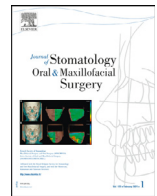




ELSEVIER

Available online at
ScienceDirect
 www.sciencedirect.com

Elsevier Masson France
EM|consulte
 www.em-consulte.com



Original Article

Mandibular reconstruction after post-traumatic complex fracture: Comparison analysis between traditional and virtually planned surgery

Stefania Troise^{a,*}, Gianluca Renato De Fazio^a, Umberto Committeri^{a,b}, Raffaele Spinelli^a, Maria Nocera^a, Emanuele Carraturo^a, Giovanni Salzano^a, Antonio Arena^a, Vincenzo Abbate^a, Paola Bonavolontà^a, Antonio Romano^a, Giovanni Dell'Aversana Orabona^a, Luigi Angelo Vaira^c, Pasquale Piombino^{a,d}

^a Maxillofacial Surgery Unit, Department of Neurosciences, Reproductive and Odontostomatological Sciences, University Federico II of Naples, University Federico II, Via Pansini 5, Naples, Italy

^b Department of Maxillo-Facial Medicine Surgery, Hospital of Perugia, Perugia, Italy

^c Maxillofacial Surgery Operative Unit, University Hospital of Sassari, Sassari, Italy

^d Department of Oral and Maxillofacial Surgery, Hospital Sant'Anna e San Sebastiano, Caserta, Italy

ARTICLE INFO

Article History:

Received 7 August 2024

Accepted 28 August 2024

Available online xxx

Keywords:

Virtual surgical planning
 Complex mandibular fractures
 Mandible reconstruction
 3D-printing, CAD/CAM

ABSTRACT

Background: Jaw reconstruction after complex post-traumatic fracture is still a challenge for surgeons using traditional surgery. Virtual surgical planning has proven to be a valid tool for managing these fractures. The aim of this study is to quantitatively evaluate the VSP effectiveness compared to traditional surgery in the management of complex mandibular fractures.

Methods: 30 patients with diagnosis of complex mandibular fracture were enrolled and divided in two groups: Group A (virtually planned surgery), The plate was pre-modeled and employed during the surgery; Group B (traditional surgery), the plate was shaped directly during the surgery. Virtually planned and post-operative Computer Tomography were after compared for both the groups to highlight discrepancies in mm.

Results: Fracture surgical reduction was successful without intraoperative complications. In Group A, all the mean discrepancies' values were <1 mm while in Group B the values were included between 1.36 and 1.94 mm. The mean operative time was 69 min for Group A, while 106 min for Group B.

Conclusions: Fracture virtual reduction and realization of pre-modeled plate are able to guarantee a more anatomically correct reduction and a decrease in operating times. These outcomes translate into a decrease in both short and long-term complications.

© 2024 The Author(s). Published by Elsevier Masson SAS. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>)

1. Introduction

Mandibular fractures are the most common fractures of the facial skeleton, caused by accidents, assault or sports injuries. Based on the number of fragments and on the fracture lines these fractures can be divided into two categories: simple and complex. Simple fractures are linear resulting in two fragments. Complex fractures involve at least two fracture lines with three or more fragments. This category includes: basal triangle fractures, segmental fractures, comminuted fractures, defect fractures. In presence of infection or of atrophic mandible, the fracture is also considered complex. In these cases, the treatment's aim is to restore anatomical bony continuity, facial symmetry and to make a prosthetic rehabilitation possible [1]. Open Reduction and Internal Fixation (ORIF) is the most valuable approach

[2–4], even though this kind of fractures are still a challenge for the maxillo-facial surgeon, considering that the reduction and the fixation of multi-fragmented fractures are technically difficult and require longer surgical time. The absence of a stable and reliable occlusion in case of atrophic edentulous mandibles, deprives the surgeon of the main guide for a correct fragments' reduction; swelling, pus exudation and possible mouth-opening limitation will make the surgery harder in case of concomitant infection [5,6]. When the reduction of the fragments is not anatomically correct, the risk of both short- and long-term post-operative complications increases; for this reason, in case of a complex fracture, a load-bearing fixation is mandatory due to obtain the most stable reduction possible [7].

In order to overcome these problems and to obtain a stable reduction, Virtual Surgical Planning (VSP) and 3-dimensional printing (3-DP) are therefore increasingly used in case of complex fractures.

VSP is a tool which can translate computed tomographic scans into stereolithographic models [8], in order to plan complex cases in a more

* Corresponding author.

E-mail address: stefy.troise@gmail.com (S. Troise).

precise fashion, also decreasing surgical time [9]. The virtual reduction of the fractures and the following 3D printing of the stereolithographic resin model of the mandible allow the surgeon to customize the reconstruction plate already preoperatively, saving surgical time and gaining treatment precision. Computer-assisted design (CAD) and computer-assisted manufacturing (CAM) technology has already found several applications in Oral and Maxillo-Facial Surgery field. Currently, it is already part of the clinical practice in orthognathic surgery, reconstructive surgery and craniofacial traumatology [9–13].

Based on the previous evidence, CAD/CAM and VSP technologies could be a support to the surgeon in the treatment of these fractures, to guide the surgery and avoid postoperative complications but, based on our current knowledge of the scientific literature, there are little data that can quantitatively objectify the effectiveness of VSP with statistical data. Hence, the aim of this study is to quantitatively evaluate the effectiveness of VSP in the management of complex mandibular fractures, comparing the traditional surgery with the virtual planned surgery and performing a statistical analysis.

2. Materials and methods

2.1. Study design

This work is a single-center observational case-control study and was conducted at the Maxillofacial Surgery Unit of the “Federico II” University Hospital of Naples, between September 2020 and October 2023. All the investigations and the clinical procedures were conducted according to the Declaration of Helsinki and the study was approved by the Ethics Committee of Biomedical Sciences the “Federico II” University of Naples with protocol number 270/2023.

Patients who satisfied these inclusion criteria were enrolled in the study:

- Age \geq 18 years;
- Complex post-traumatic mandibular fractures, diagnosed by a CT scan performed within 24 h of the trauma;
- Loss of dental occlusion
- Surgical treatment of Open reduction and internal fixation (ORIF)
- Post-operative CT performed the day after surgery
- Sign of written informed consent

Patients were excluded from the study according to the following criteria:

- General contraindication to surgery
- Previous treatments for maxillofacial fractures
- Chronic bone pathologies (osteoporosis, osteomalacia, craniofacial malformations or other pathologies affecting the skeletal system that could influence the study)
- Non-complex fracture with no loss of dental occlusion
- Closed treatment with maxilla-mandibular fixation (MMF)

Considering these inclusion and exclusion criteria, 30 patients were enrolled in the study and divided into two groups:

- Group A (cases group - virtually planned surgery), 15 patients in which the virtual reduction of the fractured bone fragments was realized and, through a digital workflow, a pre-modeled plate was obtained and employed for the intraoperative surgical reduction of the fracture;
- Group B (controls group – traditional surgery), 15 patients in which the plate was shaped directly during the surgery.

The patients' belonging to one of the groups depended on the availability of virtual surgical planning software in the Maxillofacial

Surgery Unit, thus the patients of Group A were treated starting from January 2022.

For all the patients, a preoperative clinical and radiological evaluation was performed. The step-by-step digital protocol for the virtual reduction of the fracture is described below.

2.2. Step-by-step digital workflow for fracture virtual reduction

All the included mandibular fractures were subjected to a “in-house” digital workflow for virtual reduction of bone fragments; in the Group A (cases) this digital workflow aimed to obtain a pre-modeled plate to guide the surgery; in the Group B (controls), treated by a traditional surgery shaping the plate intraoperatively, the digital workflow aimed to compare the preoperative virtually reduced CT with the real post-operative CT. For each patient, the same protocol was applied as defined below:

- (1) CT image quality control and Conversion from DICOM (Digital Imaging and Communications in Medicine) files to STL (Stereolithography) files

The first step was to upload the preoperative CT images in DICOM format in the software RadiAnt viewer 64bit (Medixant, Poland) (Fig. 1a), to verify the quality of the scans. The images were imported in the software InVesalius 3.1 (CTI Renato Archer, Campinas, Brazil) to obtain a 3D model and a rapid segmentation of the facial skeleton with the mandibular fractures (Fig. 1b), thus the files were converted into STL format.

- (2) Segmentation and virtual reduction of bone fragments

To perform segmentation and virtual reduction of bone fragments, STL files were processed using the open-source software Meshmixer 3.5 (Autodesk Inc, California, USA).

Each bone fragment of the mandibular fracture was selected using the “select” tool (Fig. 2) and then repositioned correctly using the “transform” function. To avoid any bias, two different maxillofacial surgeons (RS, MN) performed the procedure. The reduction was obtained by considering the positioning of the condyles in the glenoid fossa. At the end of the procedure, using the “plain cut” and “discard” instruments, the virtually reduced mandible was isolated and exported as “objects” file and was converted into a STL file adapted for the “Formlab-Form 3B” 3D printer (Fig. 3).

This phase was performed for both Group A (cases) and Group B (controls).

- 1) Rapid prototyping 3D Printing and plate modelling

For the Group A (cases), the reduced virtual model of mandible was processed using the software “Formlab-Form 3B” 3D printer in order to set the model for 3D printing and to model the plate to guide the surgery. Supports were set to obtain the highest possible quality of the model (Fig. 4a).

A resin StereoLithography Apparatus (SLA) 3D printer (Formlab-Form 3B+, located in Somerville, Massachusetts, USA,) was employed for rapid prototyping; the selected material was the Formlab Model Resin V3 (ISO 10,993–5: 2009) with a tensile strength of 27 MPa and modulus of elasticity of 1.1 GPa. Once the print was completed, the model was washed in isopropyl alcohol using the Form Wash (Form Wash -located in Somerville, Massachusetts, USA) device for 20 min and photopolymerized using the Form Cure (Form Cure located in Somerville, Massachusetts, USA) device for other 20 min (Fig. 4b).

After the manufacturing of the reduced mandible model, a 2.4 titanium plate was modeled by applying manual pressure in order to obtain a customized device for each patient (Fig. 5). The shaped plate

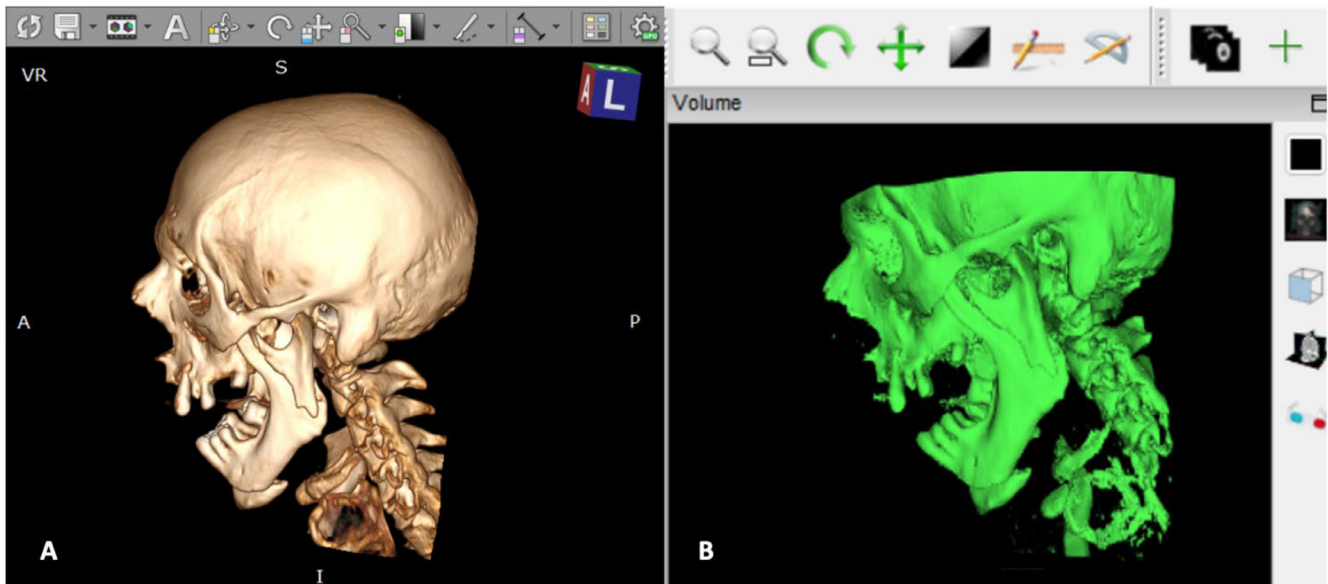


Fig. 1. Pre-operative 3D CT image in DICOM files: (a) Visualization with the RADIANT viewer 64bit software; (b) Visualization with InVesalius 3.1 software.

was sterilized in an autoclave at a temperature of 160 °C for 60 min, 24 h before the surgery.

(1) Surgery

For the Group A (cases), the pre-shaped plate was employed during the surgery to guide the reduction of the fracture bone fragments, while for the Group B (controls) the plate was modeled intraoperatively, based on the manual reduction of bone stumps. Based on the position of the fracture, the surgical approach was intraoral or extraoral. In case of atrophic mandible, the periosteum was not detached from the bone so as not to affect vascularization. At the end of the

procedure, for both groups, the surgeon checked the facial symmetry, temporomandibular joint function and the correct position of the condyles in the glenoid cavities. A surgical procedure example is shown in Fig. 6 (Fig. 6).

All the patients underwent antibiotic therapy and corticosteroids therapy after surgery for 5–7 days.

2.3. Post-operative outcomes

2.3.1. Clinical evaluation

For both the groups, the postoperative results in term of facial symmetry, temporomandibular joint function, mouth opening and

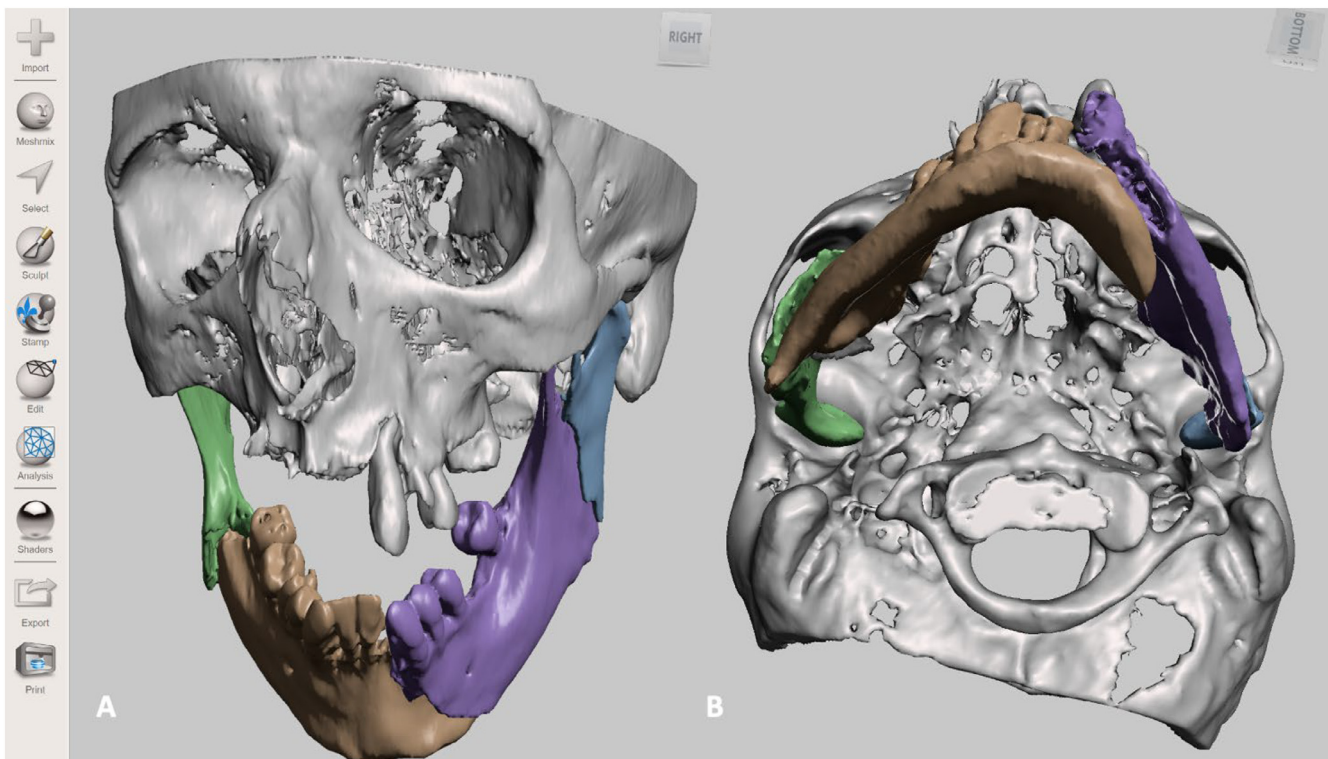


Fig. 2. Segmentation of the mandibular fracture fragments with the Meshmixer 3.5 software: (a) frontal view; (b) bottom view.

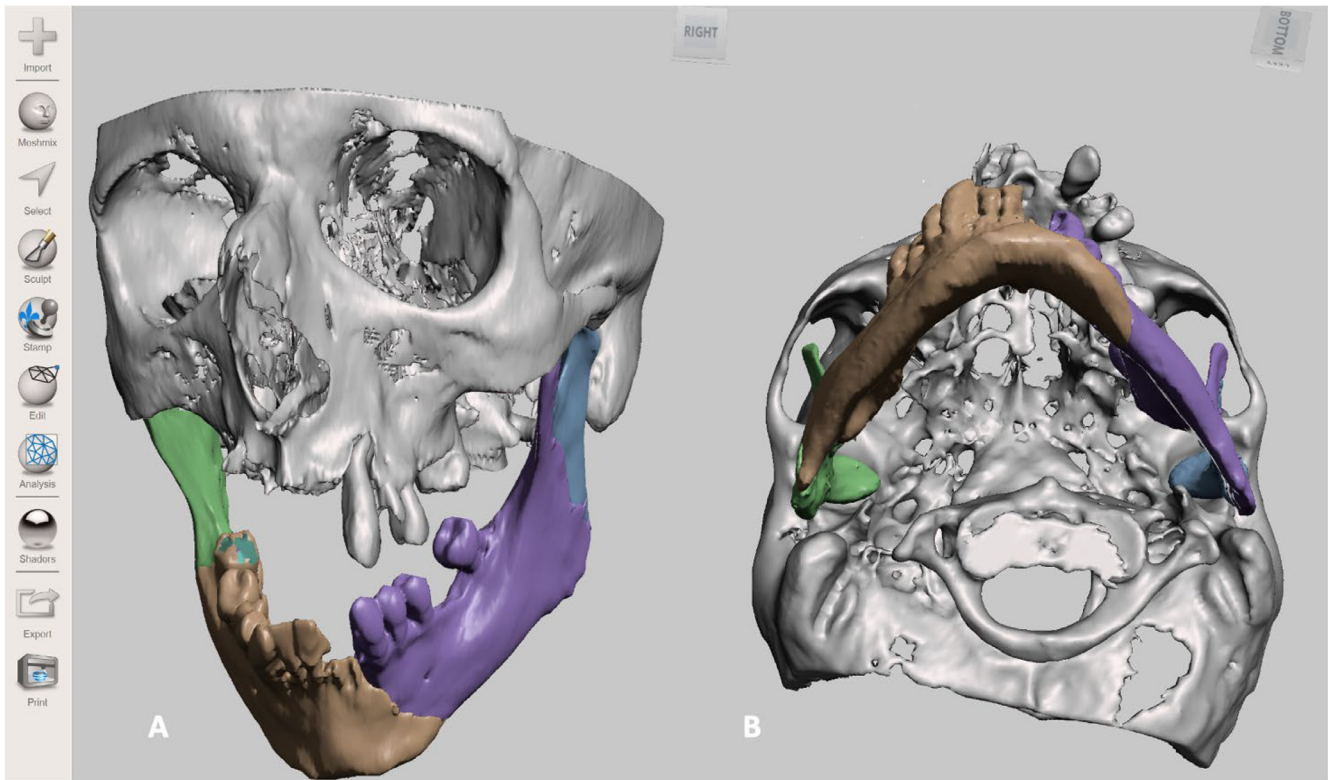


Fig. 3. Mandibular reconstruction after the reduction of fracture fragments with the Meshmixer 3.5 software: (a) frontal view; (b) bottom view.

dentil occlusion were evaluated. Thus, the immediate and long-term complications were recorded. The minimum follow-up was 6 months.

2.3.2. Radiological evaluation

For all the patients, a postoperative clinical and radiological evaluation was carried out; a post-surgical CT scan was performed the day after the surgery. The STL files of the 3D image of the postoperative CT were obtained as described previously for both the groups. In order to compare the virtual reduction of the fracture with the postoperative outcome and, therefore, the effectiveness of the proposed protocol, a visual color map of the overlapping of the virtually reduced CT and postoperative CT was performed. This procedure was

possible thanks to the software Geomagic Design X (11 Breedewees, I-1259 Senningerberg—Production, Logistics&Service Center): through the "automatic alignment between scans" function, it was possible to align and superimpose the virtually reduced jaw model and the post-operative image, obtaining a visual color map. In this distanced color map, the different discrepancies in mm between the two superimposed images were coded with different colors: the upper/lower limits for color coding of the discrepancies were fixed as +2 mm and -2 mm and steps of 0.25 mm were used, so each color encoded a distance interval of 0.25 mm. To avoid any bias in the overlapping process, the automated protocol of the Geomagic software was used and the mean discrepancy value at the whole cloud point was automatically calculated by the software. However, to identify

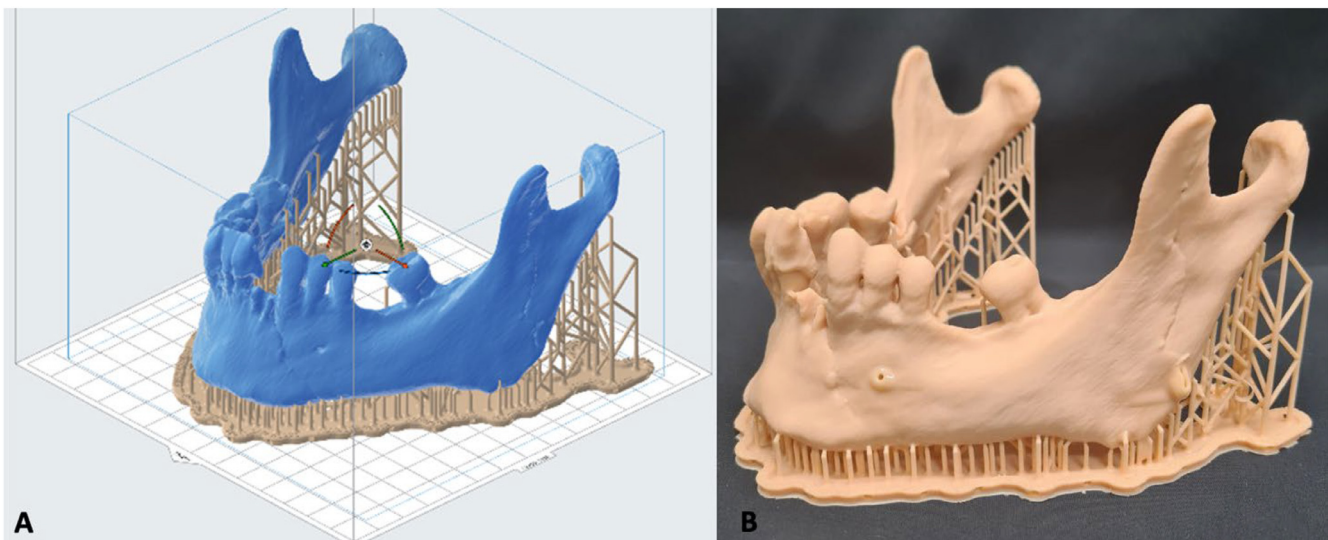


Fig. 4. (a) Pre-printing process of the reduced mandible model with the Preform 3D-Printing Software (Formlabs 3B+); (b) Final reduced mandible 3D-Printed model.

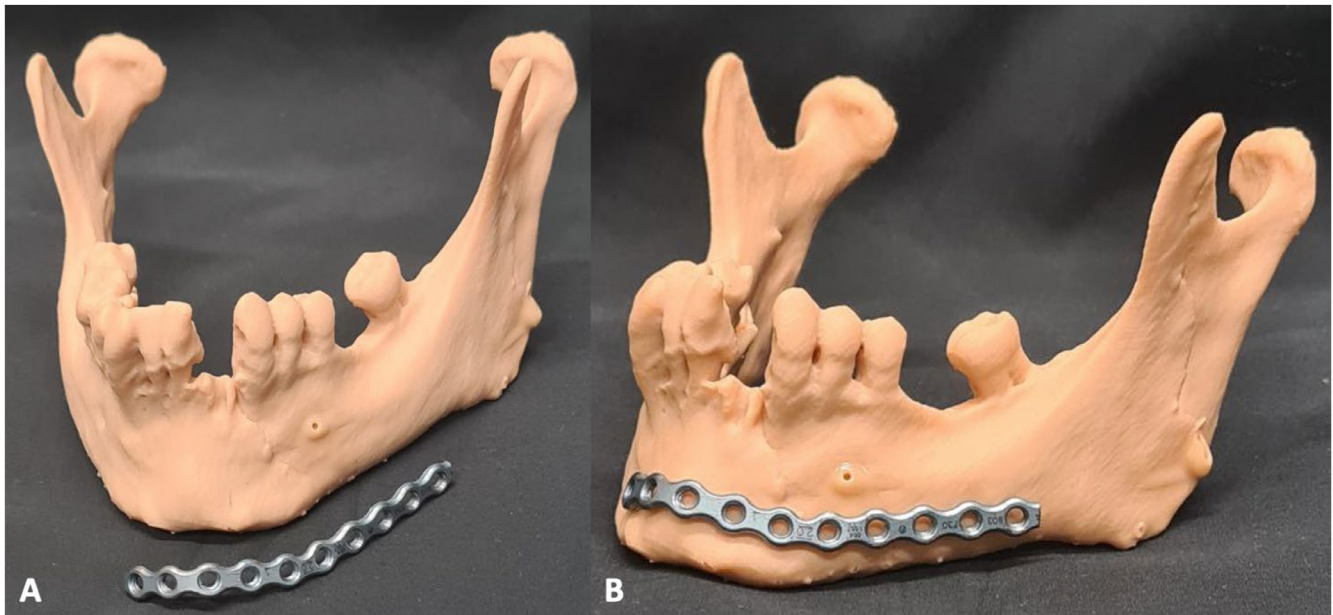


Fig. 5. (a) Pre-plate of the 2.4 reconstruction plate on the reduced mandible 3D-printed model; (b) the pre-modeled plate fits perfectly on the model.

the portion of mandible more predictable, the discrepancies were also manually calculated in 6 cephalometric points: menton, B point, left and right condyle, left and right gonion.

This comparison was performed for both the groups (cases and controls), obtaining for each patient a discrepancy value in the cloud point and in all the considered anatomic landmarks (Fig. 7).

2.4. Data evaluation and statistical analysis

The statistical analysis was performed with the software Statistical Package for Social Sciences (SPSS), version 16.0, for Windows (SPSS, Chicago, IL, USA) and R (software), version 4.0.2, for Windows (R Foundation for Statistical Computing, Vienna, Austria).

To compare the discrepancies values in the two groups, a data distribution test for continuous variables was performed. The data distribution was abnormal due to the small sample size; therefore, a non-parametric test was applied. Using the non-parametric Mann-Whitney U test (group comparison), the data were examined for

signs of significant differences. A p-value < 0.05 was considered statistically significant.

The non-parametric Mann-Whitney U test was also employed to compare the operative times in the two groups.

3. Results

3.1. Population

The general features of the 30 patients enrolled in the study and divided in two groups of 15 patients, were shown in Table 1. The distribution of the patients' features (sex, age, smoke, dynamics of trauma, side of fracture, fracture complexity, portion of mandible involved and comorbidities) was homogeneous between the two groups. In particular, the male sex was predominant in both groups with 80 % and 86.7 %, respectively in Group A and Group B; the average age was 44 years in Group A and 41 years in Group B. The most frequent dynamic of trauma was road accident in both groups (33.3 %

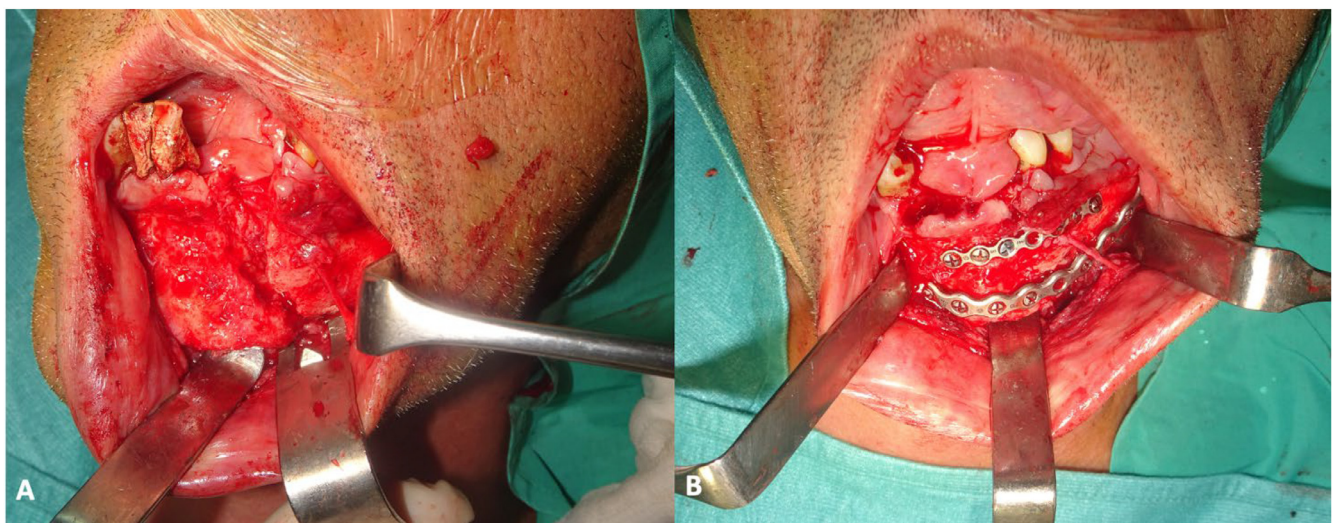


Fig. 6. Surgical treatment: (a) identification of fracture fragments; (b) fragments fixation using the pre-shaped plate.

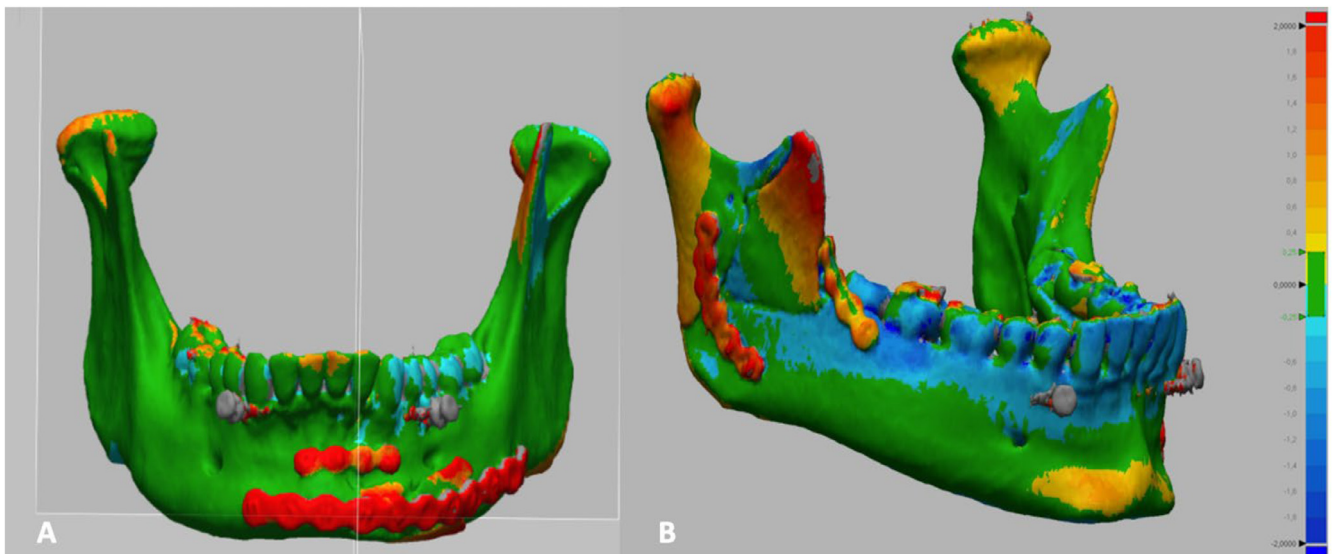


Fig. 7. Overlapping and comparison between the pre-operative 3D virtually reduced model and the post-operative CT images using Geomagic Design X software: (a) Example case of Group A, in which the color map shows a good overlapping; (b) Example case of Group B, in which the color map shows a worse overlapping.

Table 1
General features of the population.

Characteristics	Group A	Group B
Sex	- Male 12 (80 %) - Female 3 (20 %)	- Male 13 (86.7 %) - Female 2 (13.3 %)
Age	Mean age: 44 y Range (18–88 y)	Mean age: 41 y Range (19–84 y)
Dynamics of trauma	- Road accident 5 (33.3 %) - Aggression 4 (26.7 %) - Accidental fall 2 (13.3 %) - Syncopal episode 2 (13.3 %) - Sports injury 1 (6.7 %) - Work Accident 1 (6.7 %)	- Road accident 6 (40 %) - Aggression 3 (20 %) - Accidental fall 3 (20 %) - Syncopal episode 1 (6.7 %) - Sports injury 1 (6.7 %) - Work Accident 1 (6.7 %)
Side of fracture	- Bilateral 11 (73.3 %) - Right 2 (13.3 %) - Left 2 (13.3 %)	- Bilateral 13 (86.7 %) - Right 1 (6.7 %) - Left 1 (6.7 %)
Fracture Complexity	- Comminute 9 (60 %) - Trifocal 4 (26.7 %) - Atrophic 2 (13.3 %)	- Comminute 8 (53.3 %) - Trifocal 4 (26.7 %) - Atrophic 3 (20 %)
Portion of mandible involved	- Condyle 7 (46.7 %) - Body 12 (80 %) - Angle 7 (46.7 %) - Symphysis 3 (20 %) - Ramus 1 (6.7 %)	- Condyle 8 (53.3 %) - Body 13 (86.7 %) - Angle 5 (33.3 %) - Symphysis 2 (13.3 %) - Ramus 2 (13.3 %)
Comorbidities	- Cardiovascular 4 (26.7 %) - Neurological 1 (6.7 %) - Diabete mellitus 1 (6.7 %)	- Cardiovascular 3 (20 %) diseases - Neurological 1 (6.7 %) diseases - Diabete mellitus 1 (6.7 %)
Smoke	- Smokers 5 (33.3 %) - No Smokers 10 (66.7 %)	- Smokers 6 (40 %) - No Smokers 9 (60 %)

and 40 % respectively in Group A and Group B) followed by aggression (26.7 % and 20 % respectively in Group A and Group B). In the most of cases (73.3 % in Group A and 86.7 % in Group B), the fractures were bilateral, resulting comminuted, trifocal or atrophic as showed in Table 1.

The most involved regions of mandible were the condyle (46.7 % in Group A and 53.3 % in Group B) and the body (80 % in Group A and 86.7 % in Group B). The patients presented different comorbidities but the most frequent were the cardiovascular diseases, both in the Group A (26.7 %) and in the Group B (20 %).

The mean operative time was 69 ± 8 min using a pre-modeled plate for the Group A, while 106 ± 11 min shaping intraoperatively the plate, for the Group B.

3.2. Analysis of times and costs of digital workflow

The time spent for virtual surgical planning of each case was approximately 2 h, while the printing and sterilization processes took approximately 6 h for each model.

An evaluation of the costs relating to the printing process was also conducted. The initial cost for the 3D printer Formlabs-form 3B+ was approximately 5130.00 euros. The amount of resin employed for each model was approximately 50 ± 2 ml, with a cost of about 7.00 euros, resulting in a total amount of about 750 ml, for a total price of 105.00 euros.

3.3. Post-operative outcomes

3.3.1. Clinical results and complications

In all the patients the surgical reduction of the fracture was successful without intraoperative complications. All the patients were discharged between 3 and 5 days after surgery. The minimum follow-up was 6 months. In the Group A, one case of wound dehiscence (6.7 %) in a smoking patient was recorded; in the Group B, two cases of residual malocclusion (13.3 %) and one case of temporomandibular

joint dysfunction (6.7 %) were recorded. No cases of iatrogenic nervous lesions, infections or mouth opening limitation were recorded.

3.3.2. Analysis of discrepancies

The complete discrepancies analysis was shown in Table 2 for the Group A and in Table 3 for the Group B. In the Group A all the obtained mean discrepancies' values were <1 mm (range 0.21 – 0.61 mm) with a mean cloud point value of 0.46 ± 0.16 , while in the Group B the mean discrepancies' values were included between 1.36 mm and 1.94 mm with a mean cloud point of 1.58 ± 0.15 . In particular, for the Group A the higher mean value was recorded in the condylar site (Right: 0.60 ± 0.34 mm—Left: 0.61 ± 0.36 mm), while the lower mean value was obtained in the Menton (0.21 ± 0.23 mm). Similarly, for the Group B the higher mean value was recorded in the condylar site (Right: 1.90 ± 0.16 mm—Left: 1.94 ± 0.19 mm), while the lower mean value was obtained in the B point (1.36 ± 0.17 mm).

3.4. Results of data statistical analysis

The results of the statistical analysis were shown in Table 4. The Mann-Whitney *U* test was applied comparing, for all the considered points, each value in the two groups: for all the points the difference of the discrepancies values resulted statistically significant ($p < 0.05$). The analysis was conducted also for the mean operative time and the difference resulted statistically significant ($p < 0.05$).

Table 2
Discrepancies analysis in the group A (cases - virtually planned surgery).

Case	Menton	B point	Right Condyle	Left Condyle	Right Gonion	Left Gonion	Cloud Point
1	0.07	0.09	0.22	0.11	0.51	0.5	0.16
2	0.13	0.05	0.54	0.07	0.55	0.54	0.28
3	0.08	0.25	0.51	0.16	0.53	0.55	0.33
4	0.03	0.08	0.11	1.04	0.45	0.44	0.35
5	0.04	0.06	0.13	1.02	0.49	0.47	0.36
6	0.11	0.13	0.57	0.43	0.5	0.51	0.38
7	0.21	0.04	0.15	1.12	0.47	0.46	0.4
8	0.01	0.54	0.73	0.21	0.51	0.53	0.45
9	0.06	0.11	0.44	1.01	0.52	0.51	0.47
10	0.15	0.01	0.85	0.82	0.53	0.53	0.49
11	0.26	0.24	0.77	0.51	0.56	0.57	0.52
12	0.14	0.15	1.08	0.56	0.65	0.69	0.61
13	0.52	0.49	0.98	0.59	0.55	0.56	0.62
14	0.71	0.53	0.96	0.71	0.61	0.6	0.68
15	0.68	0.61	1.01	0.75	0.66	0.68	0.74
A\pmSD	0.21 \pm 0.23	0.23 \pm 0.21	0.60 \pm 0.34	0.61 \pm 0.36	0.54 \pm 0.06	0.54 \pm 0.07	0.46 \pm 0.16

A: Average; SD: Standard deviation.

Table 3
Discrepancies analysis in the group B (controls - traditional surgery).

Case	Menton	B point	Right Condyle	Left Condyle	Right Gonion	Left Gonion	Cloud Point
1	1.08	1.17	1.77	1.73	1.4	1.43	1.36
2	1.23	1.24	1.75	1.75	1.42	1.41	1.39
3	1.07	1.15	1.73	1.98	1.55	1.54	1.43
4	1.41	1.32	1.74	1.74	1.56	1.55	1.48
5	1.27	1.24	1.79	2.05	1.57	1.56	1.51
6	1.31	1.19	1.87	1.89	1.55	1.53	1.51
7	1.47	1.46	1.84	1.74	1.61	1.63	1.55
8	1.27	1.49	1.95	1.78	1.53	1.55	1.55
9	1.48	1.45	1.96	1.84	1.59	1.57	1.6
10	1.73	1.41	1.78	1.97	1.59	1.58	1.62
11	1.32	1.19	2.01	2.11	1.66	1.65	1.64
12	1.24	1.47	1.92	2.14	1.64	1.63	1.66
13	1.53	1.65	2.08	1.89	1.68	1.67	1.74
14	1.55	1.58	2.16	2.27	1.71	1.7	1.83
15	1.56	1.54	2.21	2.25	1.88	1.89	1.89
A\pmSD	1.37 \pm 0.19	1.36 \pm 0.17	1.90 \pm 0.16	1.94 \pm 0.19	1.60 \pm 0.12	1.59 \pm 0.11	1.58 \pm 0.15

A: Average; SD: Standard deviation.

Table 4
Results of statistical analysis, using the Mann-Whitney U-Test.

	Z-score	U-value	P-value
Menton	-2.617	272.5	0.009
B point	-2.521	279.0	0.012
Right condyle	-2.092	308.0	0.037
Left condyle	-2.410	286.5	0.016
Right gonion	-2.380	288.5	0.017
Left gonion	-2.188	301.5	0.029
Whole Cloud Point	-2.277	295.5	0.023

4. Discussion

The management of complex fractures is a particularly discussed topic in the literature. The difficulties encountered by the surgeon are not limited to surgery alone, such as multifragmentation, edentulism, bone loss, or the presence of infection and adjacent fibrosis, but these patients are often old, affected by medical comorbidities, with poor bone quality and decreased vascularity [1,5].

For all these reasons, surgery often does not lead to a proper reduction, avoiding the achievement of a nice mandibular contour and of a functional occlusion. Different treatment protocols were then discussed.

Historically, infected mandibular infections were treated through the extraction of involved teeth and rigid immobilization of the fracture with maxillomandibular fixation (MMF), intraoral splints, external fixation devices, or a combination of these techniques [14]. Drainage of surrounding abscesses with prolonged antibiotic treatment was considered to be one of the main steps for a good final result. However, subsequently, the debridement of infected bone fragments has gained great value in mitigating further infection and bone sequestrum formation [15]. Debridement of infected or devitalized tissue followed by rigid internal fixation has shown outcomes comparable to noninfected mandibular fractures. However, debridement of an extensively infected fracture site could lead to a bony defect. Thus, the immediate primary bone grafting with autogenous particulate has shown its efficiency with decreased overall time to recovery [16].

Closed reduction with or without intermaxillary fixation was the standard treatment in case of fractures of atrophic mandibles. However, this protocol has lost favor due to statistically significant increase rates of malunion and nonunion [17-20]. So, the standard care became the open reduction via a supra-periosteal extraoral approach with placement of locking reconstruction plates fixated either along the lateral or inferior border. The use of reconstructive plates or multiple mini-plates has been associated with very satisfactory results [21-23].

About mandibular comminuted fractures, historically, open reduction was not pursued as the risk of vascular compromise of the fragments and resultant sequestration was believed to preclude such intervention [24]. Recently, open reduction and internal fixation techniques have been implemented in these injury patterns. Rigid fixation of bone fragments not only decreases sequestration but also promotes an earlier recovery of function. [25-29]

In recent years, to obtain an adequate rigid fixation in order to reproduce the correct mandibular anatomical profile and to reduce complications, virtual surgical planning has been widely employed. VSP allows to virtually reproduce the surgical procedure and, therefore, program the different phases of surgery: the recent scientific literature revealed that VSP is a valid tool of assisting surgeons in various procedures, ranging from orthognathic surgery to reconstructive surgery with free flaps, correction of congenital malformations and craniosynostosis, cranio-facial traumatology, distraction osteogenesis, and implantology [10-13,30,31]. The use of VSP for the treatment of complex jaw fractures has already been discussed in the literature. In patients with atrophic mandible fractures, the VSP has proven to lead to a more accurate reduction, also decreasing the operating time, that should not be ignored in earlier patients that often have concomitant comorbidities [5,32].

Also comminuted mandibular fractures are successfully treated with the use of virtual surgical planning, increasing precision of the reduction and restoration of the normal anatomic profile of the mandible, leading to a more accurate and stable occlusion and reducing the operative time [33,34].

However, in the literature the effectiveness of VSP has hardly been statistically quantified and objectified, therefore the objective of our study was to quantitatively demonstrate the validity of the virtually planned surgery approach compared to the traditional surgery performing a statistical analysis. With our study we want to propose an "in-house" digital-surgical workflow, to maximize the results of the surgical intervention and minimize complications. Through the virtual reduction of the fragments, and the 3D printing of the final STL model, the surgeon is able to three-dimensionally visualize the ideal surgical outcome. It is then easy to pre-model a plate on the printed model. Preoperative shaping not only allow to achieve a customized plate, but also to short the intraoperative time. Preoperative shaping is also carried out by the surgeon in a stress-free condition, unlike intraoperatively. We indeed experienced a clear decrease in the mean operational time from 106 ± 11 min for Group B to 69 ± 8 min for Group A. Through the analysis of discrepancies, the post-operative outcome in group A appears to be closer to the ideal virtual planned reduction than the group B. This data demonstrates in a statistically significant way ($p < 0.05$) that VSP-assisted surgical treatment leads to a more accurate and predictable reduction than the traditional procedure. Considering the discrepancies analysis, it is possible to confirm that the reduction of the posterior mandibular regions is more difficult to predict and to achieve as planned. In both group A and group B, the discrepancy values are significantly higher, suggesting that a perfect reduction of fractures at this level as planned is, more difficult. The condylar discrepancy appears to be greater than the anterior regions; the smallest discrepancy values are instead observed in the anterior portion in both groups, suggesting that the reduction of these region is more predictable and easy to achieve as planned. This result is explained due to the applied action/force of the plate on the bone that stabilizes the bony fragments compared to other regions which are more unstable, in particular the condyles that are influenced by the position in glenoid fossa.

The pre-shaping of the plate not only determines an operating time decrease but also a better outcome. In fact, the greater accuracy of VSP-assisted reduction influences the lower number of complications observed in Group A (one case of wound dehiscence in a smocking patient) compared to Group B (two cases of residual malocclusion and one case of temporomandibular joint dysfunction). This result confirms that in case of incorrect anatomical reduction, the complications rate is higher [32-34].

This study certainly has some limitations: the limited sample size; single-center study; the learning curve for using VSP software may be quite long; relatively long digital workflow times; prices of the tools necessary for the workflow. Nevertheless, for those centers already equipped with 3D printers and VSP software, printing the 3D model alone is very economical and thanks to the pre-operative shaping of the plate, notable advantages are obtained, both in terms of operating times and clinical-surgical outcome.

5. Conclusion

Mandibular reconstruction after complex post-traumatic fracture still remains a challenge for the surgeon. Virtual surgical planning is a valid support tool for the management of these fractures: the virtual reduction of the fracture and the realization of a pre-modeled plate are able to guarantee a more anatomically correct reduction and a decrease in operating times. These outcomes translate into a decrease in both short and long-term complications, although studies with a larger sample size are necessary to confirm these results.

Funding statement

All the authors declare that the study did not receive any funding.

Ethics approval statement

Ethical review and approval for this study were edited by the Ethics Committee for biomedical activities of the University Federico II of Naples with PROT. 270/2023.

Patient consent statement

Informed consent was obtained from all subjects involved in the study according to the World Medical Association Declaration of Helsinki.

Institutional review board statement

Ethical review and approval for this study were edited by the Ethics Committee for biomedical activities of the University Federico II of Naples. PROT. 270/2023.

Informed consent statement

Informed consent was obtained from all subjects involved in the study according to the World Medical Association Declaration of Helsinki.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Stefania Troise: Conceptualization, Project administration, Validation. **Gianluca Renato De Fazio:** Writing – original draft. **Umberto Committeri:** Writing – original draft. **Raffaele Spinelli:** Data curation, Formal analysis, Software. **Maria Nocera:** Formal analysis, Resources, Software. **Emanuele Carraturo:** Writing – review & editing. **Giovanni Salzano:** Writing – review & editing. **Antonio Arena:** Writing – review & editing. **Vincenzo Abbate:** Investigation, Methodology. **Paola Bonavolonta:** Investigation, Methodology. **Antonio Romano:** Investigation, Methodology. **Giovanni Dell'Aversana Orabona:** Supervision. **Luigi Angelo Vaira:** Investigation, Methodology. **Pasquale Piombino:** Validation.

Acknowledgments

None

References

- [1] Brucoli M, Boffano P, Romeo I, et al. The epidemiology of edentulous atrophic mandibular fractures in Europe. *J Craniomaxillofac Surg* 2019;47:1929–34. doi: [10.1016/j.jcms.2019.11.021](https://doi.org/10.1016/j.jcms.2019.11.021).
- [2] Müller S, Bürgers R, Ehrenfeld M, Gosau M. Macroplate fixation of fractures of the edentulous atrophic mandible: immediate function and masticatory rehabilitation. *Clin Oral Invest* 2011;15(2):151–6. doi: [10.1007/s00784-009-0375-0](https://doi.org/10.1007/s00784-009-0375-0).
- [3] Nasser M, Fedorowicz Z, Ebadifar A. Management of the fractured edentulous atrophic mandible. *Cochrane Database Syst Rev* 2007(1):CD006087. doi: [10.1002/14651858.CD006087.pub2](https://doi.org/10.1002/14651858.CD006087.pub2).
- [4] Ravikumar C, Bhoj M. Evaluation of postoperative complications of open reduction and internal fixation in the management of mandibular fractures: a retrospective study. *Indian J Dent Res* 2019;30(1):94–6. doi: [10.4103/ijdr.IJDR_116_17](https://doi.org/10.4103/ijdr.IJDR_116_17).
- [5] Abbate V, Committeri U, Troise S, et al. Virtual surgical reduction in atrophic edentulous mandible fractures: a novel approach based on “in house” Digital work-flow. *Appl Sci* 2023;13(3):1474. doi: [10.3390/app13031474](https://doi.org/10.3390/app13031474).
- [6] Clayman L, Rossi E. Fixation of atrophic edentulous mandible fractures by bone plating at the inferior border. *J Oral Maxillofac Surg* 2012 Apr;70(4):883–9. doi: [10.1016/j.joms.2011.03.052](https://doi.org/10.1016/j.joms.2011.03.052).
- [7] Perez D, Ellis E. Complications of mandibular fracture repair and secondary reconstruction. *Semin Plast Surg* 2020;34(4):225–31. doi: [10.1055/s-0040-1721758](https://doi.org/10.1055/s-0040-1721758).
- [8] Neumann P, Siebert D, Schulz A, et al. Using virtual reality techniques in maxillofacial surgery planning. *Virtual Real* 1999(4):213–22. doi: [10.1007/BF01418157](https://doi.org/10.1007/BF01418157).
- [9] Saad A, Winters R, Wise MW, Dupin CL, St Hilaire H. Virtual surgical planning in complex composite maxillofacial reconstruction. *Plast Reconstr Surg* 2013 Sep;132(3):626–33. doi: [10.1097/PRS.0b013e31829ad299](https://doi.org/10.1097/PRS.0b013e31829ad299).
- [10] Antony AK, Chen WF, Kolokythas A, Weimer KA, Cohen MN. Use of virtual surgery and stereolithography-guided osteotomy for mandibular reconstruction with the free fibula. *Plast Reconstr Surg* 2011;128(5):1080–4. doi: [10.1097/PRS.0b013e31822b6723](https://doi.org/10.1097/PRS.0b013e31822b6723).
- [11] Hirsch DL, Garfein ES, Christensen AM, Weimer KA, Saddeh PB, Levine JP. Use of computer-aided design and computer-aided manufacturing to produce orthognathically ideal surgical outcomes: a paradigm shift in head and neck reconstruction. *J Oral Maxillofac Surg* 2009;67(10):2115–22. doi: [10.1016/j.joms.2009.02.007](https://doi.org/10.1016/j.joms.2009.02.007).
- [12] Roser SM, Ramachandra S, Blair H, et al. The accuracy of virtual surgical planning in free fibula mandibular reconstruction: comparison of planned and final results. *J Oral Maxillofac Surg* 2010;68(11):2824–32. doi: [10.1016/j.joms.2010.06.177](https://doi.org/10.1016/j.joms.2010.06.177).
- [13] Swennen GR, Mollemans W, Schutyser F. Three-dimensional treatment planning of orthognathic surgery in the era of virtual imaging. *J Oral Maxillofac Surg* 2009;67(10):2080–92. doi: [10.1016/j.joms.2009.06.007](https://doi.org/10.1016/j.joms.2009.06.007).
- [14] Koury M, Ellis III E. Rigid internal fixation for the treatment of infected mandibular fractures. *J Oral Maxillofac Surg* 1992;50(05):434–43 discussion 443–444. doi: [10.1016/s0278-2391\(10\)80310-6](https://doi.org/10.1016/s0278-2391(10)80310-6).
- [15] Koury ME, Perrott DH, Kaban LB. The use of rigid internal fixation in mandibular fractures complicated by osteomyelitis. *J Oral Maxillofac Surg* 1994;52(11):1114–9.
- [16] Benson PD, Marshall MK, Engelstad ME, Kushner GM, Alpert B. The use of immediate bone grafting in reconstruction of clinically infected mandibular fractures: bone grafts in the presence of pus. *J Oral Maxillofac Surg* 2006;64(01):122–6. doi: [10.1016/0278-2391\(94\)90525-8](https://doi.org/10.1016/0278-2391(94)90525-8).
- [17] Wittwer G, Adeyemo WL, Turhani D, Ploder O. Treatment of atrophic mandibular fractures based on the degree of atrophy— experience with different plating systems: a retrospective study. *J Oral Maxillofac Surg* 2006;64(02):230–4. doi: [10.1016/j.joms.2005.10.025](https://doi.org/10.1016/j.joms.2005.10.025).
- [18] Madsen MJ, Haug RH, Christensen BS, Aldridge E. Management of atrophic mandible fractures. *Oral Maxillofac Surg Clin North Am* 2009 May;21(2):175–83. doi: [10.1016/j.coms.2008.12.006](https://doi.org/10.1016/j.coms.2008.12.006).
- [19] Bradley JC. Age changes in the vascular supply of the mandible. *Br Dent J* 1972;132(4):142–4. doi: [10.1038/sj.bdj.4802812](https://doi.org/10.1038/sj.bdj.4802812).
- [20] Bradley JC. A radiological investigation into the age changes of the inferior dental artery. *Br J Oral Surg* 1975;13(1):82–90. doi: [10.1016/0007-117x\(75\)90027-x](https://doi.org/10.1016/0007-117x(75)90027-x).
- [21] Ellis E III, Price C. Treatment protocol for fractures of the atrophic mandible. *J Oral Maxillofac Surg* 2008;66(03):421–35. doi: [10.1016/j.joms.2007.08.042](https://doi.org/10.1016/j.joms.2007.08.042).
- [22] Melo AR, de Aguiar Soares Carneiro SC, Leal JL, Vasconcelos BC. Fracture of the atrophic mandible: case series and critical review. *J Oral Maxillofac Surg* 2011;69(05):1430–5. doi: [10.1016/j.joms.2010.05.078](https://doi.org/10.1016/j.joms.2010.05.078).
- [23] Van Sickels JE, Cunningham LL. Management of atrophic mandible fractures: are bone grafts necessary? *J Oral Maxillofac Surg* 2010;68(06):1392–5. doi: [10.1016/j.joms.2010.06.023](https://doi.org/10.1016/j.joms.2010.06.023).
- [24] Ellis E III, Muniz O, Anand K. Treatment considerations for comminuted mandibular fractures. *J Oral Maxillofac Surg* 2003;61(08):861–70. doi: [10.1016/s0278-2391\(03\)00249-0](https://doi.org/10.1016/s0278-2391(03)00249-0).
- [25] Alpert B, Tiwana PS, Kushner GM. Management of comminuted fractures of the mandible. *Oral Maxillofac Surg Clin North Am* 2009;21(02):185–92. doi: [10.1016/j.coms.2008.12.002](https://doi.org/10.1016/j.coms.2008.12.002).
- [26] Klotch D. Use of rigid internal fixation in the repair of complex and comminuted mandible fractures. *Otolaryngol Clin North Am* 1987;20(03):495–518.
- [27] Prein J, Kellman RM. Rigid internal fixation of mandibular fractures—basics of AO technique. *Otolaryngol Clin North Am* 1987;20(03):441–56.
- [28] Assael LA. Results in rigid internal fixation of highly comminuted fractures of the mandible. *J Oral Maxillofac Surg* 1989;47(08):119–20.
- [29] Anderson T, Alpert B. Experience with rigid fixation of mandibular fractures and immediate function. *J Oral Maxillofac Surg* 1992;50(06):555–60 discussion 560–561. doi: [10.1016/0278-2391\(92\)90432-y](https://doi.org/10.1016/0278-2391(92)90432-y).
- [30] Ramanathan M, Panneerselvam E, Krishna Kumar Raja VB. 3D planning in mandibular fractures using CAD/CAM surgical splints - A prospective randomized controlled clinical trial. *J Craniomaxillofac Surg* 2020;48(4):405–12. doi: [10.1016/j.jcms.2020.02.004](https://doi.org/10.1016/j.jcms.2020.02.004).
- [31] Voss JO, Varjas V, Raguse JD, Thieme N, Richards RG, Kamer L. Computed tomography-based virtual fracture reduction techniques in bimaxillary fractures. *J Craniomaxillofac Surg* 2016;44(2):177–85. doi: [10.1016/j.jcms.2015.11.010](https://doi.org/10.1016/j.jcms.2015.11.010).
- [32] Castro-Núñez J, Shelton JM, Snyder S, Sickels JV. Virtual surgical planning for the management of severe atrophic mandible fractures. *Craniomaxillofac Trauma Reconstr* 2018;11(2):150–6. doi: [10.1055/s-0037-1601865](https://doi.org/10.1055/s-0037-1601865).
- [33] Kupfer P, Saadad N, Hughes PJ. Open reduction and internal fixation of bilateral atrophic mandible fractures utilizing virtual surgical planning, custom cutting guides and reconstruction plate. A case report. *J Oral Maxillofac Surg* 2016;74:e89. doi: [10.1016/j.joms.2016.06.159](https://doi.org/10.1016/j.joms.2016.06.159).
- [34] Broyles JM, Wallner C, Borsuk DE, Dorafshar AH. The role of computer-assisted design and modeling in an edentulous mandibular malunion reconstruction. *J Craniomaxillofac Surg* 2013;24(5):1835–8. doi: [10.1097/S0013e3182997f50](https://doi.org/10.1097/S0013e3182997f50).