessels.

Evaluation of CAD/CAM technology accuracy

We assessed the accuracy of the CAD/CAM surgical technology by comparing the virtual surgical planning STL file (planned-target mesh) with the STL file from an early postoperative CT scan (postoperative-achievement mesh); (Third comparative model in van Baar et al. [9]).

We aligned the two meshes according to the surface of the reconstruction plate (iterative closest reference point) in software-aided superimposition. Based on the automated Hausdorff distance, used in this superimposition, the deviation between pre- and postoperative STL models was measured in relation to five constant orthognathic landmarks (right condyle, right gonion, gnathion, left gonion and left condyle). The average linear distance was estimated for calculation of minimum, maximum and average error values for each reconstruction, which minimised human error in deviation measurement. Finally, the average minimum, maximum and mean errors were determined to obtain a comprehensive outlook on the accuracy of CAD/CAM application in our patient sample. To minimise interpersonal human bias, a blind third partner separate from Proplan (Materialise, Leuven, Belgium) company and the reconstructive surgeons performed the superimposition and software processing. In addition, data interpretation was performed according to average linear distances to minimise human calculation error.

Statistical analysis

Statistical analyses were performed using the SPSS software (ver. 14.0 for Windows; SPSS Inc, Chicago, IL). The significance level was set at $P < 0.05$.

Results

This study included 25 adult patients (13 females and 12 males) and 26 reconstructive cases (patients 6 and 15 are the same patient, whose first reconstructive surgery was complicated by total flap loss, necessitating a second reconstructive surgery 1 year after the first reconstruction). The patient age ranged from 16 to 70 years (mean, 44 years). The mandibular defects had various aetiologies, with odontogenic keratocysts being the most common pathology, $n = 6$ (23.07%). The sample varied in terms of the timing of reconstruction [primary reconstruction, $n = 21$ (80.7%); secondary reconstruction, $n = 5$ (19.3%)]; mandibular defect size (mean, 8.75 cm), site and shape; and fibular segmentation (average number of fibular segments = 2.88, average number of osteotomies = 5.92, single-barrel:double-barrel FFF = 12:14; Tab. I).

Five patients underwent secondary mandibular reconstruction, due to pseudarthrosis in three cases, osteoradionecrosis that resulted in mandibular fracture (after partial mandibular resection due to squamous cell carcinoma) in one case and total flap necrosis after the first jaw reconstruction procedure in one case. The aforementioned patient was thus included twice in the study. The average follow-up period was 27 months (range, 5-48 months). During this follow-up period, total flap loss occurred in one (3.8%) patient and no sign of locoregional recurrence was observed in the six patients with malignant aetiologies.

Regarding CAD/CAM accuracy, we obtained an average minimum error of 0.37 mm (range, 0-1.7 mm), average maximum error of 2.52 mm (range, 1.6-3.4 mm) and average mean error of 1.34 mm (range, 0.6-2.2 mm). Mean errors were ≥ 2 mm in only 2 (7.7%) of 26 cases analysed. The least discrepancy between planned and achieved outcomes was observed in the midline (symphysis-gnathion) area (1.05 ± 0.92 mm), followed by the condyles (right and left means of 1.43 and 1.17 mm, respectively); the greatest variation was observed in the gonion area (right and left means of 1.6 and 1.46 mm, respectively; Tab. II).

Many variables can potentially affect the accuracy of CAD/CAM-guided reconstruction. To elaborate on the data provided in Tables I and II, we assessed the significance of the effects of the following variables on surgical outcomes: 1) defect length, 2) defect type and site, 3) number of fibular segments used, 4) reconstruction type (primary or secondary), 5) flap technique (double-barrel or single-barrel) and 6) aetiology (malignant or benign; Tab. III). Only the number of fibular segments significantly affected the accuracy of CAD/CAM-aided reconstruction; contrary to common sense, mandibular defect reconstruction with one or two fibular segments was less accurate (with a greater mean error) than reconstruction performed with three or more segments ($P = 0.0210$). Thus, reconstructive accuracy was greater for more-complex defects requiring the use of more fibular segments.

Postoperatively, total flap loss occurred in one (3.8%) case; thus, the overall FFF success rate was 96.2%. Four (15.4%) cases required re-intervention due to total flap loss, plate exposition, postoperative bleeding at the anastomosis site and condylar osteomyelitis, respectively. A donor-site complication (skin graft loss) occurred in only one (3.8%) case.

Discussion

Mandibular reconstruction represents a genuine challenge, as it should re-establish the aesthetics of the face, restore the patient's ability to eat in public, maintain the intelligibility of speech and achieve an accessible airway [11]. Reconstructive surgeons are in consensus that CAS yields outcomes superior to those of conventional surgery, with a comparable cost burden [6,12].

Despite the popularity and accuracy of CAD/CAM-aided mandibular reconstruction, few objective analyses have been performed to examine the reproducibility of virtual planning with large samples [5]. Moreover, different methods have been used to evaluate the outcomes of CAD/CAM-aided procedures, including the comparison of pre- and postoperative DICOM files, unrevised preoperative and postoperative STL files and revised virtually operated preoperative and postoperative STL files. van Baar et al. (2018) argue that the latter

Table I. Demographic data, mandibular defect data and fibula free flap data of patients.

	Sex	Age	Etiology	Mandibular defect		Fibula reshaping	
				Site/types (Urken's classification)	Length (cm)	No. of fibular segments	Double-barrelled technique
1	F	37	Ameloblastoma	R-B	8	2	No
2	F	38	Odontogenic keratocysts	B-R-C	13	2	No
3	F	53	Malignant mesenchymal tumour	B dx	5	2	Yes
4	F	61	Low grade mucoepidermoid CA	R-B	6	2	Yes
5	F	55	2ry reconstruction pseudoarthrosis	S-B	6	4	Yes
6	M	31	Ameloblastoma	R-B	8	3	Yes
7	F	70	Squamous cell carcinoma	S-B	5	4	Yes
8	M	59	Squamous cell carcinoma	B-S-B	13	3	No
9	M	62	Squamous cell carcinoma	S-B-R	14	5	Yes
10	M	60	Low grade mucoepidermoid CA	B-R	3,5	1	No
11	M	23	Odontogenic keratocysts	R-B	11,5	4	Yes
12	F	46	Ameloblastoma	B-R	9	4	Yes
13	M	65	2ry reconstruction pseudoarthrosis	B sx	7	2	No
14	F	29	Pseudoarthrosis	B dx	3,5	1	No
15	M	32	2ry reconstruction due to total flap necrosis (no.6)	C-R-B	10,5	3	No
16	M	31	Chronic slerosing osteomyelitis	C-R-B	12,5	3	Yes
17	M	67	2ry reconstruction pseudoarthrosis	B-S	5	2	No
18	M	18	Odontogenic fibromyxoma	R-B	10	5	Yes
19	F	38	Odontogenic keratocysts	B dx	7	3	Yes
20	F	32	Odontogenic keratocysts	B-R	6	3	Yes
21	M	16	Odontogenic fibromyxoma	B-S-B	15,5	4	No
22	F	55	Ossifying fibroma	B sx	6	3	Yes
23	F	55	2ry reconstruction pseudoarthrosis	R-B-S-B-R	18	3	No
24	F	58	Ameloblastoma	S-B	5,5	5	Yes
25	M	26	Odontogenic keratocysts	C-R-B	10	2	No
26	M	29	Odontogenic keratocysts	B-R	9	2	No

method is the most reliable, as it takes into consideration the remnant bony parts of the mandible and the fibular segments (neomandible) [9].

Software superimposition has yielded reliable results, but the scattering effect of the titanium plate on postoperative CT scans and human error during the conversion of DICOM files to STL files are inevitable drawbacks [13]. The choice of the reference iterative closest point may also vary according to the method of superimposition used. For example, the gold standard for superimposition is the comparison of the largest remnant mandible portion between pre- and postoperative best-fit models on a fully computerised 3D overlapping image, although a patient-specific reconstructive plate surface or screw site could also be used as a reference point for linear measurements [5-7,9].

In this study, the accuracy and reproducibility of CAD/CAM-aided reconstruction were shown by low mean error values (range, 0-2.2 mm). Mean errors were ≥ 2 mm in only 2 (7.7%) of 26 cases analysed. The least discrepancy between planned and achieved surgical outcomes was observed in the midline (symphysis-gnathion) region (1.05 ± 0.92 mm), followed by the condyles (right and left means of 1.43 and 1.17 mm, respectively); the greatest error was observed in the gonion area (right and left means of 1.6 and 1.46 mm, respectively; Tab. II). These results are in contrast to those obtained by Tarsitano et al. (2018) [5], who found that the symphysis was the site of maximum error using colour maps. We found that neither the size nor site of the mandibular defect, nor the aetiology, use of the double- or single-barrel technique or timing of reconstruction (primary vs. secondary) influenced the reproducibility and accuracy of CAD/CAM-assisted surgery (Tab. III). This finding supports the characterisation of CAD/CAM technology as an operator-independent modality that minimises human error. The only factor showing a significant influence was

the number of fibular segments used; contrary to expectations, reconstructions performed with three or more fibular segments were more accurate than those performed with one or two fibular segments ($P = 0.0210$). To our knowledge, no other statistically supported study has analysed factors affecting the use of CAD/CAM technology.

Although this technique is 'operator independent', with a high degree of reproducibility, the postoperative results never fully match the preoperative virtual plan. Inaccuracies might be introduced at various stages, including image acquisition, segmentation, 3D printing, surgery and evaluation of the postoperative results [14,15]. van Baar et al. [9]. recommended the acquisition of pre- and postoperative images with the same multidetector CT device using identical scanner parameters and a slice thickness < 1.25 mm to minimise possible deviation.

The main limitation of this study is that we were not able to evaluate human factors affecting CAD/CAM surgery, as the same bioengineer and surgical team performed all procedures. This issue could be evaluated in the future in a multi-centre study or systematic review. In addition, the number of fibular segments used should be evaluated as a potential prognostic factor for CAD/CAM accuracy in a homogenous, site-specific group to clarify its influence.

Conclusions

Our results suggest that the application of CAD/CAM technology in the microvascular reconstruction of mandibular defects using FFFs is an operator-independent approach characterised by high degrees of accuracy and reproducibility, regardless of the aetiology of the lesion (benign or malignant), site of the lesion (condyle, body, ramus or symphysis), length of

Table II. Linear distance measurements (Deviation and accuracy assessment; error value).

	Variation in 5 landmarks					Error interpretation		
	Right condyle	Left condyle	Gnathion	Right gonion	Left gonion	Mean	Minimum error	Maximum error
1	2.0	0.9	**0**	2.0	0.2	1.2	0	2
2	0.3	2.3	**0**	0.3	2.7	1.12	0	2,7
3	3.1	**0.3**	0.9	2.4	**0.3**	1.4	0,3	3,1
4	**0.4**	2.7	2.7	1.1	1.7	1.7	0,4	2,7
5	**0.3**	2.2	2.1	1.2	2.1	1.6	0,3	2,2
6	**0.3**	**0.3**	1.6	0.4	0.4	0.6	0,3	1,6
7	**0.4**	0.6	0.9	0.7	2.1	0.9	0,4	2,1
8	0.9	1.2	**0**	2.1	2.1	1.26	0	2,1
9	0.4	0.6	0	3.1	2.1	1.24	0	3,1
10	1.2	1.4	0	3.2	2.1	1.58	0	3,2
11	**0.6**	1.5	1.7	0.7	2.4	1.4	0,6	2,4
12	**0.5**	0.7	1.6	1.4	1.3	1.1	0,5	1,6
13*	1.8	2.3	**1.7**	3.1	2.1	2.2	1,7	3,1
14	1.1	2.2	**0.4**	2.7	2.7	1.8	0,4	2,7
15	1.2	**0.3**	1.2	**0.3**	2.2	1.0	0,3	2,2
16	0.4	0.6	0.6	1.7	**0.3**	0.7	0,3	1,7
17	0.7	1.2	3.1	2.1	**0.6**	1.5	0,6	3,1
18	2.1	0.6	**0.4**	**0.4**	1.2	0.9	0,4	2,1
19	3.1	1.4	**0.3**	2.1	0.6	1.5	0,3	3,1
20*	3.2	3.1	**0.7**	2.1	1.4	2.1	0,7	3,2
21	0.7	**0.4**	**0.4**	2.1	1.5	1.0	0,4	2,1
22	1.4	**0.3**	1.5	2.1	1.1	1.3	0,3	2,1
23	3.2	**0.3**	0.7	2.1	2.1	1.7	0,3	3,2
24	2.1	0.4	2.3	0.5	**0.2**	1.1	0,2	2,3
25	2.3	2.2	2.2	**0.6**	2.2	1.9	0,6	2,3
26	3.4	**0.3**	0.3	1.2	**0.3**	1.1	0,3	3,4
Mean	1,43	1,17	1.05	1,60	1,46	1,34	0,37	2,52

Bold values refer to minimum values and underlined values refer to maximum values. (*) refers to cases with error values > 2 mm.

Table III. Factors affecting accuracy of CAD/CAM technology.

	Factors affecting CAD/CAM accuracy	No. of patients	Average of error ± SD	P-value
A	Defects < 9 cm	14	1.46 mm ± 0.42	P-value = 0.0960
	Defects ≥ 9 cm	12	1.20 mm ± 0.33	
B	Number of segments < 3 cm	10	1.55 mm ± 0.36	P-value = 0.0210 *
	Segments ≥ 3 cm	16	1.21 mm ± 0.33	
C	Double barreled fibula	14	1.25 mm ± 0.41	P-value = 0.2170
	Single barreled fibula	12	1.45 mm ± 0.39	
D	Primary reconstruction	21	1.28 mm ± 0.38	P-value = 0.0931
	Secondary reconstruction	5	1.62 mm ± 0.44	
E	Malignant aetiology	6	1.35 mm ± 0.28	P-value = 0.9588
	Non-malignant aetiology	20	1.34 mm ± 0.44	
F	Defects not involving any of 5 landmarks i.e. defects located in body of the mandible	5	1.64 mm ± 0.36	P-value = 0.0654
	Defects involving any of 5 landmarks RT-LT condyle, RT-LT gonium, gnathiun	21	1.27 mm ± 0.39	
G	Defects involving midline (symphysis)	8	1.29 mm ± 0.29	P-value = 0.6501
	Defects not involving midline (symphysis)	18	1.37 mm ± 0.45	
H	Defects involving one or both angle of the mandible (ramus)	15	1.29 mm ± 0.43	P-value = 0.4638
	Defects not involving any angle of the mandible (ramus)	11	1.41 mm ± 0.37	
I	Defects involving one or both condyles of the mandible	4	1.18 mm ± 0.51	P-value = 0.3989
	Defects not involving any condyles of the mandible	22	1.37 mm ± 0.39	

the defect, timing of the reconstruction (primary or secondary) or number fibular segmentations (single- or double-barrel technique).

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