A Novel "Surgeon-Dominated" Approach of Designing 3D-Printed Patient-Specific Surgical Plates in Mandibular Reconstruction: A Proof-Of-Concept Study

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Conflict of Interest

The study was supported by Health and Medical Research Fund (Project no.: 05161626), Food and Health Bureau, Hong Kong.

Xian-shuai Chen and Chun-yu Zhang work in Guangzhou Janus Biotechnology Co., Ltd., where the 3D-printed plates were fabricated.

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Keywords:

Mandibular reconstruction; software workflow; patient-specific surgical plate; surgeon-dominated; head and neck reconstruction; virtual surgery; computer-assisted surgery; titanium; fibula; bone plates; three-dimensional printing; 3d print

Abstract

Three-dimensional/3D-printed patient-specific surgical plates have been proposed to facilitate mandibular reconstruction and are attracting extensive attention. We have recently reported the high accuracy of using 3D-printed patient-specific surgical plates in head and neck reconstruction. Based on that, we proposed a novel “surgeon-dominated” approach of designing 3D-printed patient-specific surgical plates. Therefore, this proof-of-concept study aimed to explore the workflow and technical procedures of the “surgeon-dominated” approach. Our workflow included the virtual surgery, design and printing of patient-specific surgical devices, and real surgery. The prototype of the patient-specific surgical plate was designed by the surgeon and further optimized for 3D-printing by the engineer. Different types of mandibular defects were demonstrated to confirm the wide applicability of this approach. We reviewed the cases using this approach and studied the duration of time spent on each case. Based on a total of 16 patients, the time spent on virtual surgery and plate designing was 18.83±13.19 hours, and the time taken by 3D printing, post-processing, and product delivery was 162.9±55.15 hours. Therefore, this novel “surgeon-dominated” approach is feasible and time-saving, which would likely promote the wide application of patient-specific surgical plates and lead to a new era of “digitalization and precision” in mandibular reconstruction. ClinicalTrials.gov registration No.: NCT03057223.

Introduction

Surgical reconstruction of mandibular defects remains a challenging issue for surgeons. Currently, the vascularized autologous bone flaps are most commonly used to repair mandibular defects due to neoplasm, trauma, or inflammatory diseases to fully restore the aesthetics and functions.(1) Optimal mandibular reconstruction necessitates the arrangement and fixation of bone grafts using surgical plates.(2) However, the conventional commercial surgical plates are manufactured in large-scale with general design specifications, which should be manually bent and twisted to match the anatomical contour of mandible.(2, 3) The plate contouring procedures are technique-demanding and time-consuming. Even for the experienced surgeons, it is not always easy to achieve a complete bone-plate congruence.(3, 4)

To prevent the drawbacks of conventional surgical plates, the advanced metal three-dimensional (3D) printing technology has promoted the development of patient-specific surgical plates in recent years.(5, 6) The 3D-printed surgical plates are customized in 3D architecture based on patient’s CT data, which precisely match the reconstructed bone contour.(5) Owing to the overwhelming advantages of individualization, the 3D-printed surgical plates have been proposed to facilitate surgical operation, improve efficiency and accuracy of mandibular reconstruction.(5) Meanwhile, the benefits of patient-specific surgical plates have been initializing and promoting the growth of relevant medical device industries.(7) A couple of companies have started to provide commercial service for designing and manufacturing 3D-printed patient-specific surgical plates around the world.

However, the major limitation restricting the application of patient-specific surgical plates is likely due to the inefficiency of mainstream production processes. At present, patient-specific surgical plates are designed by engineers hired by medical device companies as per surgeon's requirements.(6, 8) Whereas, it is difficult to convey the customized design specifications (e.g. shape, profile, span length, anatomical position, screw hole position and angulation) according to tumor locations and anatomical landmarks between surgeons and engineers. Thus, multiple video teleconferences are necessitated.(9, 10) In some complicated cases, such as reconstruction of zygomaticomaxillary composite tissue defects or simultaneous dental implantation with free flap, the communication through video teleconferences between surgeons and engineers may become extremely difficult, if not impossible. As a result, this current "engineer-dominated" approach has partially led to the expensive cost and a long processing cycle, which is not suitable for the vast majority of malignant cases.(6, 9)

To overcome the current barriers, we herein proposed an alternative approach, that is, the "surgeon-dominated" designing of 3D-printed patient-specific surgical plates. In this approach, surgeons performed the virtual surgery and designed the prototypes of surgical plates, which were transferred to engineers for structural optimization to enhance the in vivo product performance. The primary purpose of this proof-of-concept study was to explore the workflow and the technical procedures of the "surgeon-dominated" designing of patient-specific surgical plates. We focused on the fabrication of patient-specific reconstruction plates for different types of mandibular defects after oncological resection, and discussed the inherent pros and cons of this approach. Meanwhile, we investigated the duration of time spent on the designing and 3D printing of patient-specific surgical plates based on our cases. The enclosed approach was intended to ultimately promote the application of 3D-printed patient-specific surgical plates in reconstructive surgery.

Methods

A standard skull model was taken to demonstrate the workflow of using 3D-printed patient-specific surgical plates for the fibula-based mandibular reconstruction. The complete procedures included the virtual surgery, designing of patient-specific surgical plate and cutting guides, 3D printing and surgery. We also reviewed the clinical cases underwent this approach in our unit and studied the duration of time spent on each case. The study protocol has been registered in ClinicalTrials.gov with a No. of NCT03057223. Ethical approval has been granted and patients' informed consents have been obtained.

Virtual Surgery

The patient's skull model was virtually reconstructed from CT data prior to surgical manipulation. In clinical practice, initially the patient's head and neck was scanned using spiral CT with a slice thickness less than 1.0mm, or high-resolution cone-beam CT (CBCT). The donor site was scanned in the meanwhile to retrieve information of bone grafts. Herein we took the fibula for demonstration purpose. **(Figure 1)** CT data could then be transported in DICOM format and read in Materialise Proplan CMF 3.0 (Materialise, Leuven, Belgium).(11) The Proplan CMF 3.0 software supported interactive surgery simulation, which was developed specifically for surgeons.(11) The mandible and fibula were separately segmented using the threshold segmentation method, which automatically differentiated the high-density bone tissues from adjacent low-density soft tissues. The mandible and fibula were then virtually reconstructed in 3D models using the built-in commands automatically.

The mandibular lesion was clearly visualized and outlined in 2D and 3D images, **(Figure 1A)** which, with the information from clinical examination and MRI whenever necessary, facilitated to adequately locate the resection margins. **(Figure 1B)** After mandibular resection, the fibular bone flap was harvested in one or multiple segments which were orderly aligned to restore the mandibular contour. **(Figure 1C-E)** Similar to the freehand surgery, the contralateral fibular flap was used when the repair of intraoral soft tissue defect was indicated.(12) The lateral fibular bone surface should face outwards for plate fixation to not interrupt blood supply. The reconstructed mandible was superimposed onto the original, or the mirrored contralateral mandible, to fully recover the original mandibular contour through adjusting the position and orientation of each fibular segment. **(Figure 1F)** In the meanwhile, the fibular segments were rotated to ensure the ideal interrelationship with maxillary dentition. The bone segments were automatically trimmed to ensure the optimal bone-to-bone contacts. After virtual surgery, the virtually reconstructed mandible was exported to design the patient-specific surgical plate.

Designing of Patient-Specific Surgical Plates

The prototype of the patient-specific surgical plate was designed by a trained junior surgeon, under the supervision of the chief surgeon, which was carried out based on the virtually reconstructed mandible in Materialise 3-matic 13.0 (Materialise, Leuven, Belgium). **(Figure 2)**

The plate path was firstly delineated through drawing a smooth curve on the outer surface of the reconstructed mandible. **(Figure 2A)** Secondly, screw holes were placed along the curve discretely. **(Figure 2B)** At least three to four holes were placed on each mandibular stump. The exact specifications of the patient-specific surgical plates, such as plate width and thickness, were defined individually according to the patient's circumstance. Considering that there are no standards on the specifications of 3D-printed patient-specific surgical plates, the general principle was to design the surgical plate slender while preserving adequate mechanical strength. With the plate specifications defined, the patient-specific surgical plate was generated. **(Figure 2C)** Further modifications were made to countersink screw holes and smooth plate edges. The patient-specific surgical plate could fit the contour of the reconstructed mandible perfectly in this manner. Afterwards, the digital prototype of the surgical plate was transported to engineers in compatible format. Engineers could directly work on the prototype to optimize the product structure, especially to take structures at risk into account, and were responsible for the optimal in vivo performance of the 3D-printed patient-specific surgical plates.

3D Printing of Patient-Specific Surgical Plates

The patient-specific surgical plates were printed using commercially pure grade 2 titanium powder with the selective laser melting (SLM) technology in SLM®125 (SLM Solutions, Germany). **(Figure 3A)** The SLM used the high-energy laser to fully melt titanium powders into a solid entity with excellent surface quality and microstructure.(13) The digital surgical plate was exported in STL format and imported into the proprietary software for configuring processing parameters. The porous support structures were attached to the inner surface of surgical plate, **(Figure 3B)** followed by the component sliced in optimal distance and the build path determined in ideal orientation. From our experience, the SLM parameters were optimized with a laser power of 100W, laser scanning velocity of 275mm/s, hatch distance of 130μm, and layer thickness of 30μm. After 3D printing, the support was removed manually and surface was polished. **(Figure 3C-D)** The surgical plate were further treated to enhance the mechanical quality before thoroughly cleansed and sterilized for in vivo implantation, which were independently conducted and quality controlled by engineers.(14)

Designing and Printing of Patient-Specific Cutting Guides

In addition to the surgical plates, the patient-specific cutting guides were concurrently designed in Materialise 3-matic 13.0 (Materialise, Leuven, Belgium) in the routine manner by surgeons.(15-18) Briefly, cutting guides were generated by thickening the marked bone surface where the guides would be mounted on. Subsequently, the osteotomy planes and drilling holes were integrated for guiding the accurate osteotomies and screw hole drilling. The screw holes embedded in the cutting guides were in the same position and angulation as those in the patient-specific surgical plate, by which the cutting guides functioned to direct the accurate positioning of the surgical plate.(5, 6) The cutting guides were also transported in STL format for 3D printing. Cutting guides were printed in house (The University of Hong Kong) using the Fused Deposition Modeling (FDM) technology with ULTEM^{TM} 1010 or MED610 Resin (Stratasys Ltd., United States), which are ISO-certified biocompatible materials resistant to high-temperature autoclaving.(19) Alternatively, cutting guides could also be printed using pure grade 2 titanium.

Model Surgery

An in vitro model surgery was carried out to demonstrate the working principle of patient-specific surgical plates in mandibular reconstruction. **(Figure 4)** A mandible replicate was printed in resin (Somos Imaging 8000, DSM Engineering Plastics B.V., Netherlands). The mandible was precisely resected with the aid of patient-specific cutting guides. **(Figure 4A)** After the mandible was resected, the cutting guides were released while the drilled screw holes were left in situ for the accurate positioning of the patient-specific surgical plate. Simultaneously, the fibular bone graft was harvested, assisted by a cutting guide. **(Figure 4B)** The bone graft was folded in line with the patient-specific surgical plate and secured by registering the screw holes left in the fibular bone and those of the surgical plate. **(Figure 4C)** Afterwards, the fibula-plate complex was transferred in whole to the defect site.(5) **(Figure 4D)** The positioning of the fibula-plate complex was accurately directed by the pre-drilled screw holes in mandibular stumps.(5)

Time Spent on Designing the Patient-Specific Surgical Plates

We reviewed the patients underwent mandibular reconstruction using patient-specific surgical plates in the Queen Mary Hospital in Hong Kong.(5) The duration of time spent on designing and printing the patient-specific surgical plates were studied. The time spent on designing was calculated as the duration of time in virtual surgical planning, designing the prototype of patient-specific surgical plates and cutting guides in Materialise 3-matic 13.0 (Materialise, Leuven, Belgium), which were conducted by surgeons. Meanwhile, the time spent on plate optimization, 3D printing and delivery was calculated as the interval between the time when the digital files were sent out to company by email and the time when the final products were received by surgeons.

Results

We successfully developed the workflow of the “surgeon-dominated” designing of patient-specific surgical plates in mandibular reconstruction and proved its feasibility. **(Figure 5A)** The workflow included the virtual surgery, designing of patient-specific surgical plates and matched cutting guides, plate optimization, 3D printing and real surgery. All virtual surgery and designing procedures were performed in house using the “surgeon-dominated” approach, and the digital files of surgical plates were further optimized by engineers and printed in company.

Technical procedures of designing and 3D printing of patient-specific surgical plates were presented step-by-step, which were also depicted graphically in **Figures 1-4**. Various software packages were employed sequentially to perform the virtual surgery, designing and 3D printing of patient-specific surgical plates. A standard mandible model was taken for demonstration. Virtual mandibular resection was done to create a Class I mandibular defect (according to Brown’s Classification),(1) and followed by the fibula-based reconstruction to repair the defect. **(Figure 1)** The reconstructed mandible was used to design and print the patient-specific surgical plate in individualized 3D architecture. **(Figure 2-3)** The patient-specific surgical plate adapted to the bone contour precisely and greatly facilitated the surgical procedures without the need of plate contouring. **(Figure 4)**

To fully simulate different clinical scenarios, the mandible model was utilized to create different types of mandibular defects, which further confirmed the wide applicability of patient-specific surgical plates in mandibular reconstruction. **(Supplementary Figure 1)** In the first scenario, a Class IIc mandibular defect was created with the left hemi-mandible from the condylar head to parasymphysis resected. **(Supplementary Figure 1A)** The fibular flap was adopted to restore the natural mandibular contour in three segments. The patient-specific surgical plate was designed in the same procedures with an overall length of 145mm. In the second scenario, the patient-specific surgical plate was designed for a Class IV mandibular defect spanning from mandibular angle to angle. **(Supplementary Figure 1B)** The fibular grafts were orderly arranged in six segments. The overall length of the surgical plate was 321.5mm.

We reviewed the cases underwent mandibular reconstruction using the patient-specific surgical plates in our unit. A total of 16 patients were included for investigating the time spent on designing and printing the patient-specific surgical plates. All surgical plates were fabricated using this “surgeon-dominated” approach. The duration of time spent on plate design, optimization, 3D print and delivery of each case were shown in **Figure 5B**. The time spent on virtual surgery and plate designing was 18.83±13.19 hours. The time taken for plate structural optimization, 3D printing, post-processing, and product delivery was 162.9±55.15 hours, ranging from about four to nine days. Henceforth, the “surgeon-dominated” approach was feasible and time-saving. A representative case of using the patient-specific surgical plate in mandibular reconstruction is shown (**Figure 6, Supplementary Figure 2)**. By superimposing the postoperative model to the virtual plan, the mean absolute distance deviation of integral mandible was 0.89±1.02 mm, indicating an optimal accuracy.

Discussion

Our study proved the “surgeon-dominated” approach for designing 3D-printed patient-specific surgical plates is feasible and time-saving. The proposed workflow has potential to change the current commercial pattern to a more efficient way, which will eventually promote the popularity of 3D-printed patient-specific surgical plates.

In the past decade, the computer-assisted design (CAD) technology has been widely applied to ultimately revolutionize the mandibular reconstruction to a new era of precision surgery.(8, 20) The precision mandibular reconstruction transfers the preoperative simulation results to the real surgery by virtue of patient-specific devices, aiming to improve surgical precision, simplify procedures, increase maneuverability, and optimize surgical outcomes.(5, 6) Multiple types of surgical guides and models have been created to more efficiently and accurately perform bone resection, graft alignment and plate contouring.(20) Most recently, owing to the development of metal 3D printing technology, the patient-specific surgical plate has evolved to be the missing link connecting the preoperative virtual surgery and real surgery.(5, 6) The individualized 3D architecture of the patient-specific surgical plate could not only facilitate the accurate alignment of bone segments, but also register the correct position of screws to the predesigned screw holes, contributing to the enhanced functional and aesthetical outcomes.(5) Previous studies have indicated the superior properties of patient-specific surgical plates in mandibular reconstruction, which would certainly be promoted with the increasing availability of metal 3D printing technology in the near future.(5)

Unlike the large-scale manufacturing of conventional surgical plates, the 3D printing is more adept at fabricating products with mass customization.(7) Henceforth, the upstream design software is of vital importance in achieving design freedom and easy manipulation. Different software packages are routinely employed to deal with different procedures, which are mostly undertaken by specialized engineers who should stay in close contact with surgeons to address different clinical scenarios.(10) Multiple teleconferences and email communications are necessary to decide the surgery plan and plate parameters. The misunderstandings between engineers and surgeons are unavoidable, especially when different surgeons may prefer different reconstruction options, which may induce prolonged lead times and additional costs.(6) In the present study, we demonstrated a novel “surgeon-dominated” approach of designing and printing patient-specific surgical plates, by which surgeons could perform the virtual surgery and design the digital prototypes to convey the plate shape, span length and screw hole parameters. Afterwards, the digital prototypes could be directly modified and optimized by specialized engineers to improve structures in line with the fundamental biomechanical principles. Compared to the current commercial “engineer-dominated” approach which took a turnaround time of about four weeks,(6) this “surgeon-dominated” approach significantly increased the efficiency and reduced the processing time, which would hopefully extend the application of 3D-printed patient-specific surgical plates, especially in patients with malignant tumors.

As the simplified “surgeon-dominated” approach of plate designing and printing has been introduced in this study, we anticipated that this approach could also be utilized to develop a “surgeon-friendly” software to more efficiently design and optimize patient-specific surgical plates in the near future. Currently with the combination of Materialise Proplan and 3-matic software, the time spent for patient-specific plates designing by surgeons is still to some extent long, which restricts the popularity of this approach. Thus, a new “surgeon-friendly” software is warranted, which can empower the surgeon with a more convenient way for plate designing with limited training. Basically this “surgeon-friendly” software should be capable of working on patient’s CT data, designing and assessing patient-specific surgical plates in an intuitive manner, and most importantly, the software should be easy to manipulate by surgeons. For further refinement of the patient-specific surgical plates, the software should be able to integrate with other third-party software for improving the final design by engineers. For instance, for a newly-admitted patient, the surgeon comes up with a proper plan and then designs the patient-specific surgical plate based on his knowledge and experience. The surgeon’s design will be transferred to the company for printing. The specialized engineer would refine the parameters in accordance with the biomechanical principles to optimize the plate structure and facilitate the printing.(21) The surgical plate is then printed and processed by the engineer before delivered to the surgeon. Finally, with the aid of the patient-specific surgical plate, the surgery can be performed totally following the surgeon’s perception without violating the biomechanical principles. In the near future, with the utilization of the machine learning and artificial intelligence algorithm, new surgical planning software that can incorporate different imaging modalities need to be developed with automatic surgical planning function.(9, 22) This will hasten a paradigm shift in surgical planning by simplifying and accelerating the process.

Regarding the biomechanical properties, there are some unanswered questions in this field. First, there are certain differences in the biomechanical properties of 3D-printed patient-specific surgical plates compared to conventional plates.(21) Whether and how the SLM technology affects the metallography, mechanical properties and clinical performance should be thoroughly studied, whereas no answer is available yet for this brand new technology.(13, 23) Since no plate bending is required for the patient-specific surgical plates, the better fatigue properties and longer service life could be predicted.(2, 4) Meanwhile, for the individualized architecture of surgical plates, the Finite Element Analysis could be combined to evaluate and optimize load-bearing structures. The patient-specific surgical plates can be strengthened in some critical sites such as the mandibular angle and parasymphysis to prevent fatigue failures based on the FEA results.(21) In a word, with the high-tech CAD and 3D printing technologies, the patient-specific surgical plates are supposed to be fabricated in any optimized shapes and structures fulfilling biomechanical principles and meeting specific clinical demands.(10) Second, the post-processing could affect the mechanical properties of surgical plates like strength, fatigue, corrosion and surface topography.(24) The altered mechanics will subsequently influence the final device performance in vivo.(4) Since there is still no regulatory guidance on the post-processing of 3D-printed medical implants, it is important to conduct relevant studies to identify the potentially detrimental effects and therefore establish a standard post-processing algorithm which will improve efficiency and simultaneously ensure quality.(14, 24) Based on this proof-of-concept study, further studies are warranted to add our knowledge in this exciting and promising field.

Although we have put forward the “surgeon-dominated” approach of designing patient-specific surgical plates, it doesn’t mean that surgeons can independently produce 3D-printed surgical plates on their own without the participation of engineers. On the contrary, only by the good cooperation and instant feedbacks from engineers, can the design be improved and the final products optimized.(21, 22) The major function of this “surgeon-dominated” approach is to accurately convey the surgeon’s perception, which would likely increase efficiency and reduce costs, while the design refinement and product quality should be well controlled by engineers.

In conclusion, we proposed a “surgeon-dominated” approach for designing 3D-printed patient-specific surgical plates, which significantly increased the efficiency compared to the current “engineer-dominated” approach adopted by medical device suppliers. It is anticipated that this “surgeon-dominated” approach will lead to the popularity of 3D-printed patient-specific surgical plates. Further researches on the development of a “surgeon-friendly” software preferably with an artificial intelligence algorithm, optimization of biomechanical properties and post-processing of 3D-printed surgical plates will help standardize this fast-developing technology, eventually leading to a new era of “digitalization and precision” in mandibular reconstruction.

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Figure Legends

Figure 1. Preoperative virtual resection of right mandibular lesions, followed by reconstruction with the vascularized fibula flap.

Figure 2. An intuitive "surgeon-dominated" method in designing patient-specific surgical plates for mandibular reconstruction.

Figure 3. 3D printing of titanium surgical plates using the selective laser melting (SLM) technology by engineers.

Figure 4. The working principles of patient-specific surgical plates in mandibular reconstruction depicted by the model surgery.

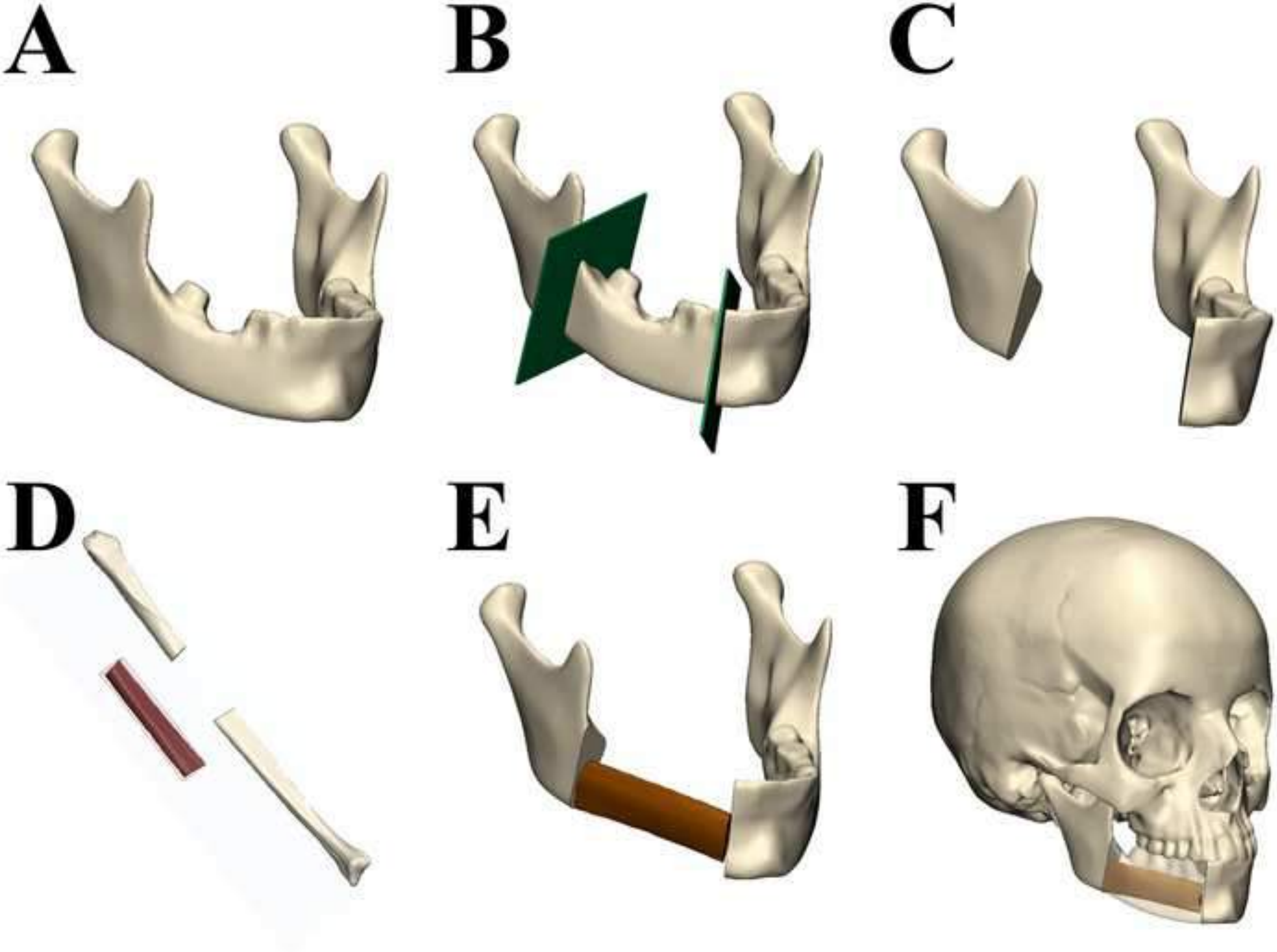
Figure 5. (A) The workflow of "surgeon-dominated" designing of patient-specific surgical plates in mandibular reconstruction. (B) Time spent on virtual surgery and plate designing, plate optimization, 3D printing, post-processing, and delivery of patient-specific surgical plates for mandibular reconstruction.

Figure 6. A fibula-based mandibular reconstruction using the patient-specific surgical plate.

Supplementary Figure 1. Patient-specific surgical plates in different mandibular defects using the “surgeon-dominated” method.

Supplementary Figure 2. The postoperative panoramic image indicated the optimal reconstruction outcome.

Figure1



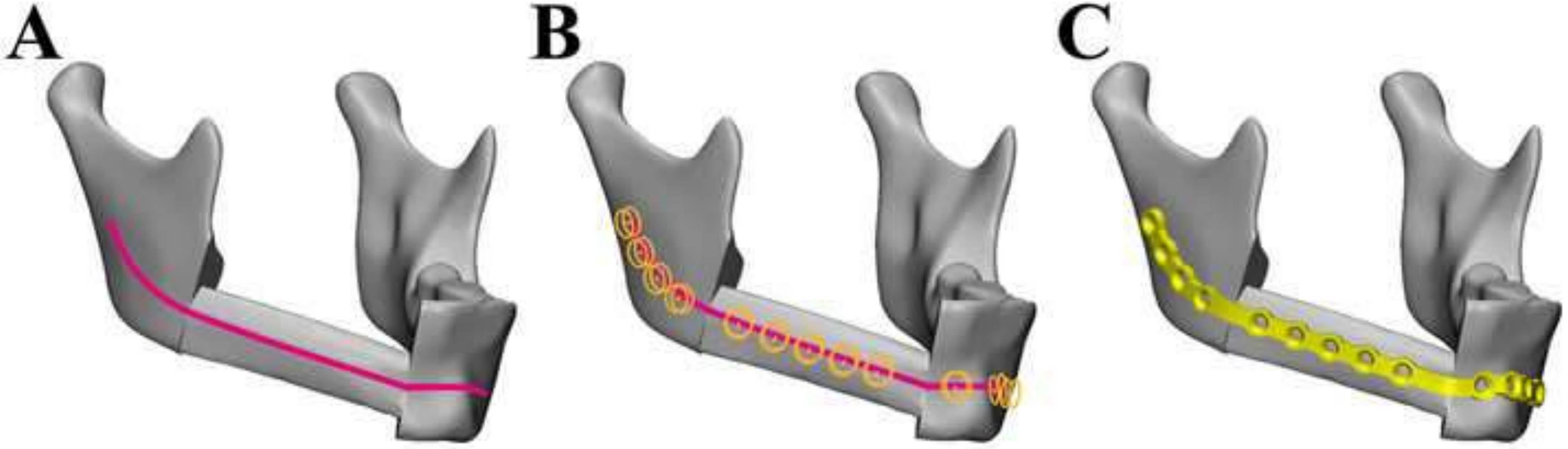

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Figure3

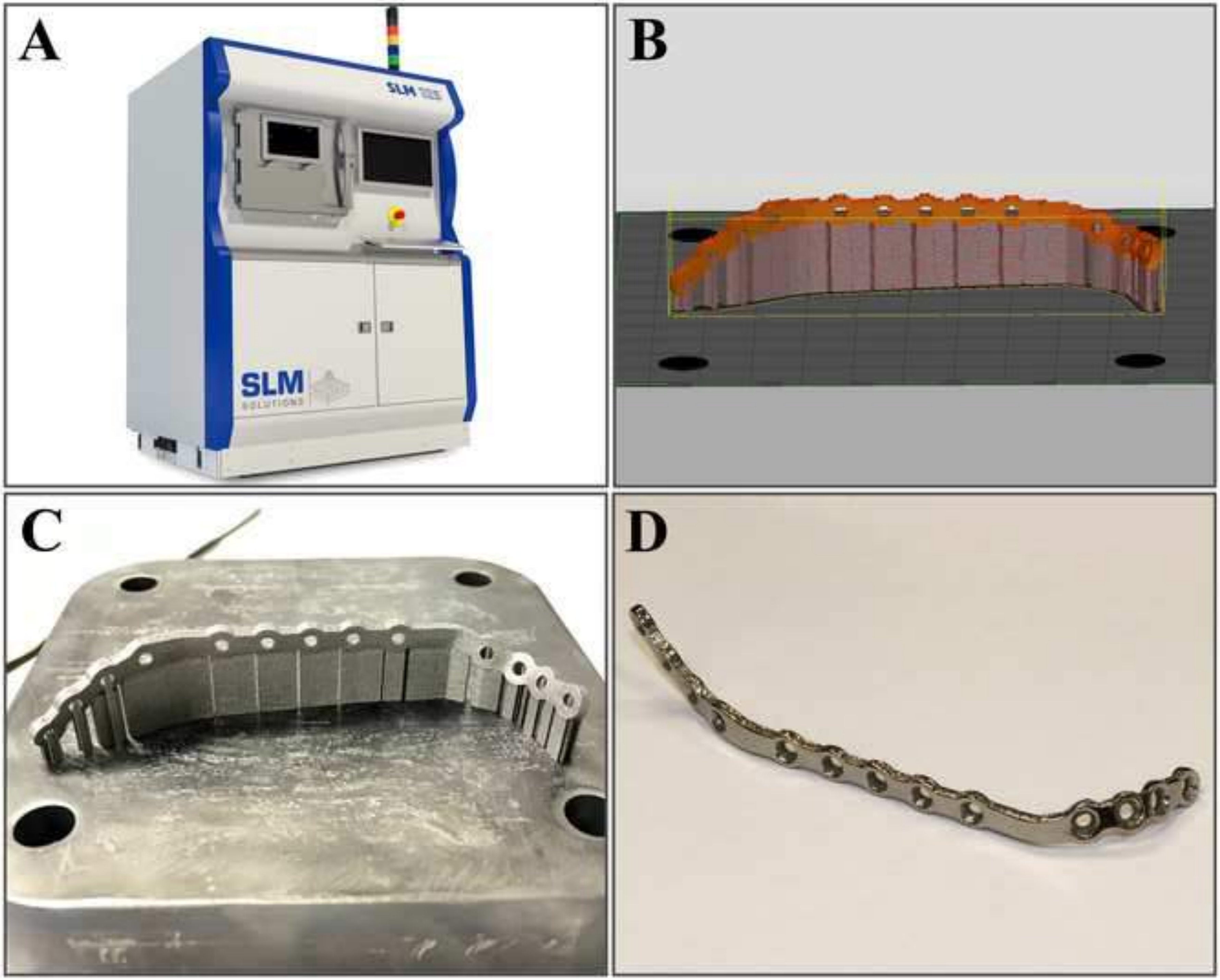


Figure4

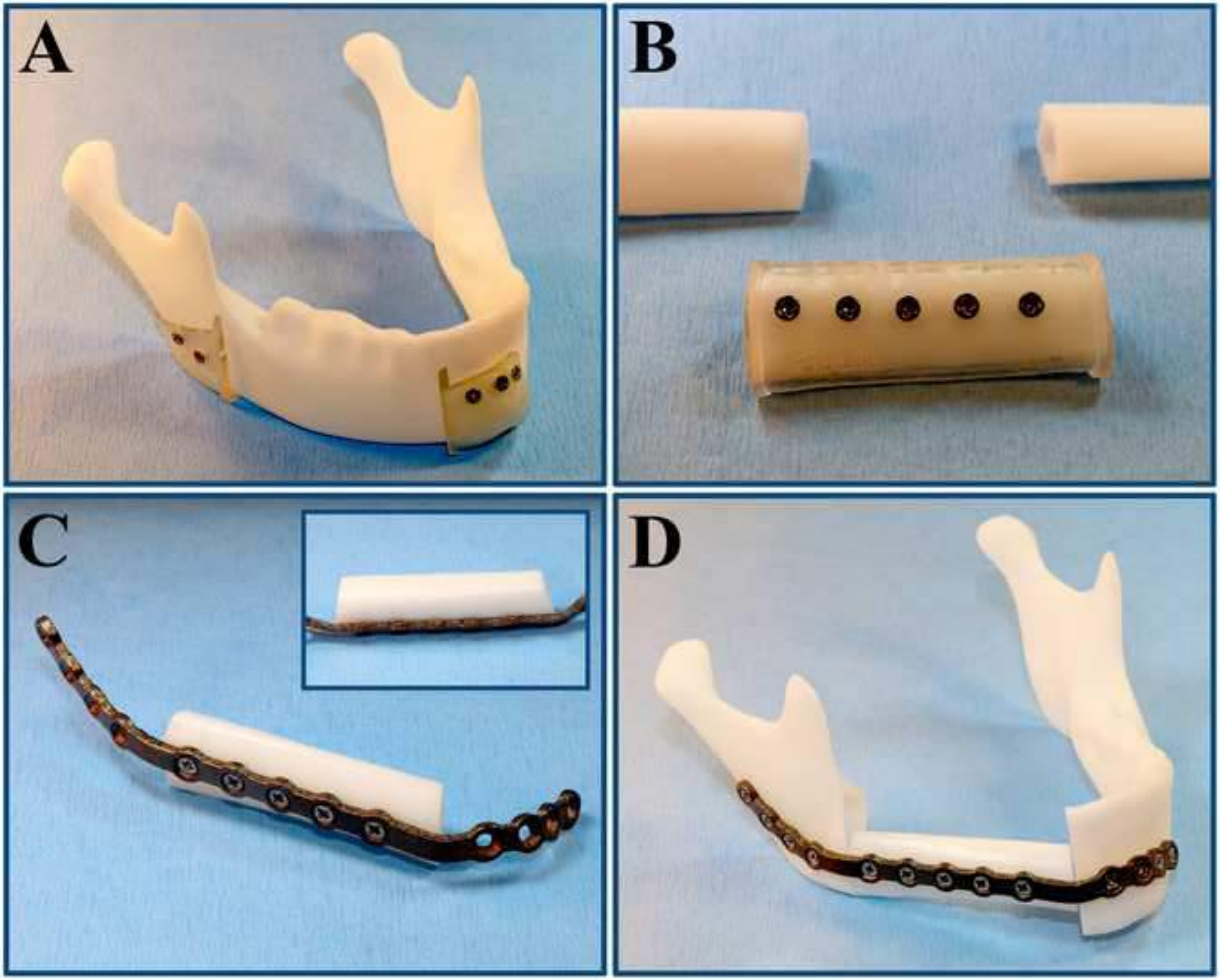
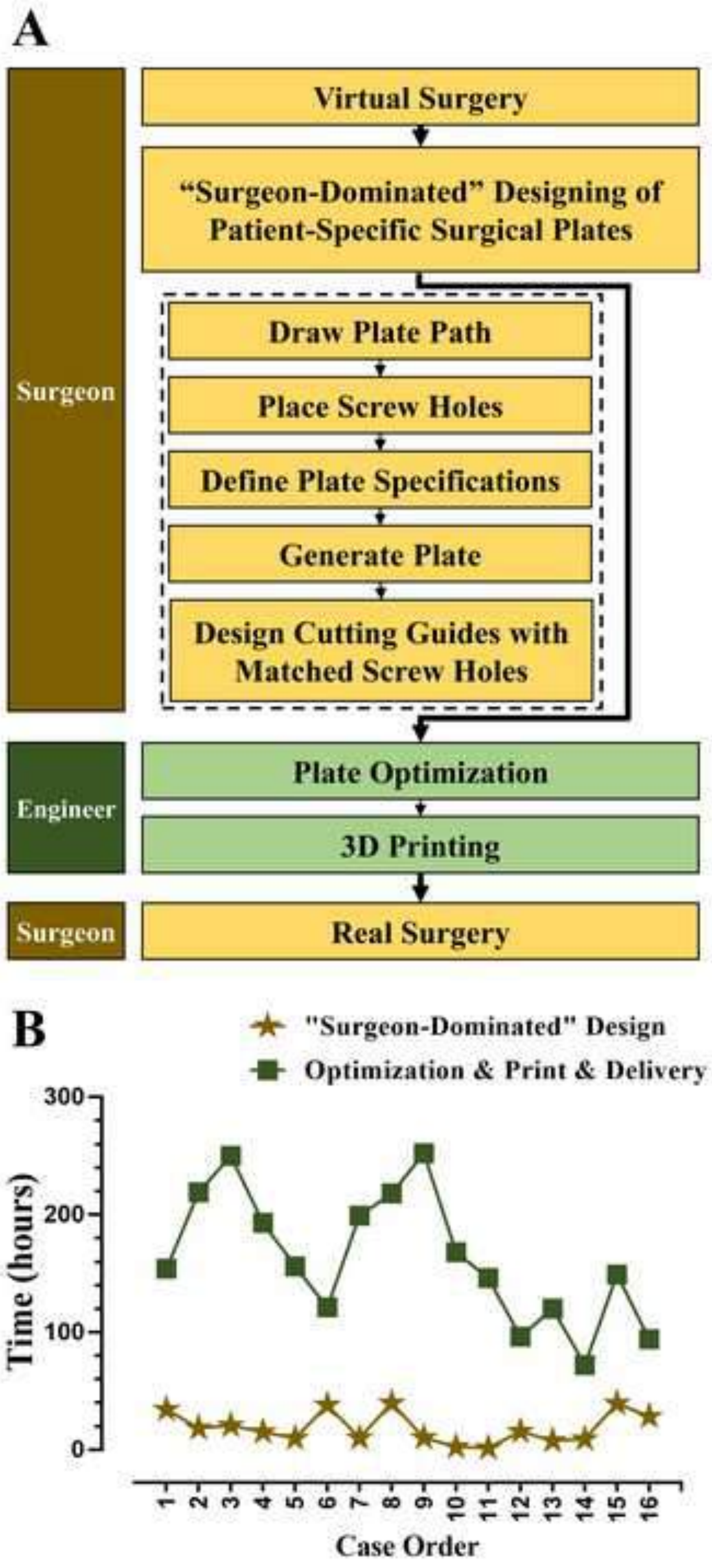


Figure5


A
Surgeon
Virtual Surgery
"Surgeon-Dominated" Designing of Patient-Specific Surgical Plates
Draw Plate Path
Place Screw Holes
Define Plate Specifications
Generate Plate
Design Cutting Guides with Matched Screw Holes
Engineer
Plate Optimization
3D Printing
Surgeon
Real Surgery
B
"Surgeon-Dominated" Design
Optimization & Print & Delivery
Time (hours)
300
200
100
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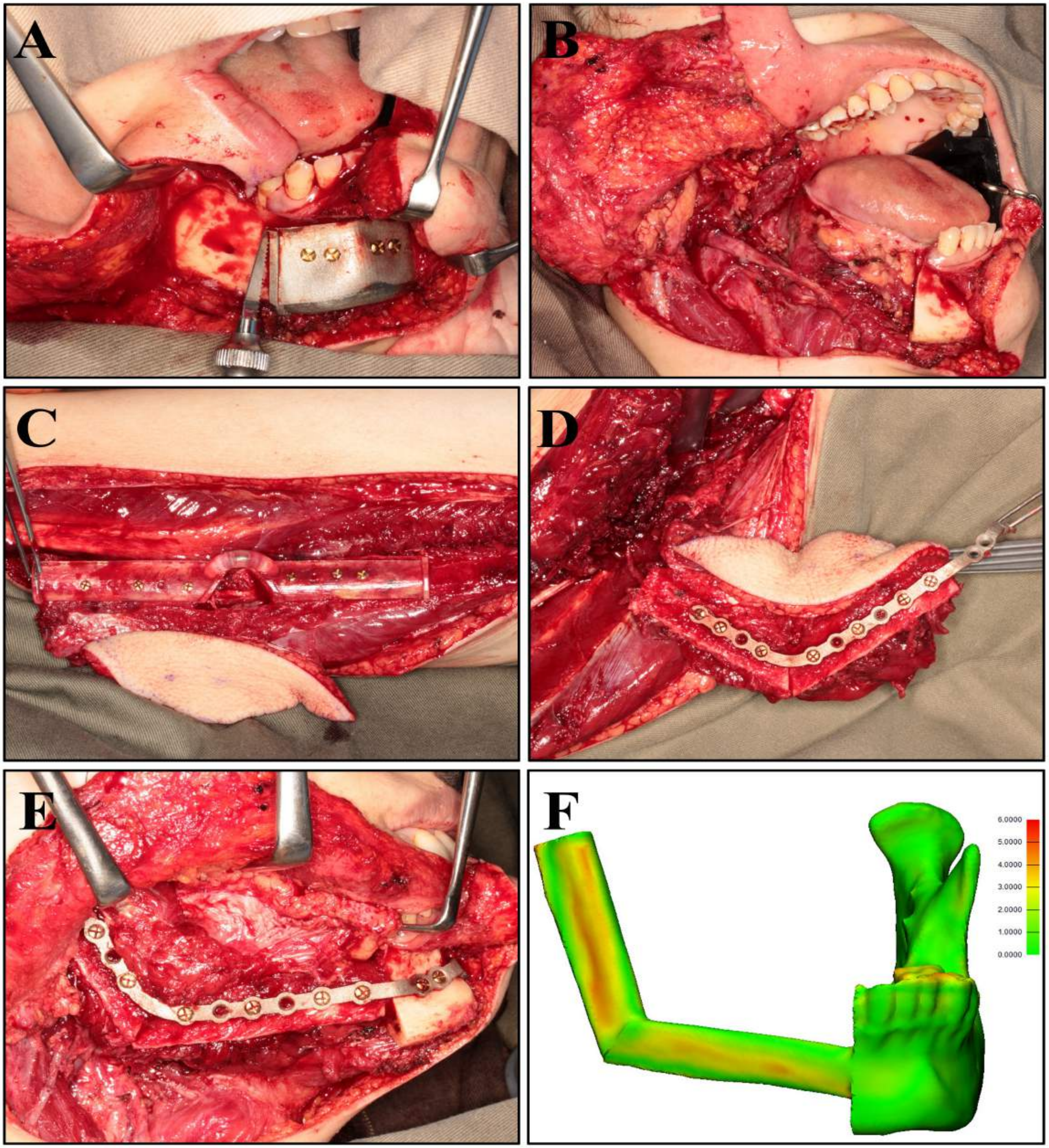
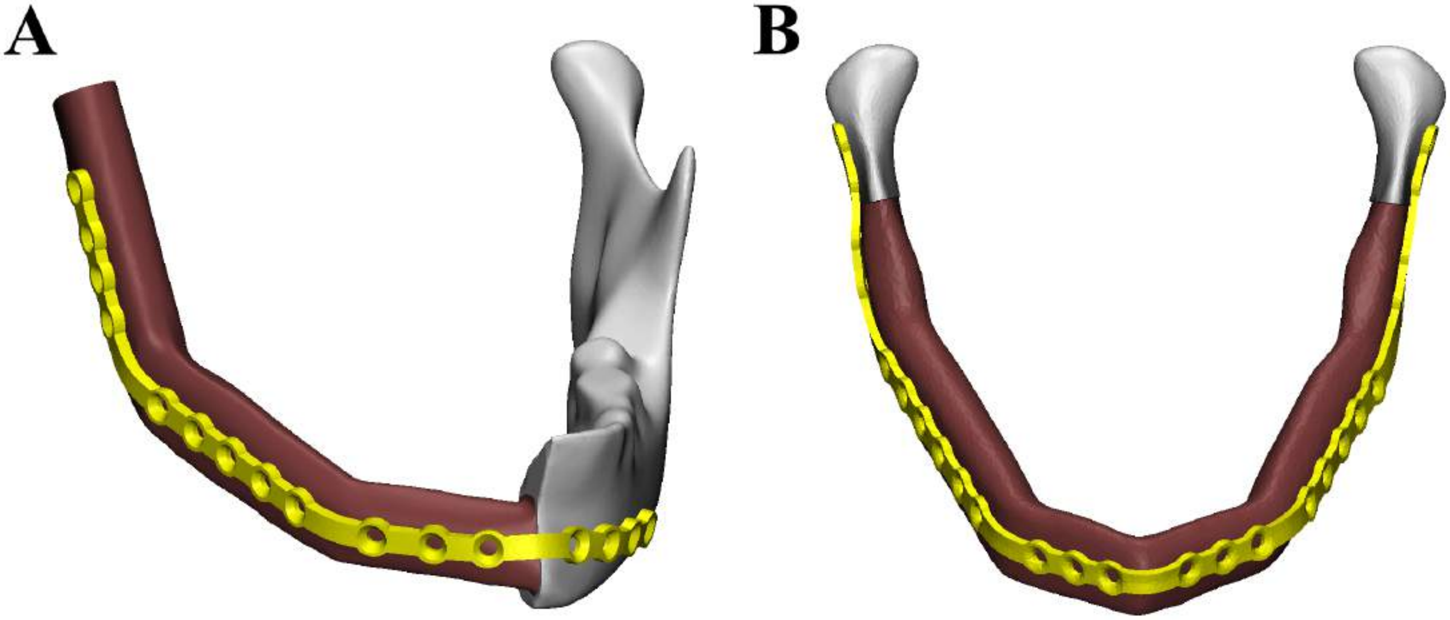
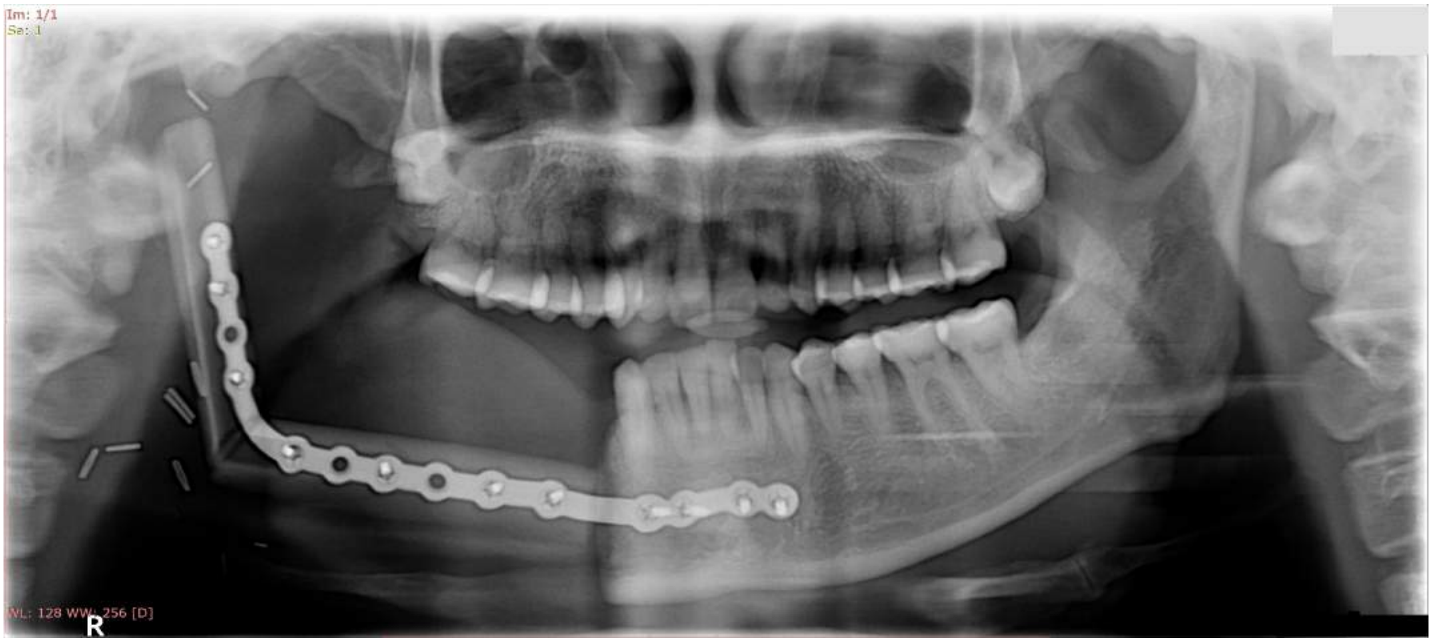
16
Case Order


A
B
C
D
E
F
6.0000
5.0000
4.0000
3.0000
2.0000
1.0000
0.0000


A
B


Im: 1/1
Se: 1
WL: 128 WW: 256 [D]
R