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HEAD AND NECK

Evaluation of virtual surgical planning systems and customized devices in fibula free flap mandibular reconstruction

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Abstract

Purpose The purpose of this study was to evaluate the accuracy of virtual planning using customized surgical devices (VP3D) in fibula free flap mandibular reconstruction.

Methods Fourteen patients received VP3D and 16 patients underwent conventional surgery (CS). Virtual planning was compared to postoperative scans using cephalometric and three-dimensional (3D) measurements. Operative times of both VP3D and CS groups were compared.

Results Comparisons of cephalometric measurements revealed no significant difference between virtual planning and post-operative scans. 3D analysis demonstrated a high level of virtual planning accuracy. In the VP3D group, total operative time gain was 88 min ($p < 0.001$) and total ischemia time gain was 36 min ($p = 0.04$).

Conclusion Virtual surgical planning using customized devices enables 'tailored' surgery that is accurate and reliable and results in operative and ischemia time gain.

Clinical trial NCT03869723.

Keywords Mandibular defect · Fibula flap · Reconstruction · Virtual planning · Pre-bent plate

Introduction

The fibula free flap is the most common flap used in reconstructing loss of mandibular bone substance resulting from tumor resection or secondary to osteoradionecrosis [1–3]. One of the inherent difficulties in performing mandibular reconstruction lies in contouring the bone to match the resected mandible, requiring osteotomy so as to obtain optimal esthetic and functional outcomes [2, 4, 5]. Conforming a fibula flap to reconstruct loss of mandibular bone substance is a delicate task, even in the most expert of hands. It is a time-consuming surgical procedure which frequently requires adjustment [6]. There are numerous causes of imprecision and time-loss related to execution of osteotomies, adjustment of fragment size and shaping of osteosynthesis plates [1, 7–9].

By virtue of imaging, virtual planning of both resection and mandibular reconstruction can be achieved

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preoperatively by three-dimensional modeling. Advances in 3D printing technology have been instrumental in transposing this type of virtual planning to the field of surgery due to the fabrication of cutting guides and osteosynthesis plates that are preshaped and customized. These devices are adjusted to the type of intended reconstruction, thus facilitating the shaping and osteosynthesis of the fibula. This technology would appear to save time and contribute to esthetic outcomes that replicate native morphology as closely as possible [6, 10–13].

Even though this technique is highly attractive, it incurs additional cost and the advantages of its routine use have only recently begun to be evaluated. A number of studies have reported shorter operative and ischemia time [13–17] yet few studies compare preoperative contouring with postoperative outcomes.

The main objective of our study was to compare preoperative virtual planning models with outcomes obtained postoperatively using customized devices.

Secondary objectives were to compare operative and ischemia times with those of a group of patients having undergone conventional surgery and to evaluate the quality of oncologic resection in cases involving tumors.

Patients and methods

Patients

All patients who underwent fibula free flap mandibular reconstruction between November 2013 and March 2018 were included in this study. Of these patients, some received conventional surgery (CS patients) and the others benefited from preoperative virtual planning involving customized devices (cutting guides and osteosynthesis plates) according to the technique described by Schouman et al. [11] (VP3D patients). From January 2017, patients sustaining mandibular reconstruction involving at least one osteotomy were operated using the VP3D technique. This was when funding was awarded to our department by the Hospices Civils de Lyon (Hospital Group of Lyon) for VP3D procedures.

Relevant data were recorded prospectively in electronic medical records while analysis was performed and comparisons were made retrospectively.

Preoperative demographics included the following: age, sex, comorbidities, ASA (American Society of Anesthesiologists) score, previous history of radiotherapy, neck dissection or head and neck cancer, tobacco use, and pathology (cancer or osteoradionecrosis). The site and type of substance loss were recorded according to the Jewer et al. [18] classification system (L, lateral defect: horizontal ramus ± vertical ramus with no condylar involvement; C, central defect: mandibular symphysis; LC, symphysis and 1 horizontal ramus ± vertical ramus; LCL, symphysis and both horizontal rami ± vertical ramus/rami), as was any incidence of fracture or preoperative mandibular continuity defects.

Intraoperative specifics included the number of bone fragments and osteotomies, time of incision, time of clamping and unclamping of flap pedicle and time at which microsurgical phase (under surgical microscope) began. Operative time (incision/closure) and ischemia time (clamping/unclamping) were determined, along with the time between incision and microscope phase, and clamping and microscope phase.

In terms of postoperative course, we collected the following data: length of hospital stay, flap necrosis and bone resection margins (R0, R1, R2).

Virtual planning method

Preoperative modeling was conducted by obtaining scans of patient maxillofacial skeleton and angioscans of the lower extremities. The planning phase was then carried out by the surgeon and the engineer (from MATERIALISE®, Leuven, Belgium) so as to define the clinical and technical parameters of the reconstruction. This stage consisted of discussing and determining osteotomy lines, donor side, anastomosis site, and overall reconstruction contour. Resection was decided by the surgeon and a radiologist at a multidisciplinary meeting. It was also based on systematic analysis of patient mandibular MRI scans to avoid overlooking medullary invasion of the mandible that is imperceptible on imaging.

3D modeling and the manufacture of cutting guides and customized osteosynthesis plates were then undertaken (MATERIALISE®, Leuven, Belgium) (Figs. 1, 2).

Surgical technique

All patients were operated using a two-team approach. In CS (conventional surgery) patients, fibula contouring was initiated at the donor site using a template or plates conformed to the resection site, but was thereafter not adjusted until the vascular pedicle had been clamped. In VP3D patients, the fibula was fully contoured at the donor site prior to vascular pedicle clamping (Fig. 3). The microscope phase was initiated once the fibula had been fixed to the recipient site. Regardless of the technique employed (CS or VP3D), we routinely complete osteosynthesis and mucosal sutures before embarking on the microsurgery phase. All anastomoses were performed by the same experimented surgeon.

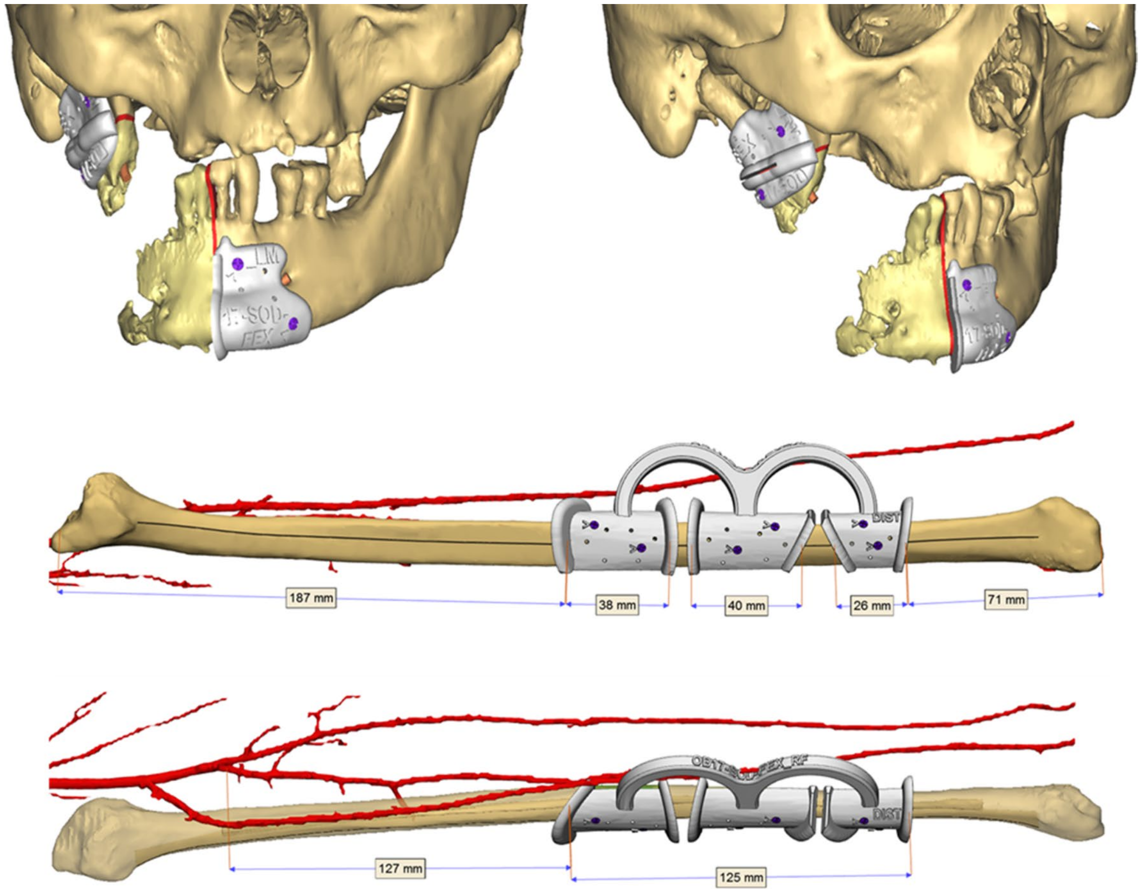
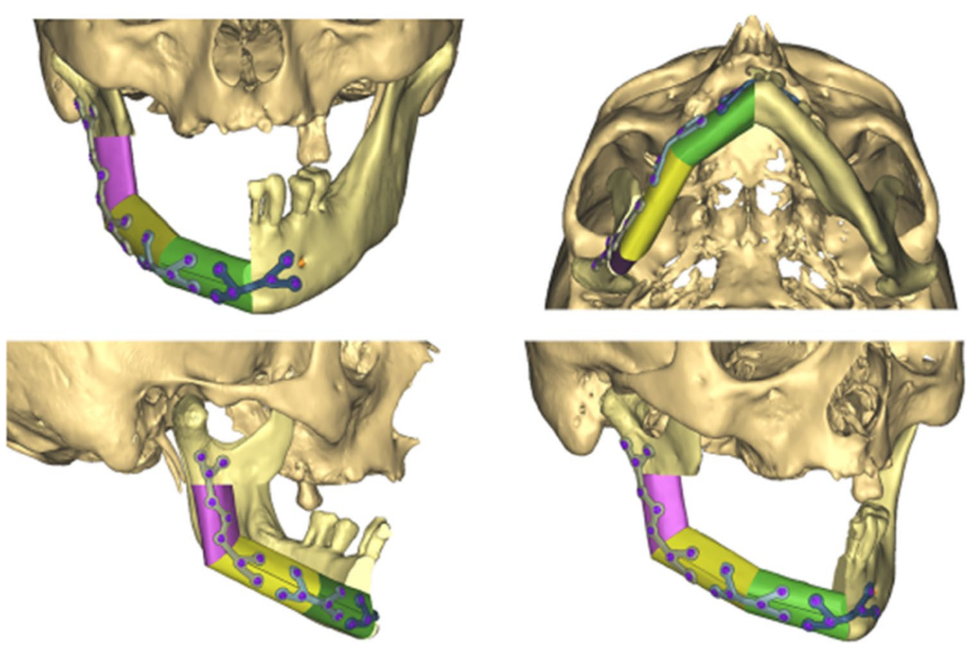


Fig. 1 Surgical planning example: mandibular and fibular cutting guides

Fig. 2 Example of preoperative virtual reconstruction planning with patient's fibula and pre-bent plates



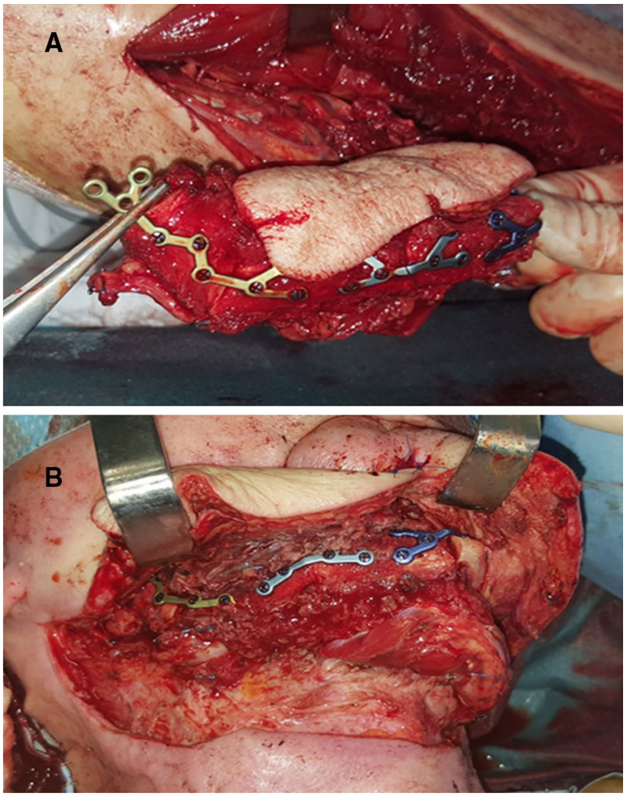


Fig. 3 Operative view of mandibular reconstruction using VP3D and pre-bent plates. **a** Fibula shaping entirely done before clamping; **b** view of final reconstruction of right hemimandible

Methods of comparison

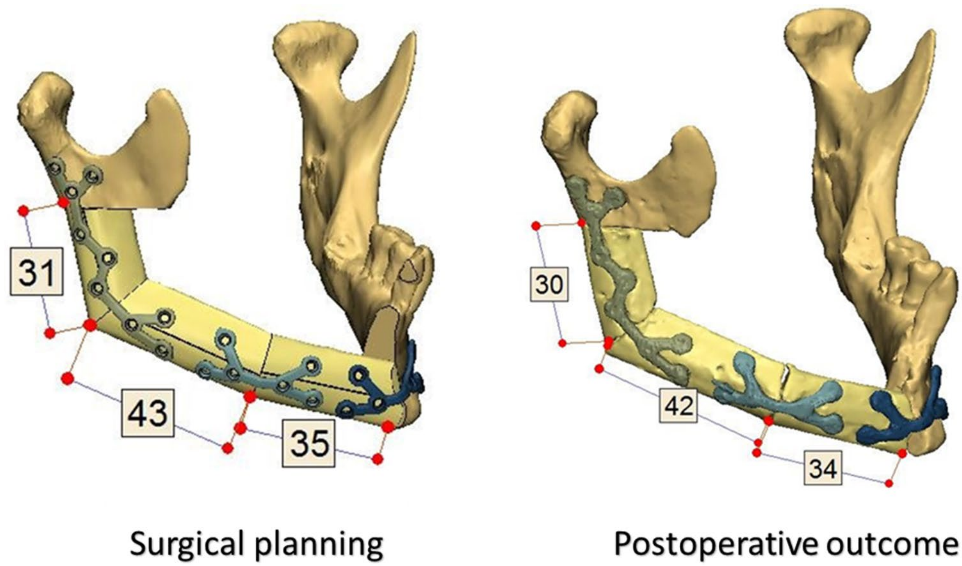
We compared the virtual model obtained using preoperative surgical planning with postoperative outcomes derived from facial bone scans conducted on all VP3D group patients 6 months after completion of treatment (MIMICS INNOVATION suite 2.1® software, MATERIALISE®, Leuven, Belgium).

Two methods of comparison were used:

The first consisted of obtaining 2D (two-dimensional) cephalometric measurements as outlined by Zhang et al. [12] to assess planning accuracy. We measured and compared: length of fragments (1); intercondylar distance (2); intergonial distance (distance between both angles) (3); anteroposterior distance (distance of the perpendicular section measured between the symphysis and the intercondylar line) (4); and the reconstructed mandibular angle (5) in preoperative models and on control scans (Figs. 4, 5). Differences and mean differences between planning and postoperative outcomes were calculated in terms of absolute value.

The second method consisted of plotting points at both ends of each fibula segment, calculating their displacement in the three spatial planes and comparing the points on the preoperative model with those found on post-therapeutic scanning whereby *x,* sagittal or anteroposterior displacement; *y,* coronal plane or right-left displacement and *z,* axial plane or cephalocaudal displacement. Differences and mean differences between planned and postoperative outcomes were calculated in terms of absolute value. Quantitative comparison was performed according to a method resulting from collaboration between MATERIALISE® and the ENSAM (Ecole Nationale Supérieure d'Arts et Métiers—French engineering school—75013 PARIS) Georges Charpak Institute of Human Biomechanics (publication in progress). This method is based on the superposition of 3D models using the axes of inertia, and it enables a quantitative description of the distances and rotations between the planned elements and their postoperative counterparts (Fig. 6).

Fig. 4 Comparison between surgical planning and postoperative outcomes: length of fragments



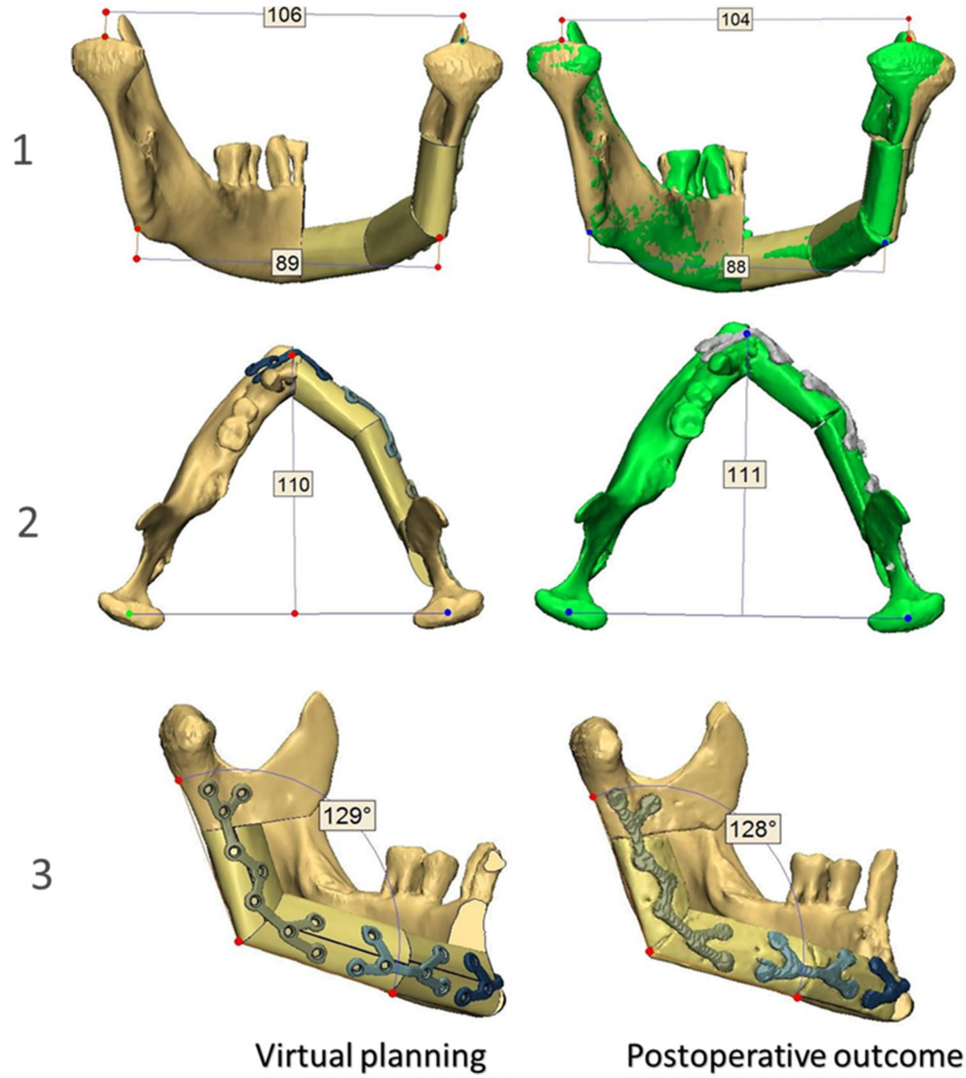


Fig. 5 Comparison between surgical planning and postoperative outcomes: 1, intercondylar distance and intergonial distance; 2, anteroposterior distance; 3, mandibular angle

Secondary objectives were to compare patients from the VP3D group with those from the CS group in terms of operative and ischemia time and to evaluate the quality of oncologic resection.

The main objective was to evaluate the feasibility and the fidelity of the virtual surgical planning but not the restoration of the initial anatomy. Knowing that the planning is only carried out in the VP3D group, we decided not to carry out the cephalometric and 3D analyzes in the CS group.

Statistical analysis

Statistical tests were conducted using the R statistical software package for Windows. Mean comparison statistics were calculated using the Mann–Whitney test (for quantitative variables) and Fisher's exact test for qualitative variables. The significance threshold was set at 5%. Mean values were calculated in terms of standard deviation (SD; ±). In the event of flap loss, these patients were excluded from comparisons between virtual planning and postoperative outcomes.

Ethical and regulatory considerations

This study was conducted in accordance with French legislation governing observational clinical studies. It has been approved by the local ethics committee and registered with the CNIL (French Data Protection Agency) under the reference number 17-148.

Results

Patients and postoperative course

Over the course of the inclusion period, 30 patients underwent fibula free flap mandibular reconstruction, of whom

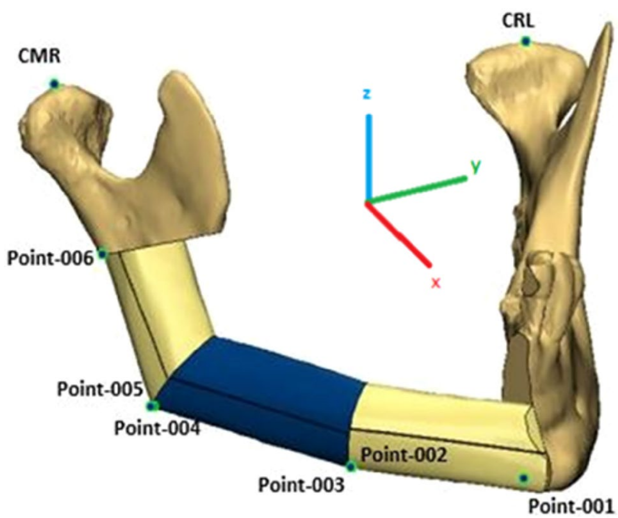


Fig. 6 3D comparison uses plotting points at both ends of each fibula segment and compares surgical planning and postoperative outcomes: *x* sagittal or anteroposterior displacement, *y* coronal plane or right-left displacement and *z* axial plane or cephalocaudal displacement

14 (47%) were operated using the virtual planning with customized devices technique (VP3D) and 16 (53%) underwent conventional surgery (CS).

Of these patients, 24 (80%) sustained malignant tumors (23 cases of squamous-cell carcinoma and 1 sarcoma) and 6 (20%) sustained mandibular osteoradionecrosis.

Patient characteristics from each group are shown in Table 1. This comparative study describes two homogenous groups with no significant difference in terms of age, sex and comorbidities. Patients from the VP3D group had higher incidence of previous surgery and/or neck radiotherapy (42% vs 25%) without reaching statistical significance.

Statistically significant difference was, however, observed in both groups in terms of quantity of fibular fragments, since an average of 2.4 fragments was found in the VP3D group compared to 1.7 in the CS group ($p = 0.009$). We also observed twice as much extensive loss of substance (LC/LCL) (50% vs 25%) and osteoradionecrosis-related fractures (29% vs 12.5%) in the VP3D group, with no evidence of significance. These findings are indicative of greater complexity in the reconstructive surgery performed in the VP3D group compared with the CS group.

Intraoperative data

Various operative times are compiled in Table 2. Data pertaining to initiation of the microscope phase were lacking in 1 (8%) patient from the VP3D group and 2 (12.5%) patients from the CS group. These patients were excluded from clamping/microscope phase analysis.

Analysis of time periods revealed significant time gain in all of the operative times investigated in the VP3D group by comparison with the CS group. Mean time gain was 88 min from incision to closure ($p < 00.1$), 83 min from incision to unclamping ($p < 0.001$), 32 min from clamping to

Table 1 Patient demographic characteristics

	VP3D	CS	$p =$
$n = (\%)$	14(47)	16(53)	–
Age (years)[a]	63 ± 12	59 ± 10	0.14
Male/female (%)	10(71)/4(29)	9(56)/7(44)	0.47
Comorbidities			
Radiotherapy: Y/N (%)	5(38)/9(56)	3(19)/13(81)	0.42
Head and neck surgeryY/N (%)	5(38)/9(56)	5(31)/11(69)	1
Neck dissection ± radiotherapy (%)	6(42)/8(57)	4(25)/12(75)	0.44
ASA score[a]	2.21 ± 0.7	2 ± 0.8	0.34
Tobacco use Active/stop/0 (%)	1(7)/10(71)/3(21)	10(63)/5(31)/1(6)	–
Pathology			
Cancer (%)	10(71)	14(87.5)	0.38
ORN (%)[b]	4(29)	2(12.5)	
Bone defect (%)[c]			
L	7(50)	7(44)	1
C	0(0)	5(31)	0.04
LC/LCL	6(43)/1(7)	1(6)/3(19)	0.26

n number of patients, *RTE* radiotherapy, *Y/N* yes/no

[a]Average and standard deviation (SD)

[b]Osteoradionecrosis

[c]Jewer et al. [18] classification

Table 2 Number of bone fragments and operative duration

	VP3D	CS	$p=$
Bone fragments			
Mean—SD[a]	2.4 ± 0.5	1.7 ± 0.8	0.009
1/2/3 (%)	0(0)/8(57)/6(43)	8(50)/5(31)/3(19)	–
Incision/closure[b]	441 ± 46	529 ± 61	< 0.001
Clamping/unclamping[b]	136 ± 43	172 ± 40	0.04
Incision/unclamping[b]	397 ± 52	480 ± 56	< 0.001
Clamping/microsurgical phase[b]	67 ± 20	99 ± 33	0.006

[a]Average and standard deviation (SD)

[b]Average time in min and SD

microscope phase ($p = 0.006$), and mean ischemia time gain was 36 min ($p = 0.04$).

Postoperative course

With respect to bone resection margins, 1 patient (7%) from the VP3D group and 2 (12.5%) from the CS group were deemed R1 ($p = 0.6$). None had macroscopically positive margins.

Of the 30 patients, 1 patient from the VP3D group sustained flap necrosis.

Comparison of planning-postoperative outcomes

Thirteen patients were subjected to analysis and comparison using superposition of 3D models (Fig. 4). Mean values for various lengths, distances and angle measurements at virtual planning and postoperative stages are shown in Table 3. Mean deviation of 2 mm was detected between programmed fibula segment lengths and actual postoperative lengths, with a difference of 3 mm regarding intercondylar distance, 1 mm regarding anteroposterior distance, and 5° regarding the mandibular angle.

Mean deviation (in terms of absolute value) of the points plotted at both ends of each fibula segment between virtual planning and postoperative outcomes was 2.8 mm (± 3.9) in the *X* sagittal (anteroposterior) plane, 3.1 mm (± 4) in the *Y* coronal (right–left) plane, and 3.6 mm (± 5.2) in the *Z* axial (cephalocaudal) plane. Mean deviation per patient of the points plotted at both ends of each segment between virtual planning and postoperative outcomes was 3.0 mm (± 2.4); in patients with three fragments the difference was 3.9 mm (± 3.8), and 2.7 mm (± 1.7) in patients with two fragments (no significance).

Discussion

Surgical teams increasingly make use of preoperative three-dimensional modeling and customized devices in fibula free flap mandibular reconstruction. This development is attributed to the fact that such technology is believed to improve surgical procedures and enable time gain while reducing flap ischemia time [13, 16, 17]. Yet very little data are available on the accuracy of this technique, and more specifically few studies compare preoperative contouring with actual postoperative outcomes. Moreover, although many surgical teams make use of preoperative virtual planning and customized osteotomy guides, the use of pre-bent 3D plates generated by selective laser melting is far less common. In the majority of published articles, the plates are shaped by hand preoperatively on the basis of stereolithographic templates or 3D-printed models, which in our view results in loss of accuracy due to human intervention.

Table 3 Comparison of distances and angles between surgical planning and postoperative outcomes

	Length of fragments	Intercondylienne distance	Intergoniale distance	Anteroposterior distance	Mandibular angle
$n=$	31	13	13	13	14
Surgical planning[a]	45 ± 18	103 ± 6	97 ± 8	112 ± 10	127 ± 7
Postoperative[a]	44 ± 17	102 ± 6	97 ± 7	112 ± 10	130 ± 10
Difference[a]	2 ± 2	3 ± 3	2 ± 2	1 ± 1	5 ± 4
$p=$	0.68	0.38	0.93	0.90	0.30

n effective

[a] Distance in millimeter and angle in degree; ±, standard deviation; difference, absolute value of the differences between surgical planning and postoperative outcomes

Hence the novelty of our study lies in the comparison made between 3D preoperative modeling and postoperative scanning. All of the 2D cephalometric comparisons included in this series not only assess the accuracy of virtual planning but also that of morphologic restoration post reconstruction (symmetry, projection, angles, etc.). Our findings indicate that using preoperative virtual planning and customized devices enables reliable planning of the desired reconstruction and converts it into reality with a high degree of accuracy and fidelity. These findings are comparable to those of Zhang et al. [12] who observed mean segment length difference of 1.34 mm. Difference in intercondylar distance, intergonial distance, anteroposterior distance and reconstructed mandibular angle was 2.97, 2.96, 4.27 mm respectively and 2.29°, equally consistent with our series [12]. To optimally evaluate virtual planning accuracy and in the most comprehensive way possible, we decided to calculate all of the results in terms of absolute value to avoid underestimation. Furthermore, we conducted three-dimensional analysis which is more accurate than linear measurements. Indeed, this type of analysis is based on perspective representation within the fragment space and thus ensures optimal reproducibility. Mean deviation of each segment was only 3.0 mm, as was deviation in the 3 spatial planes which only fluctuated by 3 mm. Tarsitano et al. [19] were the only other authors to carry out three-dimensional analysis, finding mean error of 1 mm, yet they adopted a different three-dimensional analysis method which was therefore non-comparable. Their findings, much the same as ours, corroborated the quality and reliability of virtual planning. Other studies report greater accuracy and restoration of native anatomy in mandibular reconstruction using this technique compared to conventional reconstruction [10, 12, 19]. Moreover, Weitz et al. [20] found significant difference in bone consolidation in the customized devices group ($p = 0.002$) and significant improvement in accuracy with respect to reconstruction. Wang et al. [10] also highlighted higher quality bone-to-bone contact (95.2% vs 71.4%; $p = 0.013$), hence likely improvement in long term consolidation. It would have been interesting to compare the CS and VP3D groups in terms of morphological results and restoration of the initial anatomy. Unfortunately, this study does not make it possible to evaluate the superiority or to compare one technique with respect to the other on these points. This is one of the limitation of the present study.

The accuracy of cutting guides and pre-bent plates facilitates contouring and makes this complex surgical procedure less surgeon-dependent, with the added advantage of rapid learning curves [13]. It thus enables more complex and ambitious reconstructions while reducing the difficulties and inaccuracy caused by increased fragment quantity and calculation of angles and fragment length. Monaco et al. [21] in their series documented a gradual increase in the number of osteotomies or double barrel free flaps and an increase in the number of single surgery implantation procedures. This is especially the case in large tumors or mandibular necrosis including previous fractures or loss of substance which pose particularly complex problems when embarking on anatomical restoration. On account of mirror imaging on the non-affected side, VP3D is able to replicate with greater ease the anatomy of the prospective reconstruction site [16]. By limiting technical problems, preoperative contouring therefore results in enhanced accuracy in reconstructive surgery even in the most complex of cases. As we observed in our series, although patients from both groups showed similarity in terms of age, sex and comorbidity, those from the VP3D group had a higher incidence of previous surgery and/or neck radiotherapy (42% vs 25%), making resection, neck dissection and vascular anastomosis more challenging and time-consuming. Patients from the VP3D group had as a rule sustained more complex surgical and reconstructive procedures involving more extensive substance loss. Fragment quantity was indeed significantly higher (2.4 vs 1.7; $p = 0.009$), with twice as much LC or LCL substance loss in the VP3D group (50% vs 25%). In spite of this disparity, and consistent with the findings of Culié et al. [17], no significant difference in rates of flap necrosis was detected.

Our total operative times were significantly shorter using preoperative contouring (441 vs 529 min, $p < 0.001$), much the same as findings from Wang et al. [10] whose study demonstrated a total operative time gain of 80 min. With respect to ischemia time and contouring time (clamping/microscope phase), we observed significant time gain of 35 min. These findings are consistent with previously published findings [22]. Certain authors even managed to reduce ischemia time by 50 min [12]. This time gain appeared to increase even more in proportion to the complexity of the reconstruction (quantity of osteotomies, complex angles, etc.) [17]. These findings are linked to reduced flap and osteosynthesis plate contouring time, facilitating the surgical procedure which becomes less surgeon-dependent and more reproducible. In addition, the cutting guides generate pre-drilled holes which, in conjunction with customized pre-bent plates not only dispense with the necessity of performing condylar positioning or maxillomandibular fixation, but also eliminate the difficulties inherent to fibula conformation, avoiding the adjustments and inaccuracies incurred by the execution of osteotomies and plate shaping.

We found no evidence of studies providing categorical proof of the functional advantages of VP3D compared to conventional surgery. Avraham et al. [23], however, report secondary dental implant rehabilitation in 63% of patients and primary rehabilitation in 25% of patients, with 47% of patients enjoying functional dentition. Currently several systems offer preoperative virtual planning of dental implant sites involving primary or secondary insertion which yield apparently advantageous functional outcomes [24, 25]. Tarsitano et al. [19] also compared VP3D and non-VP3D-derived morphological outcomes with preoperative scans and highlighted higher quality restoration of native anatomy in terms of mandibular angle, projection and intergonial distance. There was also an improvement in proper condylar positioning using VP3D (100% vs 54.3%; $p = 0.007$) according to Wang et al. [10], raising expectations of optimal postoperative dental occlusion.

Despite the numerous advantages of VP3D, it can also entail a number of drawbacks. One of the main theoretical limitations underlying this technique is the necessity of adhering to preoperative virtual planning without any possibility of modifying resection intraoperatively, involving a potential risk of positive margins in the event of intraoperative setbacks. In practice, this risk is attenuated by systematic recourse to MRI and TDM scans which are crucial in evaluating mandibular medullary bone invasion and anticipating osteotomy sites [26]. In our institution, these two examinations are routinely requested as part of the preoperative workup and resection is always determined by a radiologist and the surgical consultant. In our study, we found only one case of positive margins in the VP3D group whereas there were two in the CS group, concerning a patient with osteosarcoma whose margins are always difficult to gauge [27]. Another limitation is the time required to manufacture cutting guides and osteosynthesis plates. As in findings by Culié et al. [17], this time period had no knock-on effect on delivery of oncologic care. Lastly, the cost of VP3D could conceivably impede routine use of this technique. However, according to an American study conducted by Toto et al., and a Swiss series undertaken by Zweifel et al., the additional cost incurred by this technology is offset by a gain in operating room time, making such technology financially viable [28, 29].

Conclusion

Virtual surgical planning in conjunction with customized devices promotes the execution of 'tailored' surgical procedures that are accurate and reliable while facilitating operative time gain and reduction in ischemia time. This technique is particularly valuable in complex mandibular reconstruction procedures where multiple osteotomies are required. Routine use of these systems should be integrated into our therapeutic arsenal given the successful outcomes observed.

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Compliance with ethical standards

Conflict of interest The author(s) declare that they have no conflict of interests.

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