Egypt, J. Plast. Reconstr. Surg., Vol. 49, No. 3, July: 223-230, 2025

Assessment of Virtual Surgical Planning by Using 3D Modelling and Patient Specific Pre-Bent Plate for Mandibular Reconstruction: A Clinical Trial

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Abstract

Background: Vascularized bone flaps are now considered the benchmark for reconstructing the mandible. In recent years, virtual surgical planning has transformed the process of bone reconstruction. The procedure nowadays has far better outcomes in both functional and aesthetic aspects. Moreover, the operating times has significantly decreased with the continuous development of new advances. In addition, learning curve for surgeons has become less steep.

Aim and Objectives: To compare mandibular reconstruction by free vascularized fibula using 3D models and Patient specific plate (pre bent by a manufacturer) with conventional free hand reconstruction method in our practice.

Patients and Methods: This aim was achieved by comparing two groups of patients operated by the same surgeon. In group A virtual planning was used. On the other hand, a conventional free hand technique was used in group B. The 2 groups were compared regarding the operative time and the accuracy of reconstruction using radiological landmarks and measurements.

Results: Our results showed a statistically significant reduction in operative time in Group A when compared to group B. Moreover, there was a non-statistically significant improvement regarding accuracy of the reconstruction in group A.

Conclusion: The Use of Virtual Surgical Planning & Patient Specific Plate (pre bent) for mandibular reconstruction can reduce the operative time and improve the accuracy of reconstruction.

Key Words: *Mandible reconstruction – Virtual surgical planning – 3D modelling.*

Ethical Committee: Approved by the ethical committee of Faculty of Medicine, Ain Shams University FMASU MS280/2024.

Disclosure: No disclosure.

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Introduction

The mainstay of mandibular reconstruction is now the fibula free flap. Compared to other flaps, the fibula free flap's most notable feature is the numerous segmentations of bone grafts, which can completely restore the mandible's curvature. Traditionally, surgeons used the freehand technique to segment and insert the fibula flap based on intraoperative visualization. Consequently, the results of traditional freehand mandibular reconstruction primarily rely on the abilities of the surgeon and their trial and error in the operating room **[1]**.

Although modern advances have largely improved the accuracy of the reconstruction, multiple osteotomies in the fibula, together with accurate neo-mandible contouring remain a challenging part of the operation. This fact fueled the emerging of new technologies that made virtual surgical planning possible. Sequentially, the intraoperative execution has become more accurate with the help of stereolithographic models. These advances hold potential for improving precision level, together with reducing the intraoperative time needed to complete the procedure.

Even though contemporary advancements have significantly increased reconstructive accuracy, fibular osteotomy and neo-mandible contouring are still difficult procedures that heavily rely on the expertise of the surgeon **[2]**.

In the 1980s, the first 3D models were made from thick slices of CT scans. In the early 1990s, stereolithographic models were used for the virtual surgical planning. Stereolithography is part of the 3D printed models. Evolution of the process has continued with increased accuracy of the models. Moreover, in 2009, computer assisted surgery (CAS) technology has emerged and since then, mandibular reconstruction surgeries have used the technology for more precise results **[3,4,5]**.

The first trials for the usage of cutting guides were done in 1997. Also in the 90s, 3D models built from CTs to bend the plate were attempted [6].

The use of the 3D virtual models has made the progression in the learning process way faster and has avoided the steepness in the learning curve for such complex procedures. Modern Advances has emerged that enables precision on both preoperative planning and intra operative execution. All has contributed to making mandibular reconstruction easier and less time consuming [7].

Patients and Methods

After approval of local ethical committee of Faculty of Medicine, Ain Shams University, this study Included the patients who needed mandibular reconstruction by free fibula flap. All patients were admitted to our university hospital and their follow up was done in the outpatient clinic within the same institution.

Patients were divided into 2 groups: The patients in the first group (A) underwent reconstruction using VSP (using the neo-mandible 3D model, guiding osteotomies, pre-bent reconstruction plate, Malleolus cap). The patients in the second group (B) underwent reconstruction by free hand only without VSP. Patients from group (B) were collected from previous cases done by the same surgeon. Sample Size was 5 patients for each group.

Our study included both males and females from the age of 18 to 70 years old with mandibular defects of more than 6cm in different parts of the mandible. Pathologies included both benign or malignant tumors, osteomyelitis, or osteonecrosis and indicated for mandibular reconstruction. Patients with post traumatic mandibular defects were also part of our study.

Heavy smokers, patients with metastatic disease, severe systemic diseases which may contraindicate surgery were excluded from our study. In addition, Peripheral vascular disease in the lower limb, Patients who had peronea magna found by CT angiography or History of radiotherapy to the donor/recipient sites were also excluded from our study.

High resolution CT maxillofacial and CT leg was used for manufacturing the 3D models of the virtually reconstructed mandible. Cutting guides for both mandible and fibula were created together with a template for plate bending. “Materialize Mimics” software was used for the planning of the cases. The engineer along with the surgeon confirm the osteotomy lines together [8].

Multiple modifications were done after both the software medical engineer and the surgeon communicate together to optimize the results of the 3D planning. The goal is to maximize the bone-to-bone contact, optimize the cutting planes and number of the osteotomies and to modify the length of the fibular segments. The shaping and placement of fibular bone will be planned by visualizing the reconstruction superimposed on the preoperative image of the mandible such that the outer contour of the mandible will be restored [8].

When the virtual planning was completed, the cutting guides were printed by our “In house” 3D printer. The models and guides shown in Fig. (1) will then be sterilized for intraoperative use. The titanium reconstruction plate will be pre-bent along the contours of the model to save operative time. This step took place at a local Egyptian company.

Operative details:

All surgical procedure were done by the same lead surgeon. 2 teams operate simultaneously; one exposing the mandible and the recipient vessels while the other team is harvesting the free vascularized fibula flap in order to minimize the operative timing.

Cutting guides were used to determine the osteotomy points for both the mandible and the fibula (Fig. 1). The segmented fibula parts were then screwed to the reconstruction plate in the leg before division of the pedicle. the shape of the reconstructed mandible was checked for accuracy insitu. Only then the vascular pedicle was divided. The whole prelamination (neomandible and plate) was transferred as one unit and then secured to the mandibular remnant at the optimal position that was predetermined previously by the cutting guides (Fig. 2). After which, The microvascular anastomoses were done (in most cases 1 artery and 2 veins) then the soft tissue part of the flap is inset with continuous double layered sutures to confirm watertight closure.

Post-operative follow-up:

Both groups were compared together regarding (1) Operative time, (2) Complications (including vascularity of the flap, edema, hematoma, infection and limitation in mouth opening) and (3) Symmetry which was assessed using post-operative CT.

Post-operative CT maxillofacial was used to assess the accuracy level of surgical reconstruction. The objective assessment of accuracy was done by measuring the mean change in the of anatomic landmarks between the virtual plan (pre-operative CT in the case of group B) and the actual surgical outcome as seen in Figs. (2,3).

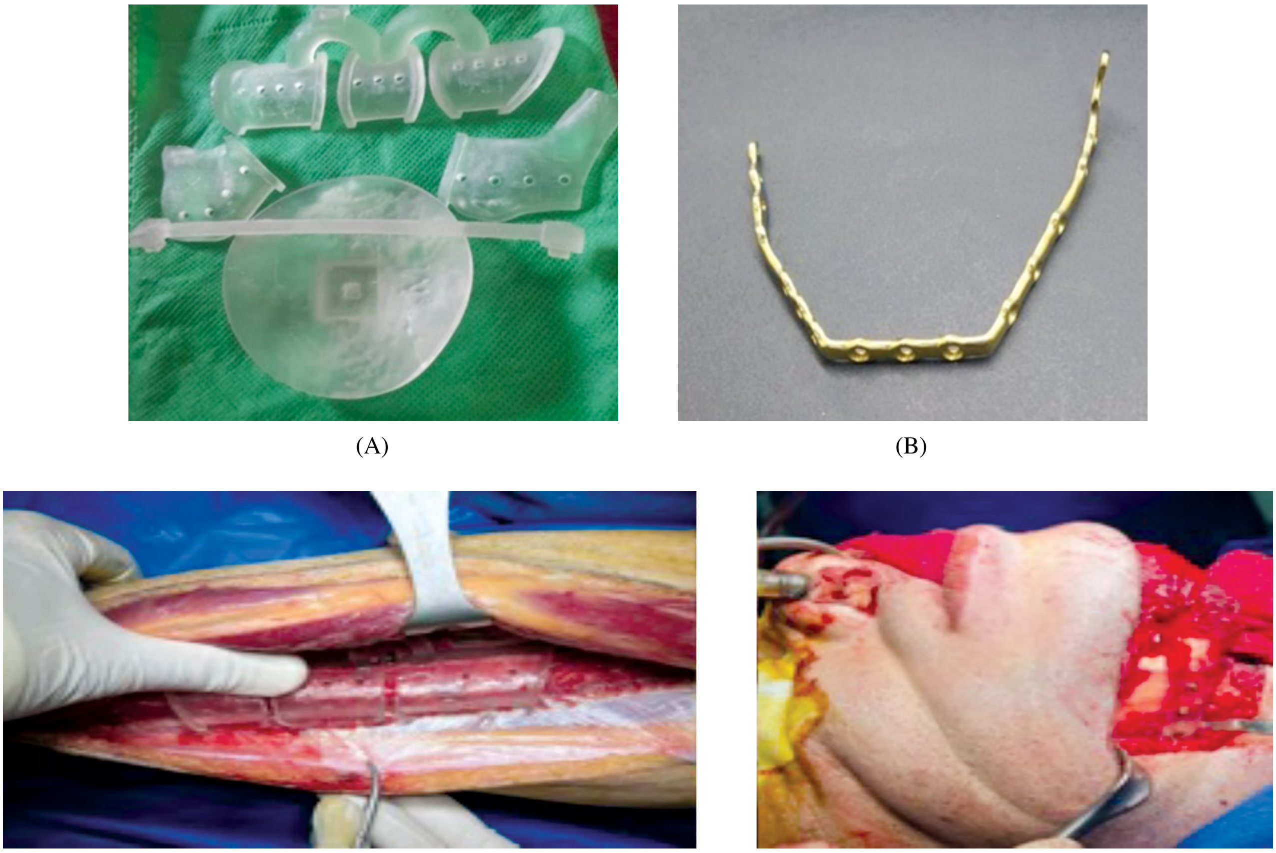
The following are the measurements used to assess the accuracy of the reconstruction (Fig. 3):

i- *Intercondylar distance:* Distance deviation of condylar heads. The intercondylar line is drawn by connecting the most upper points of the both condylar heads. The distance deviation is defined as the difference in length of the preoperative and postoperative intercondylar lines.

ii- *Intergonial distance:* The intergonial line is created by connecting the most posterior inferior points of the both angles of the mandible. The distance deviation is defined as the difference in length of the pre-and postoperative intergonial lines.

iii- *Anteroposterior distance:* Distance of the perpendicular section measured between the symphysis and the intercondylar line.

iv- *Gonial angle:* Measured as the angle formed by the base of the mandible and posterior border of ramus.



(A) (B) (C) (D)

Fig. (1): (A): 3D models used (Fibula cutting guide, mandible cutting guides, malleolus cap) (B): Pre-bent patient specific plate (C): Fibula cutting guide inserted intra-operative, (D): Mandible cutting guide inserted intra-operative.

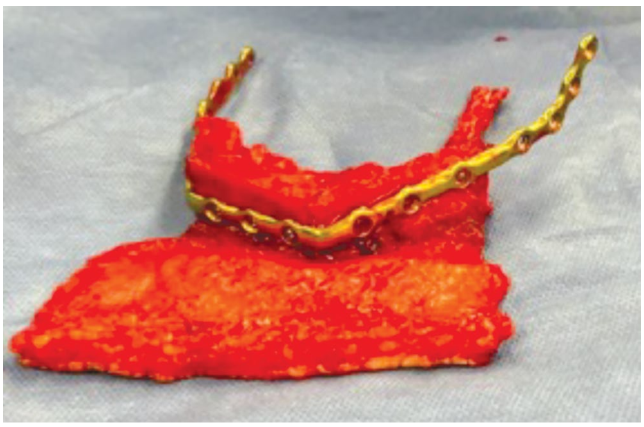


Fig. (2): The patient specific pre-bent plate overlying the segmented bone from the free fibula after the harvesting of the flap, ready to be inserted over the mandible.

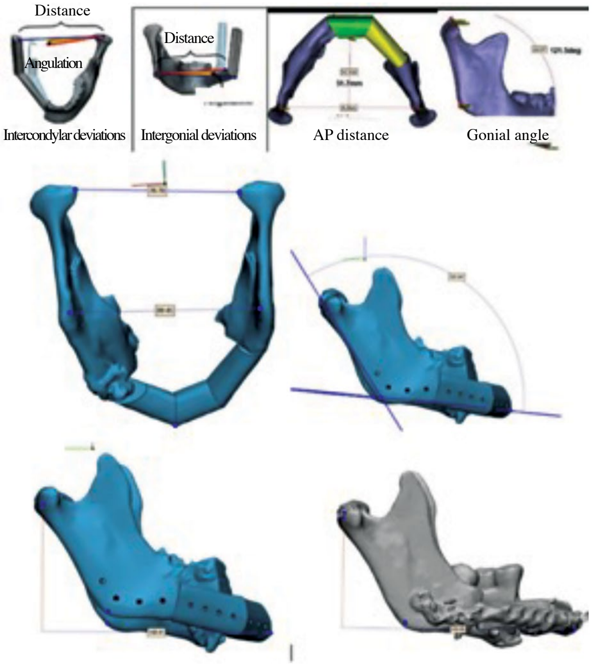


Fig. (3): Radiological measurements of accuracy of reconstruction.

Results

This clinical trial involved 10 patients, 5 patients in group A in which 3D models were used for reconstruction (Figs. 4,5) and 5 patients in group B were collected retrospectively, operated by the same surgeon from the same institution where no 3D models were used, only done by free hand.

Average ages of the cases were 41.1 in group A (with range of ages from 19 to 73) while average in group B was 43.6 (with range of ages from 25 to 68). Diagnoses included ameloblastoma (50% of the cases), post gunshot injuries (20% of the cases), osteosarcoma (10% of the cases). Ameloblastoma was the most common cause for reconstruction. (Table 1).

All the flaps survived in both groups. Infection occurred in 2 cases from group A and 1 case from group B (40% and 20% respectively). Severe edema occurred in 1 out of the 10 patients from group A, requiring tracheostomy. No cases of hematoma. 2 out the 10 cases had limitation in mouth opening (20%), one from group A and the other from group B. (Table 2).

Regarding the outcomes of the 2 groups, average operative timing in group A 465.2 minutes was while the average timing in group B was 517 minutes. (Table 4).

Regarding the operative timing, the average of group A was 51.8 minutes less than group B. Comparing the average scores of both groups, with 95% confidence interval, there was not statistical significance between both groups. Coming up to the radiological measurements, there was not significant difference in any of the measurements of both groups.

Comparing the mean difference of the accuracy measurements (Intercondylar distance, intergonial distance, gonial angle and AP distance), there was no statistically significant difference between both groups by calculating the *t*-value as seen in (Table 3).

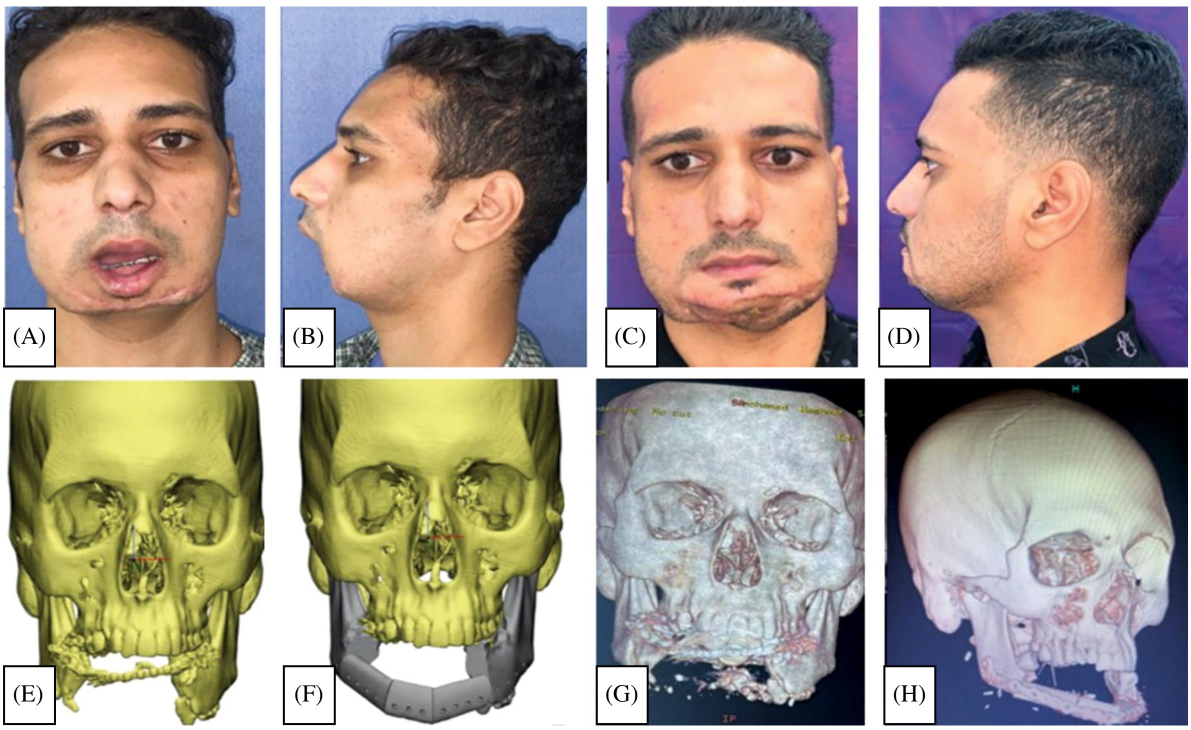


Fig. (4): Case (1): (A and B): Pre-operative photos. (C,D): Post-operative photos after 6 months from the reconstruction. (E,F): Pre-operative virtual surgical planning, (G): Pre-operative CT of the patient. (H): Post operative CT of the case.

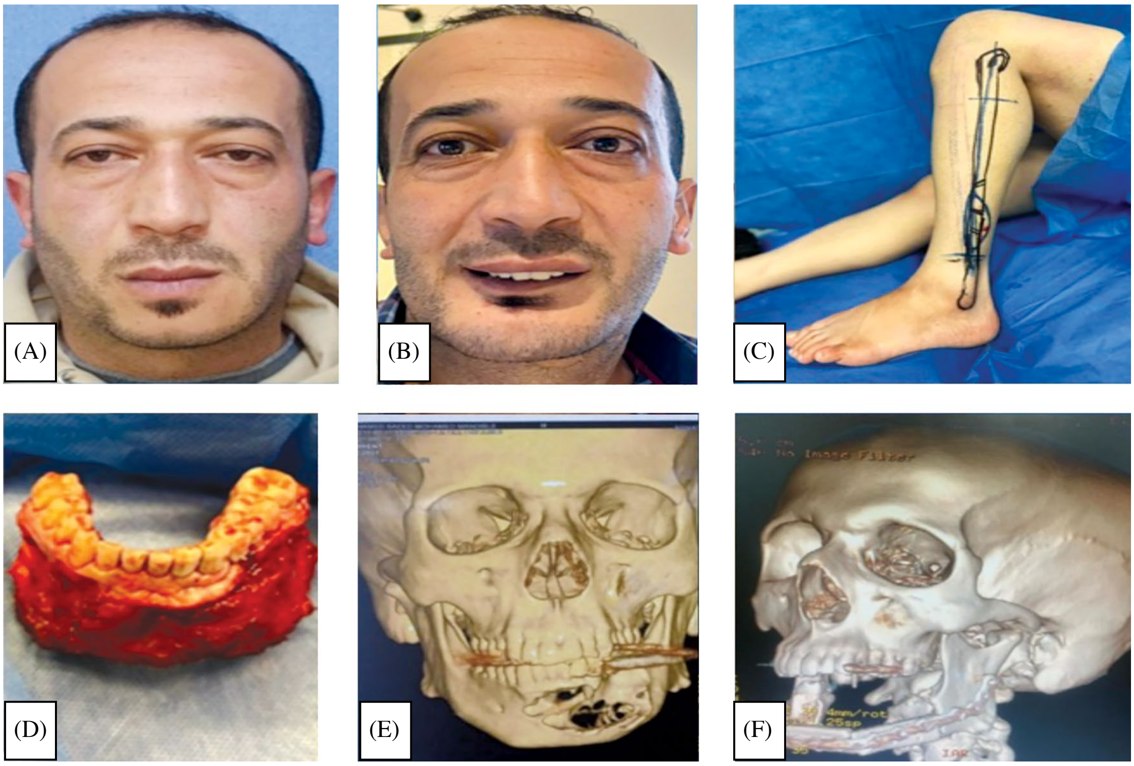


Fig. (5): Case (2): (A): Pre-operative photos of the case, (B): Post-operative photo of the patient 6 months post operative, (C): Intraoperative planning of the flap, (D): Post excision of the ameloblastoma, (E): Pre-operative CT of the patient showing infiltration of the mandible by ameloblastoma (F): Post operative CT

Table (1): Demographics of group (A) and (B).

	Group A					Group B				
	Case 1	Case 2	Case 3	Case 4	Case 5	Case 1	Case 2	Case 3	Case 4	Case 5
Sex	Male	Male	Male	Male	Female	Male	Male	Male	Male	Female
Age	31 years	49 years old	68 years old	25 years old	45 years old	31 years old	49 years old	68 years old	25 years old	45 years old
Site of the defect	Anterior mandible (LC)	Left body of mandible (L)	Left body of mandible (L)	Anterior mandible (LC)	Anterior mandible (LCL)	Anterior mandible (LC)	Left body of mandible (L)	Left body of mandible (L)	Anterior mandible (LC)	Anterior mandible (LCL)
Medically	Free	Free	Hypertension	Free	Hypertension	Free	Free	Hypertension	Free	Hypertension
Indication	Post gunshot	Post osteosarcoma	Post amelobastoma	Post gunshot	Post ameolastoma	Post gunshot	Post osteosarcoma	Post ameloblastoma	Post gunshot	Post ameloblastoma

Table (2): Complications of group (A) and (B).

	Group A					Group B				
	Case 1	Case 2	Case 3	Case 4	Case 5	Case 1	Case 2	Case 3	Case 4	Case 5
Vascularity of the flap	Intact	Intact	Intact	Intact	Intact	Intact	Intact	Intact	Intact	Intact
Edema	Severe	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
Hematoma	No	No	No	No	No	No	No	No	No	No
Infection	Yes	Yes	No	No	No	No	No	No	No	No
Limitation of mouth opening	Yes (opening at 2 fingers)	No	No	No	No	No	No	Fracture	No	No
Chewing function	All pending orthodontic intervention									

Table (3): The mean difference of each of the measurements and standard deviation in groups (A) and (B).

	Group A		Group B	
	Mean difference, mm	SD	Mean difference	SD
Intercondylar distance	–1.65	7.7	–0.86	2.9
Intergonital distance	0.63	3.2	0.40	1.6
AP distance	3.27	1.99	3.65	1.3
Gonial angle	–2.80	5.3	–2.74	2.02

Table (4): Comparative outcome of both group (A) and (B).

	Group A	Group B
Operative timing	465.2 min	517 min
Cost effectiveness	5000-15000 Egyptian pounds (excluding the expenses of the pre-operative CT)	0 (excluding expenses of the pre-operative CT)
Accuracy and symmetry:		
- Mean difference of intercondylar distance	–1.65	–0.86
- Mean difference of intergonial distance	0.63	0.40
- Mean difference of AP distance	3.27	3.65
- Mean difference of gonial distance	–2.8	–2.74

Discussion

Vascularized bone flaps are now considered the gold standard for reconstructing the mandible. because of its thickness, length, and bone homogeneity, which makes it a suitable support for the alveolar ridge and an ideal base for implants. The biggest obstacle still standing, though, is figuring out how to precisely form vascularized bone flaps to restore facial function and symmetry while also cutting down on the amount of time needed for such sophisticated surgery. Traditional methods lack efficient quantitative strategies and rely on the skill of the surgeons. In recent years, virtual surgical planning has transformed the practice of bone reconstruction **[8]**.

However, Comparison of accuracy results among studies is challenging due heterogenous patient populations, lack of uniformity in mandibular defect classification and varying methods of accuracy analysis as mentioned by Annino et al., in (2021) especially in our study as our sample size was small for concluding any patterns.

From our experience, the use of VSP in lateral defects of the mandible is less important. The mandible is straight laterally with no curvature making the reconstruction easier. In case 3 (Fig. 6), our plan was modified intra-operative and the 3D models were not used and free hand harvesting was decided to be a more suitable option at that time. This was confirmed by Superimposed pre-operative CT plan and post-operative CT as shown in (Fig. 7).

(A) (B) (C) (D)

Fig. (6): Case (3): (A): Pre-operative photo of the case, (B): Post-operative photo of the case, (C): Pre-operative CT showing a lateral mandibular defect, (D): Postoperative CT showing one bone segment of the fibula used to compensate the lateral defect without the need of the 3D models.

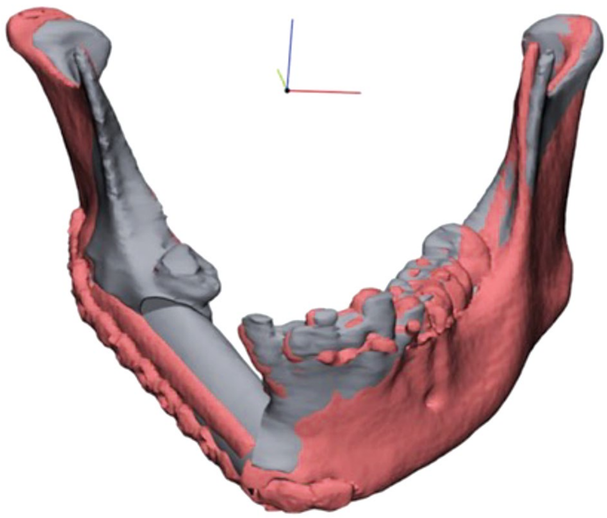


Fig. (7): Superimposed pre-operative CT plan and post-operative CT.

An important point is the progressive improvement in the learning curve and reduction in our operative timing since using the models needs experience. We assume that operating on a larger group of patients using VSP will lead to even shorter average intra-operative time.

Moreover, regarding the cost effectiveness, free hand is without a doubt a cheaper alternative to the VSP. Nevertheless, the real question is whether the VSP along with its post-operative results is worth the higher expenses?

In our study, "in house" printing of the models; the first that we are aware of to be done at any healthcare institution in Egypt, reduced around 5000 Egyptian Pounds from the overall expenses which represents around 30 to 40% of the total cost of the VSP. In addition, it is important to mention that the total amount for manufacturing the 3D models in Egypt is extremely economical (Around 310 USD $) compared to the cost abroad which have been reported at around $4000 as mentioned by Annino et al., 2021 **[9]**.

Going back to the question: "whether the VSP and 3D models along with the pots-operative results are worth the higher expenses?". From our experience, in lateral mandibular defects (not including the condyle or canine) VSP may even increase costs without significant benefits in functional outcome and aesthetics, so the site of the defect may actually help us deciding whether VSP is needed or not.

Regarding the limitations of VSP. In the experience of Succo et al. the common time for completion of the planning and modeling is 15 ± three days which is considered very long pre-operative preparation period when compared to the free hand method where nearly no pre-operative planning time is needed. From our experience in planning, typically it can be finished in around 4-6 days if "in house" printing was done and around 6 to 14 days if manufacturing from a company was used **[10]**.

As the pre-operative period is prolonged when using the VSP, multiple steps are needed for the completion of the reconstruction. Hence, mor variables or factors are going to affect the results of the reconstruction. First, the quality of CT images affects the accuracy of segmented 3D models, very thin CT cuts are needed for accurate 3D products (<1.25mm), even artifacts from metal oral prosthesis or simply from minor movements from the patient in the CT itself may negatively influence the quality of the CT. It is recommended that pre and post CT are done both by the same machine to reduce discrepancies and errors that may result from the CT cuts as recommended by Van Baar et al., in (2018) **[11]**.

Since most of the pre-operative preparation is done by the engineer, an expert is needed with excellent communication between both the engineer and the surgeon in order to achieve an optimum planning for the patient. Communication between both plays an extremely important role in the end results of the patients.

Moreover, using the 3D models needs practice even when it comes to an experienced surgeon in doing the free vascularized fibula as using the models and applying them without wasting any precious intraoperative timing is needed to augment the importance and role of the models **[12]**.

Finally, despite the increasing reports for the role of 3D osseous reconstruction, the literature is still extremely limited in reporting objective outcomes. In a recent systematic review by Rodby et al., in (2014), it was found that quantitative or objective results using survey data or preoperative/ postoperative CT scan comparisons were given for only 33% of the cases **[13,14,15]**.

Our study has provided data for quantitative results for both pre and post operative CTs for the cases adding valuable data to the literature when it comes to mandibular reconstruction by VSP. However, the sample size of 10 patients in both groups is a significant limitation in our study. We highly recommend larger sample sizes in future studies. Also, the heterogenicity in the etiology of mandibular defects in our series might have introduced some variability in outcomes. This might be avoided in future studies by unifying the cause of the defects if possible.

Conclusion:

The application of 3D printing technology in mandibular reconstruction with Free Vascularized Fibula is an invaluable tool that may help in improving the results and outcomes of the patients. It helps in reducing the operative timing, without increasing the complication rate.

We recommend using the VSP for mandibular reconstruction in anterior mandible defects and not the lateral defects where extra costs maybe added without a recognizable benefit.

Acknowledgement:

The authors have not received any funding or grants in support of this research and have no declarations to announce.

Statistical methods:

The collected data were analyzed using IBM SPSS statistics (Statistical Package for Social Sciences) software version 28.0, IBM Corp., Chicago, USA, 2021. Quantitative data described as Mean ± SD (standard deviation), and then compared using independent *t*-test. The level of significance was taken at *p*-value ≤0.050 was significant, otherwise was non-significant.

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