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Implementation of In-house Computer-aided Design and Manufacturing for Accelerated Free Fibula Flap Reconstruction of Mandibular Defects in Cancer Patients

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Background: Computer-aided design and manufacturing (CAD/CAM) is widely adopted for optimizing microsurgical reconstruction of mandibular defects. However, commercial solutions are hampered by costs and lengthy lead times, with the latter being problematic in cancer surgery. This study aimed to investigate the efficiency of an in-house CAD/CAM service for expeditious planning and execution of free fibula mandibular reconstruction in head and neck cancer patients.

Methods: This retrospective cohort study compared cancer patients undergoing segmental mandibulectomy and immediate free fibula flap reconstruction treated before and after implementation of in-house CAD/CAM. The primary endpoint was treatment delay from preoperative consultation to surgery. Cases in the two groups were matched on the number of fibula segments required for mandibular reconstruction. The control group underwent segmental mandibulectomy and fibula flap reconstruction by "freehand." The CAD/CAM group underwent preoperative virtual surgical planning and CAD/CAM of intraoperative cutting guides for the mandibulectomy and fibula osteotomies. Outcomes were compared with the unpaired *t* test or Wilcoxon rank-sum test.

Results: Sixteen patients were included in both groups. Treatment delay did not increase after implementation of in-house CAD/CAM with a median 6 (range 6–20) days wait in the CAD/CAM group and 8 (6–20) days wait in the control group ($P = 0.48$). Utilization of CAD/CAM significantly reduced fibula flap ischemia time with a mean of 18.4 [95% confidence interval 2.8; 33.9] minutes ($P = 0.022$).

Conclusions: In-house CAD/CAM was implemented for free fibula flap mandibular reconstruction in head and neck cancer patients without causing treatment delay. Furthermore, CAD/CAM reduced fibula flap ischemia time. *(Plast Reconstr Surg Glob Open 2024; 12:e6108; doi: 10.1097/GOX.0000000000006108; Published online 27 August 2024.)*

INTRODUCTION

The free fibula flap is the primary choice for reconstructing mandibular bone defects after tumor resection, trauma, and other conditions. Traditionally, the flap was harvested with osteotomies performed "freehand" to reach the desired shape of the neomandible.[1] But since the early 2010s, virtual surgical planning and computer-aided design (CAD) and manufacturing (CAM) have become widely adopted methods for microsurgical reconstruction of the mandible using the free fibula and other flap types.[2]

Virtual surgical planning involves preoperative decision-making on the mandibular resection margins based on computed tomography (CT) tumor scans. CAD

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facilitates the determination of osteotomies and angles and positioning of the fibula flap in creating the optimal neomandible. CAM follows with 3D printing of osteotomy cutting guides for the mandible and fibula designed to obtain the planned result. These cutting guides composed of photopolymer material can be autoclaved and used in surgery.[2]

Evidence supporting the utilization of CAD/CAM for mandibular reconstruction is improved operative efficiency, measured by shorter flap ischemia time and operative time, but there is no benefit in terms of flap loss or microvascular complications in a meta-analysis.[3] It seems intuitive that a more precise mandibular reconstruction is obtained with CAD/CAM but this has yet to be demonstrated with standardized methods. The dependency on commercial CAD/CAM solutions entails potentially inopportune meeting times for the surgeons participating in the virtual surgical planning and higher up-front costs. The subsequent lead time for production and delivery of the cutting guides is another drawback, which impedes the offering of CAD/CAM-assisted surgery to cancer patients who should be treated without delay.

A systematic review has suggested that overall survival for patients with oral cancer decreases with increased time from diagnosis until treatment initiation.[4] A national database study showed that treatment delay beyond 61 days significantly increased mortality compared with treatment initiation before 0–30 days of diagnosis, adjusted for tumor stage and surgical margin status.[5] The authors concluded that all reasonable efforts should be made to minimize treatment delay from diagnosis until ablative surgery in oral cancer.[4,5]

In our opinion, it is paramount that CAD/CAM-assisted mandibular reconstruction is made available for patients with head and neck cancer in an efficient treatment program. To bypass the prolonged lead time and high costs associated with commercial solutions, we have employed an engineering team with the software skills and 3D printing capabilities required to deliver in-house virtual surgical planning and CAD/CAM.

The objective of the present study was to investigate the efficiency of in-house CAD/CAM for planning and execution of head and neck cancer resection and immediate free fibula flap mandibular reconstruction.

PATIENTS AND METHODS

The design is a retrospective cohort study in a university hospital setting. Inclusion criteria were (1) patients who were 18 years of age or older, (2) diagnosed with a head and neck malignancy, and (3) who underwent tumor resection including segmental mandibulectomy and immediate reconstruction with a free fibula flap.

Patients in the control group were operated on between the years 2015 and 2017 without CAD/CAM and were a subpopulation from our previous study.[6,7] The CAD/CAM group consisted of patients operated on between the years 2021 and 2022 with the utilization of in-house CAD/CAM technology. Cases in the two groups were matched on the number of fibula segments required for mandibular reconstruction. Study approval was granted by the hospital management waiving the requirement of institutional review board approval.

Takeaways

Question: Can in-house computer-aided design and manufacturing (CAD/CAM) be implemented without prolonging treatment delay for cancer patients undergoing tumor resection and microsurgical reconstruction of the mandible?

Findings: This retrospective cohort study showed that there was no increase in treatment delay when comparing a cohort of head and neck cancer patients undergoing tumor resection and mandibular reconstruction by "freehand" compared with a cohort undergoing the same procedure after implementation of in-house CAD/CAM.

Meaning: In-house CAD/CAM performed by clinical engineers working in close collaboration with surgeons makes this advanced technology available to all cancer patients without causing treatment delay.

Surgical Planning and Procedure

After confirmed malignancy and staging, all patients were evaluated in a multidisciplinary clinic with head and neck surgeons, plastic surgeons, and maxillofacial surgeons determining indications for surgery and treatment plan. Patients were subsequently operated on by the same three-specialty team working concomitantly with head and neck surgeons performing tumor resection and neck dissection, plastic surgeons performing flap dissection and microsurgical anastomoses, and maxillofacial surgeons performing mandibular osteotomies as well as fibula flap shaping and inset. The fibula flap was fixed to the mandible with reconstruction plates before microvascular anastomoses, which were performed with nylon 9-0 interrupted sutures before inset of a potential skin paddle. The control group underwent segmental mandibulectomy and fibula flap harvest, shaping, and inset performed freehand using reconstruction plates.

In-house CAD/CAM Protocol and Workflow

The CAD/CAM group underwent preoperative virtual surgical planning of the segmental mandibulectomy (Fig. 1A) and reconstruction of the neomandible (Fig. 1B) with flap positioning on the fibula (Fig. 1C) as well as CAD/CAM of the following items: (1) preoperative 3D anatomical model of the tumor-involved mandible, (2) 3D anatomical model of the reconstructed neomandible (Fig. 1B), (3) intraoperative cutting guides for the mandibulectomy and fibula osteotomies (Figs. 1A and 1D), and (4) intraoperative support guide for the resected mandible (Figs. 1E and 1F).

The in-house CAD/CAM workflow was divided into the following phases. (**See figure, Supplemental Digital Content 1,** which displays the workflow for in-house virtual surgical planning and CAD/CAM. Step 1: Preoperative 3D anatomical model of the tumor-involved mandible. Step 2: Utilization of the 3D anatomical model in the preoperative consultation. Step 3: Virtual surgical planning of the

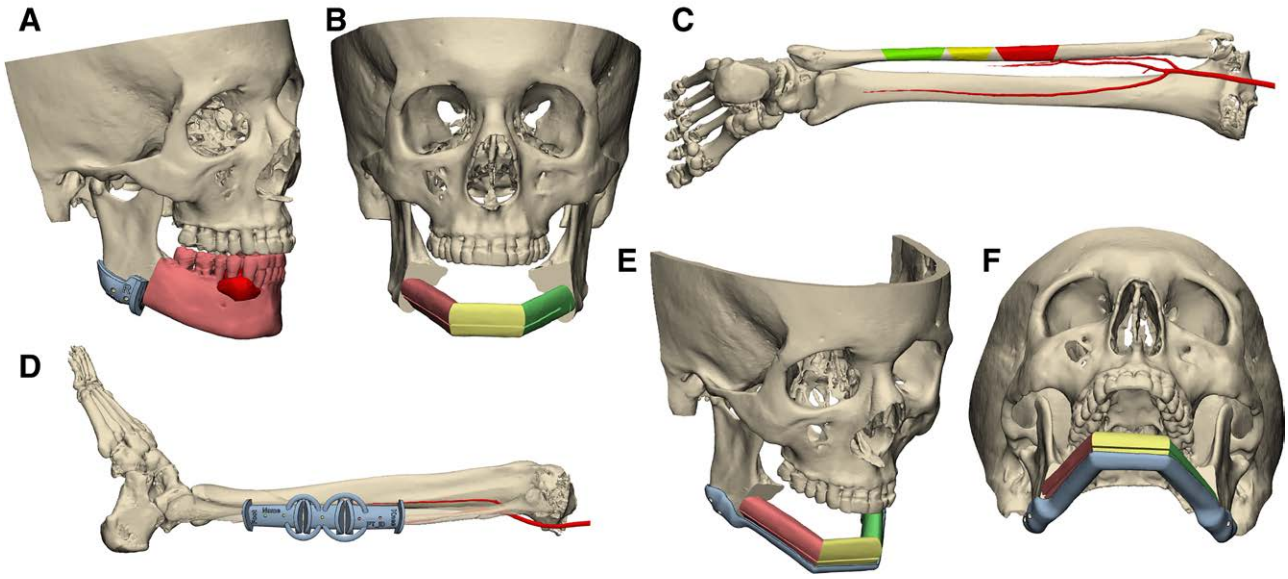

Fig. 1. A, Preoperative virtual 3D anatomical model of the skull with oral cancer involving the right mandibular body marked with solid red. The virtual surgical planning of the segmental mandibulectomy is marked with transparent red and the designed intraoperative cutting guide is marked with R for the right side of the mandible. B, Virtual surgical planning and design of the neomandible reconstructed with three fibula segments marked with red, yellow, and green. C, Virtual surgical planning of the free fibula flap harvested from the left lower limb designed with three segments. D, Computer-assisted design of the intraoperative cutting guide for the fibula flap harvest and segment osteotomies marked with patient name, patient ID, and knee-foot orientation. E, Virtual surgical planning and design of the neomandible reconstructed with the 3-segment free fibula flap including the design of an intraoperative mandibular support guide used to assist with positioning of the fibula flap. F, Demonstration of the mandibular support guide from the caudal view utilizing the same drilling holes as the mandibular resection cutting guides.

mandibular resection and fibula flap reconstruction with CAD/CAM of the neomandible. Step 4: Prebending of reconstruction plates using the 3D-printed neomandible. Step 5: CAD/CAM of the intraoperative cutting guides. Step 6: Delivery of autoclaved cutting guides for execution of the surgical plan. **http://links.lww.com/PRSGO/D466**)

Step 1. Preparation of Preoperative Anatomical Model

Before the preoperative consultation, a 3D anatomical model of the pathologic mandible was manufactured using fused deposition modeling 3D printing technology (Bambu Lab X1-Carbon Combo, Bambu Lab, Shenzhen, China) based on positron emission tomography-CT images acquired for diagnostic purposes. The segmentation process was performed using Materialise Mimics Medical 26.0 (Materialise, Belgium).

Step 2. Preoperative Consultation Utilizing the 3D Anatomical Model

During the preoperative consultation, this 3D anatomical model was used when explaining the tumor resection and planned reconstruction to the patient, and the surgical team marked resection margins directly onto the model. The patient underwent CT angiography of the bilateral lower limbs for fibula imaging immediately after the consultation.

Step 3. Virtual Surgical Planning

The marked 3D anatomical model was transferred to our in-house engineering team for further processing immediately after the consultation. The engineers used the marked model to create a preliminary virtual resection and reconstruction plan using PROPLAN CMF 3.0 software (Materialise). Vital information such as the preferred fibula source and vascular anatomy were acquired during this drafting phase. On the same day as the preoperative consultation, the virtual surgical plan underwent a comprehensive review by the surgical team for consensus and approval. Subsequently, a 3D model of the reconstructed neomandible was printed.

Step 4. Preparation of Reconstruction Plates

The 3D model of the neomandible was delivered to the maxillofacial surgeon for prebending and subsequent sterilization of reconstruction plates.

Step 5. CAD/CAM of Cutting Guides

CAD/CAM of the mandibular and fibula cutting guides commenced after approval of the virtual surgical plan. This process adhered to highly specialized work instructions to maintain continuity and precision. The design phase was conducted using Materialise 3-matic Medical 18.0 software (Materialise). The cutting guides were manufactured with a stereolithography 3D printer (FormLabs Form 3B, Formlabs, Mass.) using a biocompatible photopolymer (Biomed Clear, Formlabs). This material is compatible with standard autoclave sterilization processes.

Step 6. Sterilization and Delivery

After printing and postprocessing, the cutting guides were transferred to the sterilization department along

with the required patient-identifying documentation. Sterilization was conducted according to our institution's standard autoclaving processes. Once sterilized, the cutting guides were delivered to the operating room. Employing this workflow with in-house CAD/CAM completely integrated into our multidisciplinary head and neck cancer clinic, we have achieved a lead time from preoperative consultation to surgery at 48–72 hours.

Regulations and Quality Assurance

Our CAD/CAM solution is exclusively used within our institution, and it is not a commercial product that requires official approval from government agencies. Our center is operated with a quality management system in compliance with the International Organization for Standardization 13485 for medical devices, which has been evaluated and confirmed by external consultants. The utilized products fulfill all the conditions in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices article 5, paragraph 5, as well as the General Safety and Performance Requirements set out in Annex I.

In-house CAD/CAM Costs

The costs of in-house CAD/CAM were estimated to be approximately €820 per patient, including materials, engineer's salary, hardware, and software, based on an expected caseload of 30 patients per year requiring in-house CAD/CAM for various indications.

Study Outcomes

The primary outcome was treatment delay from preoperative consultation to surgery (days). The secondary outcome was fibula flap ischemia time (minutes).

The following data were collected from patients' electronic medical records. Preoperative data: sex, age, body mass index, smoking status, alcohol consumption, American Society of Anesthesiologists classification, and previous head and neck cancer treatment. Intraoperative data: treatment delay from preoperative consultation to surgery, surgery time, fibula flap ischemia time, free fibula flap classification, number of fibula segments, secondary free flap, and neck dissection. Postoperative data: fibula flap failure, fibula flap pedicle thromboses, fibula flap site dehiscence, fibula flap site infection treated with antibiotics or reoperation, hospital stay, and mortality. The follow-up period was 30 days after surgery.

Statistics

No sample size calculation was performed. Data distribution of continuous variables was assessed by quantile-quantile plots. Variables that followed normal distribution are presented as mean ± SD or 95% confidence intervals, and the two groups were compared with the unpaired *t* test. Variables that did not follow normal distribution are presented as median with range or interquartile range, and the two groups were compared with the Wilcoxon rank-sum test. Categorical variables are presented as frequencies and were tested with Fisher exact test. A *P* value less than 0.05 was determined as the significance level. Statistical analyses were performed in Stata/IC 13.1 (StataCorp, Tex.).

RESULTS

A total of 32 patients were included in the study, with 16 patients who underwent mandibular reconstruction with a free fibula flap transferred as one segment ($n = 5$), two segments ($n = 8$), or three segments ($n = 3$) in both groups. No patients were lost to follow-up, and there are no missing data. Preoperative patient characteristics were similar in the two groups (Table 1).

The median (range) treatment delay was 6 (6–20) days in the CAD/CAM group and 8 (6–20) days in the control group ($P = 0.48$). Fibula flap ischemia time was significantly shorter in the CAD/CAM group with mean 18.4 (95% CI 2.8; 33.9) minutes from 92.9 (78.4; 107.4) minutes in the control group to 74.6 (67.3; 81.8) minutes in the CAD/CAM group ($P = 0.022$). The mean total

Table 1. Preoperative Patient Characteristics

Variable	CAD/CAM ($n = 16$)	Control ($n = 16$)	*P*
Sex (male/female)	8/8	8/8	1.0
Age (y)	67 ± 10	63 ± 10	0.25
Body mass index (kg/m²)	22.4 ± 3.2	23.3 ± 3.7	0.45
Current tobacco use			
Yes	9 (56%)	10 (63%)	1.0
No	7 (44%)	6 (37%)	
Alcohol consumption (1 unit = 12 g)			
<14 units per week	8 (50%)	9 (56%)	1.0
≥14 units per week	8 (50%)	7 (44%)	
American Society of Anesthesiologist classification			
I	0	0	0.15
II	12 (75%)	7 (44%)	
III	4 (25%)	9 (56%)	
Previous head and neck cancer treatment			
Surgery	4 (26%)	6 (38%)	0.70
Radiotherapy	3 (19%)	3 (19%)	1.0

Continuous variables are presented as mean values with SD and *P* values from the unpaired *t* test. Categorical variables are presented as the number of patients and frequencies with *P* values from Fisher exact test.

Table 2. Intraoperative Characteristics

Variable	CAD/CAM ($n = 16$)	Control ($n = 16$)	P
Treatment delay, median with range	6 (6–20)	8 (6–20)	0.48
Surgery time (min), mean with 95% CI	507 [445; 570]	442 [396; 487]	0.08
Fibula flap ischemia time (min), mean with 95% CI	74.6 [67.3; 81.8]	92.9 [78.4; 107.4]	0.022
Fibula flap classification			
Osteocutaneous	9 (56%)	13 (81%)	0.25
Bone	7 (44%)	3 (19%)	
Fibula segments			
1	5 (31%)	5 (31%)	1.0
2	8 (50%)	8 (50%)	
3	3 (19%)	3 (19%)	
Secondary free flap	7 (44%)	3 (19%)	0.25
Neck dissection			
Not performed	0	3 (19%)	0.16
Ipsilateral	7 (44%)	8 (50%)	
Bilateral	9 (56%)	5 (31%)	

Continuous variables that followed the normal distribution are presented as mean values with 95% confidence intervals and P values from the unpaired *t test*. Continuous variables that did not follow the normal distribution are presented as medians and interquartile range with P values from the Wilcoxon rank-sum test. Categorical variables are presented as the number of patients and frequencies with P values from Fisher exact test.

Table 3. 30-day Postoperative Outcomes

Variable	CAD/CAM ($n = 16$)	Control ($n = 16$)	P
Flap Complications			
Fibula flap failure	0	1 (6%)	1.0
Fibula flap pedicle thrombosis	0	2 (13%)	0.48
Flap site dehiscence	3 (19%)	2 (13%)	1.0
Flap site infection, antibiotics	6 (38%)	4 (25%)	0.7
Flap site infection, reoperation	1 (6%)	2 (13%)	1.0
Other Clinical Outcomes			
Hospital stay, median IQR (d)	7 (7–9)	13 (7–20)	0.05
Mortality	0	0	

Continuous variables are presented as medians and IQR, with P values from the Wilcoxon rank-sum test.
Categorical variables are presented as the number of patients and frequencies with P value from Fisher exact test.

surgery time was 507 (445; 570) minutes in CAD/CAM group compared with 442 (396; 487) minutes in the control group ($P = 0.08$). The two groups did not differ in other intraoperative characteristics (Table 2).

Postoperative outcomes and complications after 30 days were comparable between the CAD/CAM and control group (Table 3). There was a trend towards a shorter hospital stay in the CAD/CAM group with median (range) 7 (7–9) days compared with 13 (7–20) days in the control group ($P = 0.05$).

DISCUSSION

Our study demonstrates the feasibility of implementing in-house CAD/CAM for planning and execution of tumor resection and free fibula flap mandibular reconstruction in head and neck cancer patients. This is the first study to assess the efficiency of an in-house CAD/CAM service with precise reporting of lead time and its impact on treatment delay. We showed that the median treatment delay decreased from 8 days before to 6 days after CAD/CAM implementation, indicating that CAD/CAM did not obstruct treatment efficiency. Our clinical operations, including the availability of multidisciplinary clinic appointments and operating rooms, remained consistent over the study period, ensuring that these factors did not impact treatment delay.

Previous studies have explored in-house CAD/CAM solutions in mandibular reconstruction performed by pioneering surgeons. Bosc et al published a case series consisting of 18 oral cancer patients undergoing free fibula flap mandibular reconstruction using cutting guides designed and manufactured by the surgeons themselves.[8] The cutting guide fabrication time was from 3 to 15 days (mean 5.1 days), with surgeons spending 12–48 hours total per patient on CAD/CAM.[8] Corresponding to this, Numajiri et al reported in-house CAD/CAM for mandibular reconstruction in cancer cases where surgical residents performed the virtual surgical planning and CAD/CAM in their free time, requiring a minimum of 3 days per case.[9] Despite a significant reduction in fibula flap ischemia time, the authors questioned the cost-effectiveness of in-house CAD/CAM when considering the extra surgeon man-hours.[9] Conversely, Ritschl et al advocated for CAD/CAM as a teaching opportunity for surgical residents using an in-house setup with a reported lead time of 2–3 days.[10]

More recent studies describe the advantage of an in-house engineering team for CAD/CAM. Geusens et al used a clinical engineer to perform virtual surgical planning and CAD/CAM in a study of 20 mixed cancer and osteoradionecrosis

patients undergoing free fibula flap mandibular reconstruction reporting a lead time of 2–4 days.[11] Vrancx et al reported their substantial experience with engineer-staffed in-house CAD/CAM in 75 cases of maxillofacial reconstructions with a preparation time of 2–4 days compared with 10–15 days lead time from commercial vendors. Other groups reported average lead time from third-party solutions to be on average 2 weeks down to as low as 6–7 days.[12,13]

To summarize, although several centers utilize in-house CAD/CAM solutions for mandibular reconstruction with reported lead times from 2 to 4 days no studies have assessed the impact on treatment delay for cancer patients. In our in-house setup with close collaboration between surgeons and clinical engineers, we consistently achieve a lead time of 48–72 hours from virtual surgical planning to autoclaved patient-specific cutting guides available for surgery.

Cost savings is a potential advantage of in-house CAD/CAM. Vranckx et al described substantial monetary savings with in-house CAD/CAM engineering service compared with commercial solutions.[14] The direct costs of commercial CAD/CAM solutions vary, depending on case-specific factors such as the inclusion of custom-made reconstruction plates, with mean prices per patient ranging from €2500 to €3750[14–16] and US $5098 to $8200.[17,18] Previous studies have estimated the total added costs associated with third-party CAD/CAM solutions, factoring in reductions in flap ischemia time and potentially operating room time, to be in the range from US $1231.50 to $3113.50[17] or US $7099.[19]

Expenses associated with establishing an in-house CAD/CAM include the acquisition of 3D printing technology, software licenses, materials, and engineering staff. Geusens et al reported material costs per patient at €250 and software costs at €20,000 per year but did not describe engineer salary expenses.[11] One study reported low material costs at mean €14.30 per patient.[10] Investing in a 3D printer is a one-time purchase, whereas software licenses are recurring annual expenses. The required man-hours paid to a clinical engineer and materials costs are fixed per patient. Therefore, in-house CAD/CAM becomes increasingly cost-effective as the caseload increases in contrast to using commercial vendors. We believe that an in-house service is financially viable once an institution-specific threshold of cases is reached. Using open-source software, as described by Ritschl et al, would further contribute to cost reduction, but the quality and safety of noncertified software should be scrutinized.[10]

Regarding clinical outcomes, we found a significant reduction in fibula flap ischemia time after implementation of in-house CAD/CAM corresponding to a recent meta-analysis investigating the effects of CAD/CAM on operative outcomes in head and neck reconstruction.[3] CAD/CAM made it possible to perform osteotomies and plate fixation with the flap still perfused at the donor site, reducing the need for adjustments at the recipient site to obtain optimal occlusion. However, bone flaps can easily tolerate ischemia for 2–3 hours, suggesting that this reduction in ischemia time does not necessarily improve flap healing or reduce complications.[20]

Total surgery time was prolonged, although not significantly, after the implementation of in-house CAD/CAM, which conflicts with the meta-analysis.[3] We do not attribute this prolongation to technical difficulties associated with CAD/CAM because the technology was implemented over 12 months before the study patients were operated on, minimizing potential learning curves to affect the results. Instead, extra surgery time may be caused by more CAD/CAM patients receiving two free flaps, due to our microsurgeons' increasing preference for combining a fibula bone flap with a separate free fasciocutaneous flap to mitigate lower limb donor site complications. Additionally, as stated in the meta-analysis by Padilla et al, the speed and extent of tumor resection and the need for neck dissection greatly influencing total surgery time is why this outcome may not be a reliable indicator of the advantages of CAD/CAM.[3] Finally, increased focus on training the next generation of surgeons may have increased procedure times over the study period.

The core strength of our in-house CAD/CAM solution lies in the close collaboration between surgeons and engineers. In contrast to using third-party solutions, which necessitate the sharing of image files and ad hoc scheduling of inconvenient teleconferences, our in-house virtual surgical planning is timetabled on the same day as the multidisciplinary head and neck cancer clinic held twice weekly. Consequently, our engineers can promptly proceed with CAD/CAM of cutting guides on the same day as the patient's clinic visit. Further, the familiarity between surgeons and engineers has been instrumental in optimizing all clinical and technological aspects of patient flow as well as in fostering new innovative applications of 3D printing in surgery.

Our study design has limitations inherent to a retrospective cohort study, particularly with the control group being operated on before the CAD/CAM cohort. Consequently, data might be affected by changes in clinical practice, such as the increased utilization of two free flaps. A direct comparison between in-house and commercial CAD/CAM in a randomized clinical trial would be the gold standard. Additionally, we did not assess the precision of the final mandibular reconstruction, as our study focused primarily on patient flow and treatment delay. The primary challenges in the implementation of in-house CAD/CAM are the large start-up costs as well as hiring and retaining skilled engineers. Like other in-house solutions, we cannot manufacture patient-specific reconstruction plates, which are instead available from commercial CAD/CAM vendors.

In conclusion, our study demonstrates the successful implementation of CAD/CAM-assisted surgery for all head and neck cancer patients requiring microsurgical reconstruction of the mandible without causing treatment delay. Through the utilization of an in-house CAD/CAM service staffed by clinical engineers, we can offer this innovative technology with minimal lead time and at a lower cost compared with commercial alternatives. Our findings have the potential to significantly impact clinical practice by providing a cost-effective and efficient approach to CAD/CAM-assisted mandibular reconstruction, making

it accessible to all patients across diagnoses and diverse health care systems.

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