

PATIENT SPECIFIC FIXATION PLATES IN ZYGOMATICO-MAXILLARY COMPLEX FRACTURE MANAGEMENT. IS IT A PRACTICAL ALTERNATIVE?

Original Article

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ABSTRACT

Objective: The objective of this study was to evaluate the accuracy of custom-made fixation plates in the management of zygomatico-maxillary complex fracture and outline the processing time required for their fabrication.

Materials and methods: The study is a single arm non-comparative clinical trial study was designed to assess the clinical performance of custom made mini-plates in the management of zygomatico-maxillary complex fractures. The study was conducted on 12 patients with unilateral displaced zygomatico-maxillary fracture that needed surgical intervention. All of the enrolled patients were radiographically examined using Multi slice-Computed Tomography (MSCT) Scan for proper diagnosis and preoperative virtual planning.

Results: Twelve patients were included in this study, Regarding the clinical follow-up parameters, all the patients reported a statistically significant decrease in the reported postoperative pain across the follow-up evaluation period ($p < 0.01$), regarding the infra-orbital nerve function and midface cheek sensation, only 3 patients reported an aberrant sensation at the first follow-up interval. By the end of the follow up period, all the enlisted patients reported a normal cheek sensation. Regarding the postoperative ocular complications, only one patient which reported an early ectropion in the lower eyelid. All patients reported resolution of the edema at the end of the clinical follow up period. In the postoperative Multi Slice-Computed Tomography (MSCT), accurate bone reduction was observed in all the cases.

Conclusion: The utilization of computer-aided surgery and rapid prototyping technologies in modern times has rendered them a viable choice with minimal drawbacks for managing zygomaticomaxillary complicated fractures. The patient-specific fixation implants that were virtually created showed positive processing, clinical, and radiographic performances with a respectable level of precision.

Key Words: zygomatico-maxillary complex, patient specific, fracture .

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INTRODUCTION:

The anatomical and functional interdependence, along with the common articulation of both the maxilla and the zygomatic bones made them vulnerable to similar traumatic events. In the cranio-maxillofacial trauma management they, along with the orbital skeleton, are considered a single entity in terms of management and complications. Hence the term Zygomatico-Maxillary-Complex (ZMC) gained its popularity in the literature ^[1,2].

Commonly known as tripod fractures, ZMC fractures are one of the most encountered fractures in the maxillofacial field owing to its prominent position. The multiple articulations and the multi-planner structure of the ZMC make its reduction a perilous procedure ^[3]. The ZMC contains a series of thick cortical buttresses system in a vertical and horizontal pillars configuration. These pillars not only provide protection from external assault, but they

also have a fundamental influence on facial projection and width ^[4,5].

The most commonly utilized approach for the management of ZMC fracture is the open reduction with fixation of the main articulations of the zygoma along with the infraorbital rim ^[6]. Despite that, Farber et al demonstrated that the significant variability in ZMC fracture category necessitates a tailored approach to their management ^[7].

The recent evolution in the quality of the preoperative radiographic examination was the main locomotor that pulled the use of computer-assisted surgeries miles ahead. The use of virtual preoperative planning in the craniomaxillofacial field is well-established in various of its departments ^[8]. Along with its countless advantages, the use of computer-assisted surgeries gives the surgeon the opportunity to create an individualized fixation hardware for each patient. This patient-specific alternative gives the surgeon

a plethora of leverages in their work in the operation [9].

The customized plates save the surgeon the time required to shape the plates to the outline of the zygoma for proper fit to the unfractured stumps. Furthermore, the preoperative virtual reduction may aid in the proper final operative reduction based on the proper seating of the Patients Specific Fixation Plate (PSFP) [5,9-10].

The use of rapid prototyping technologies allowed the transformation of virtually created designs into an actual solid form using additive manufacturing three-dimensional printing of the medical grade titanium [11]. Medical grade titanium is one of the few materials that are biocompatible for human body implantation. It has mechanical properties similar to that of the human bone, with low density, elastic modulus and lightweight. That is why there is a clinical and academic consensus regarding the use of titanium in maxillofacial fractures and other fields [12].

Despite that, the use of PSFP comes with an increase in the processing time in order to design and manufacture the plate. This time may not be available in trauma patients, which gives a privilege for the use of the conventional stock plates by many surgeons [13,14].

While the use of stock titanium fixation plates is well proven, there is a sacrifice in the literature regarding the use of PSFP in ZMC fractures. Henceforth, the preoperative processing, the operative performance, and the postoperative clinical execution of the patient specific fixation plates in the management of ZMC fractures were evaluated in this study.

MATERIALS

A single arm non-comparative clinical trial study was designed to assess the clinical performance of custom made mini plates in the management of ZMC fractures. Sample size was based on 95% confidence level to detect the absolute mean linear deviation (mm) between actual postoperative and virtual pre-operative models. ElMahallawy et al. [10] reported the mean (SD) absolute linear deviation between actual and virtual models at three different positions with an average= 0.79 (0.57), and 95% confidence interval= 0.45, 1.23. The minimum required sample size was calculated to be 11 patients per group, increased to 12 to make-up for procedural problems. [16]

Cases were selected from the emergency department of the Alexandria university teaching hospital. The study was performed based on the guidelines for studies on human participants, according to the Helsinki Declaration. All participants signed an informed consent with their native language. A permission from the Scientific Research Ethics Committee, Faculty of Dentistry, Alexandria University was obtained on 19/02/2024, international no: IORG0008839, ethics committee no.: 0882-02/2024

The study was conducted on 12 patients with unilateral displaced zygomatico-maxillary fracture that needed surgical intervention with no gender predilection and with a minimal age requirement of 18 years. Patients with bilateral midface affection, old fractures, and medically affected individuals were omitted from being enrolled in this study. All the enrolled patients were radiographically examined using Multi Slice-Computed Tomography (MSCT) Scan for proper diagnosis and preoperative virtual planning.

Preoperative Virtual Planning and Plate Printing

DICOM data from the preoperative MSCT-scan were fed into a medical segmentation software (Materialise innovation suite, Leuven, Belgium) in order to automatically threshold the bone from the radiographic scan (Mimics, Materialise).

This step provided the preoperative 3D-bone model of the fracture. On a 3D-designing software (3Matic, Materialise) the preoperative bone model was fed, and a mirroring operation was performed to copy the outline of the healthy side onto the affected side. The mirrored new model was used to precisely reduce the fractured ZMC into their ideal position. The virtually reduced bone model was used for the design of the PSFP. The designed PSFP was outlined on the zygomatico-frontal, zygomatico-maxillary, and infraorbital rim according to each case. The thickness of the designed PSFP was fixed at 0.7 mm thickness, with a crew bore hole diameter of 1.5 mm which can hold a 2.0 mm mini screw. None of the created PSFP were designed in a connected manner and they were printed separately. Each PSFP was fed in a Standard Tessellation Language (STL) to a Direct Metal Laser Sintering (DMLS) additive manufacturing machine (ASTM F3001, AP&C, Quebec, QC, Canada) which is fed medical grade titanium powder (Ti-6Al-4 V). The plate was autoclaved regularly before the operation, and regular 2.0 mm mini screws were utilized for plate fixation. The processing time was evaluated for each case, from time of patient admission till plate production.

Surgical Procedure [3,5]

The patients were managed under general anesthesia with nasotracheal intubation. The fractured ZMC was exposed using lateral eyebrow, sub-tarsal, and vestibular intraoral incisions for each corresponding zygomatic process as they act as points of fixation. The fracture lines are cleaned from any entrapped tissue, and the displaced complex was reduced with a transcutaneous zygomatic hook. The preoperatively customized plates were secured in their preoperatively determined position using mini screws of 5-7 mm length (JEIL Medical Corporation Company: Seoul, Korea). The reduction and fixation time of each case was recorded. From the start of ZMC reduction, till plate fixation. Then the incised tissue was sutured. At the end of the fixation, a forced duction test was performed to ensure unobstructed globe movement.

· All patients were prescribed to postoperative antibiotics (Intravenous cefotaxime 1 gm/12 hours on the first day followed by amoxicillin + clavulanate (Augmentin: GlaxoSmithkline,UK.)1 gm twice daily for five days, analgesics (Diclofenace potassium 50 mg (Cataflam: Novartis-Switzerland.) for five days, and anti-edematous medications Alpha-chemo-trypsin ampules (Alpha-chemo-trypsin: leurquin france,packed by Amoun pharamaceutical CO.S.A.E-Egypt.) once a day for five days, with extra-oral ice pack for 12 hours post-surgery.

Clinical Evaluation

All the enrolled patients were clinically evaluated at the one week, four weeks and six weeks post-surgery intervals. The clinical evaluation was for the assessment of postoperative pain, using 10 points Visual Analogue Scale (7). Postoperative edema was evaluated as mild, mild to moderate, moderate to severe and severe. Wound healing was assessed for any disturbance as well as and infra-orbital nerve function. The ocular complications were also assessed, as the presence of diplopia, tarsal plate ectropion or entropion, and enophthalmos. Postoperative ocular ecchymosis was evaluated based on the level of occlusion of the orbital fissure.

Radiographic Evaluation ^[2]

An immediate postoperative MSCT scan was performed for the assessment of the reduction of the fractured ZMC.

Chromatographic Analysis

For the assessment of the accuracy of the virtual reduction that was used for the creation of the PSFP, the postoperative ZMC (T1) was superimposed on the virtually reduced one (T0). Using an automatic registration tool on Geomagic Control X Software (Geomagic Control X, 3D Systems, Rock Hill, SC, USA). The software matched the deviation between two 3D-files using the automated Hausdroff distance function of the software, which then generates a color-coded histogram with a specific color and surface distance difference for each grade of deviation. For quantitative depiction of the deviation, the software generates a Root Mean Square Deviation (RMSD) value which represents the absolute deviation between the two 3D-models under investigation.

Statistical analysis

An IBM SPSS V.23.0 was used for data analysis (IBM Corp, NY, USA). The study used a descriptive manner for analysis to evaluate the performance of the PSFP in ZMC fracture management. Data significance was judged at the 5% level. Data normality was tested using the Shapiro-Wilk test. The Wilcoxon signed ranks test was used for abnormally distributed quantitative variables, while the Paired t-test was utilized for normally distributed quantitative variables. For abnormally distributed quantitative variables, Friedman test was utilized.

RESULTS:

Descriptive demographic data of the study participants is presented in Table 1.

Table 1. Demographic analysis of the study (n=12).

Sex	- Male	9 (75.00%)
/ n (%)	- Female	3 (25.00%)
Age	- Min-Max	22.00-64.00
/ years	- Mean± SD	39.42±14.39
Side	- Right	7 (58.33%)
/ n (%)	- Left	5 (41.67%)
Etiology	- RTA.	7 (58.33%)
/ n (%)	- Claimed Falls.	3 (25.00%)
	- IPV	2 (16.67%)

N: Number, RTA: Road Traffic Accident, IPV: Interpersonal Violence. SD: Standard deviation.

The mean age of the enrolled patients was 37.48 years, with a male to female ratio of 3:1. The most prevalent etiological factor was road traffic accidents with 58.33%. The processing time was evaluated for each case, from time of patient admission till plate production. The mean processing time calculated in this study was 2.9 days, ranging from 1 to 3 days.

During the surgery, the time of each case was recorded from the start of ZMC reduction, till plate fixation. The mean calculated operative time was 21 ± 16.4 minutes. Regarding the clinical follow-up parameters, all the patients reported a statistically significant decrease in the reported postoperative pain across the follow-up evaluation period (p<0.01). Regarding the postoperative reported edema, all patients reported a moderate-to-severe levels of edema in the first postoperative period. This was a temporary display as all patients reported a mild degree of edema at the second follow-up period. Across the follow up period, decrease in the degree of reported edema was statistically significant. Regarding the infra-orbital nerve function and midface cheek sensation, only 3 patients reported an aberrant sensation at the first follow-up interval. By the end of the follow up period, all the enlisted patients reported a normal cheek sensation.

Regarding the postoperative ocular complications, all enlisted patients showed an uneventful post-surgical healing period bar from one patient which reported an early ectropion in the lower eyelid.

This patient managed with triple taping of the lower eyelid for 1 week, and the patient showed normal eyelid morphology and function at the second follow up period.

Ocular edema was observed in all patients at the first post-operative follow up interval. However, all patient reported resolution of the edema at the end of the clinical follow up period.

In the postoperative MSCT, accurate bone reduction was observed in all of the cases (Figure X). Superimposition and chromatographic analysis of the accuracy of the PSFP in the management of ZMC fractures revealed an overall RMSD of 1.55 ± 0.4 mm, with a range of deviation that spans from -2.97 ± 0.90 to 3.18 ± 1.01 (Table 2).

Table 2. Quantitative Chromatographic analysis for the accuracy of the virtually designed fixation implant (n=12)..

3D Superimposition	
Min.	-2.97 ± 0.90
Max.	3.18 ± 1.01
RMSD	1.55 ± 0.45

SD: Standard deviation.

RMSD: Root mean square deviation

DISCUSSION:

The contemporary improvement in reverse engineering and virtual planning is becoming an integral part in the medical field, which embraces the oral and maxillofacial domain [10]. The literature falls short in providing data regarding the management of midface fracture with the aid of virtual planning and custom-made fixation plates [17]. Hence, this study aimed at appraising the processing, clinical, and radiographic performance of patient specific fixation implant in the management of ZMC fracture.

The study was performed on unilateral cases that need management for ZMC fracture. This was mandated owing to the fact that preoperative virtual planning was conducted based on a mirror image mesh file of the opposite unaffected ZMC. In contrast to the manual reduction virtual planning technique, the mirroring method is the most commonly utilized preoperative planning method for the reconstruction of the symmetry of the midface. This agrees with El-Mahallawy et al in which the mirroring method was utilized to create the same contour to the defective side of the mandible from the normal contralateral., it was concluded to have acceptable results for mandibular reconstruction after resection [10].

This virtual technique allowed a reduction in the processing time which is much needed in trauma management cases, as admission to the operation room is mandated in a short notice from the patient admission. The reduction in the processing time is presented in this study, as the mean required processing time from the period of clinical decision making till PSFP production and autoclaving was 2.9 days. A similar result was provided by Xu et al, where they reported a plate production mean time period of 2.6 ± 1.3 days [18].

However, Kuehle et al conducted a processing time assessment for orthognathic patients managed with custom made plate. They reported ten days mean period [19]. The lengthy processing time was one of the main drawbacks of computer assisted surgery in the maxillofacial trauma domain as stated by El-mahallawy et al [10].

In this study, the production time of the PSFP didn't cause any delays or change in the determined treatment plan in any of the managed cases. Zeiderman and Pu reported that the optimal time for management of cases of midface trauma is 4-7 days, for the resolution of traumatic facial edema [20]. This further complements the results reported in this study, as the reported mean processing time falls in the optimal treatment period of midface fractures.

The use of 3D-printing technologies has Strick the medical field with an enormous impact [10]. The most commonly utilized materials in the maxillofacial field are polylactic acid and photoinitiated resins for guides fabrication, where both utilized different techniques [10]. The ideal material for the management of midface fractures is titanium alloy [21]. They are biocompatible for tissue implantation, rigid enough to mandate primary bone healing, and provides a somehow compatible modulus of elasticity to the midface bone [21]. Rapid prototyping of metal materials is conducted with direct metal laser sintering additive manufacturing technology.

This provides more precision implant fabrication, with no waste of materials in comparison to the regular milling techniques. This concurs with Rotaru et al who conducted laser melted titanium implants for reconstructing defects of the ZMC, reporting accurate geometric conformation [22].

The stock titanium miniplates that are regularly used in midface trauma management. The stock titanium miniplates possess an innate degree of flexibility to allow the surgeon to shape the plate to the grooves and peculiar shape of the ZMC (2). This is a time-consuming procedure which results in an unjustified increase in the operating time. The PSFP shows a superior advantage over the stock titanium since it overcomes this waste of time, by adapting easily on the reduced segments of the fractured bones. The use of PSFP in this study resulted in a mean operative time of 21 ± 16.4 minutes.

This reported time shows a significant improvement from the reported periods utilizing the conventional plates in the literature. Bonitz et al, conducted a long-term analysis of cases with midface fracture and reported a mean fixation period of 33 ± 27.4 minutes^[23].

Our experience in this study may outline that the PSFP are also helpful in reduction of the fractures in the ZMC fracture. Midface fractures due to high impact energy trauma are usually arduous in reduction and fixation, that is why they report elongated fixation operative time^[22]. The utilization of preoperatively determined fixation points, and the fixed shape of the plate into the final position helped in determining the optimal reduction and fixation level. This allowed for reduction in the fixation time and preventing time wasting in deciding which is the optimal fixation position. This agrees with Rotaru et al since the prefabricated titanium implants used in ZMC defects provided a perfect fit and required no adjustments, thus, reducing the total operation time^[22].

The machined titanium could hold a mechanical geometric configuration with a desired minimal thickness, all of this without losing its desirable mechanical properties^[12]. All of the PSFP in this study were machined into a profile thickness of 0.7 mm. All of the PSFP reported adequate manufacturing, proper clinical handling, and proper healing in all of the treated patients. Sukegawa et al reported that the use of 0.5 mm plates in midface is of sufficient rigidity to allow primary healing and without excessive thickness that would be palpable through the skin^[24]. In this study, with utilizing the 0.7 mm thickness, none of the patients reported any discomfort from the implanted plates^[3-5].

The study demographic data reported a mean age of 37.48 years with a male to female ratio of 3:1 and road traffic accident as the main etiological factor with 58.33%. The demographic data of this study falls in line with the literature^[1,2]. Ellis et al reported that the main prevailing age group are the young-adult male population, which correlates with road traffic accidents as the dominant etiological factor^[1]. Road traffic accidents usually yield in a high impact trauma incident with lack of the normal pattern of fracture especially in midface fractures^[25].

The analyzed clinical performance in this study reported a favorable outcome, where all patients with infra-orbital nerve affection reported regain of normal sensation at the end of the follow up period.

This falls in line with the study reported by El-Mahallawy et al^[2].

The crashed infraorbital canal during the traumatic event, the intraoperative manipulation to achieve bone exposure and the reduction of the fractured segments make the occurrence of altered midface cheek sensation a normal finding. The regain in normal sensation is one of the goals set during the management of ZMC fractures, which is usually conducted when an accurate reduction is achieved, and rigid fixation is maintained (26). Ozer et al reports that the occurrence of midface cheek paresthesia is a common finding in ZMC fracture and one of the indications for open intervention^[26].

Ocular edema was observed in all patients at the first post-operative follow up interval although the orbital incision utilized in this study was the sub tarsal trans-cutaneous variant, with minimal disturbance of the canthal lymphatic tissues. However, all patients reported resolution of the edema at the end of the clinical follow up period. Postoperative orbital edema is a normal finding that usually take 14 days to resolve, according to Dickinson and Gausas^[27]. The lymphatic vessels located at the canthus area that drains the preorbital tissues are usually affected by either the traumatic event, bone manipulation or the incision placement^[2,27].

Only one patient reported eyelid morphology complication and was recorded as ectropion of the lower eyelid, which was managed accordingly and uneventfully. Similar outcome was reported by El-mahallawy et al^[2]. The use of sub tarsal trans-cutaneous approach with postoperative triple tapping of the eyelid may prevent the occurrence of high rates of scleral show^[28]. Ellstrom and Evans reported that the ocular postoperative complication in patients with ZMC fracture is a common finding with a high percentage of occurrence^[29].

No preoperative or postoperative diplopia was reported in this study. Chepurnyi et al reported an ocular diplopia in 29.4% of their study population, while Zimmerer et al reported 24.6%^[30,31]. The force duction intraoperative test may have given us an insight regarding the favorable postoperative clinical result, as the test was performed intraoperatively, to confirm that all tissues were released from the fixation plate or between the reduced bony segments.

A favorable radiographic performance was reported in this study, where all cases reported a symmetrical appearance on the postoperative radiograph, in comparison with the contralateral unaffected side. The use of multi-slice computed tomography was not only imperative for virtual planning, but also important in postoperative follow up as it allowed visualization of the outcome of the reduction and the outline of the orbit and midface structure^[2]. The use of multislice CT allowed accurate visualization with less hazardous radiation exposure^[32].

The use of postoperative MSCT allowed the use of 3D superimposition chromatographic analysis for the assessment of the accuracy of the virtual planning and the degree of deviation of the obtained postoperative result from the preoperative virtual setting [10,33]. The Surface-based Superimposition Chromatographic analysis technique provides an automated and quantifiable way for the analysis of the accuracy of two superimposed 3D meshes [34]. Furthermore, it provides a qualitative color-coded error map for rapid visualization [35- 37].

Superimposition and chromatographic analysis of the accuracy of the PSFP in the management of ZMC fractures revealed an overall RMSD of 1.55 ± 0.4 mm. Chromatographic accuracy analysis is a contemporary modality for assessment of the topographic degree of deviation between three dimensional models. This method provides qualitative assessment, using the topographic histogram coloring, and quantitative assessment, using the computer-generated absolute value of deviation represented as the RMSD. The Chromatographic analysis gains accuracy in the assessment of the accuracy of virtually designed medical devices and implants to outline the accuracy of the whole procedure [37].

Zhang et al utilized this modality to report the accuracy of virtual planning in maxillofacial surgery, where they reported a 3.7 ± 1.0 deviation [38]. The automated nature of this surface-based topographic superimposition analysis was used in order to assess the accuracy with elimination of any human confounding factor. This may be interpreted as an obvious advantage over other accuracy assessment methodology. The outcome of this study demonstrates the accuracy of the PSFP in transferring the virtual setting intraoperatively with great accuracy, acceptable processing time, and vastly reduced operative time.

CONCLUSIONS

The utilization of computer-aided surgery and rapid prototyping technologies in modern times has rendered them a viable choice with minimal drawbacks for managing zygomaticomaxillary complicated fractures. The patient-specific fixation implants that were virtually created shown positive processing, clinical, and radiographic performances with a respectable level of precision.

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Conflict of Interest

The authors declare that they have no conflicts of interest. The authors declare that they received no funding to perform this study.

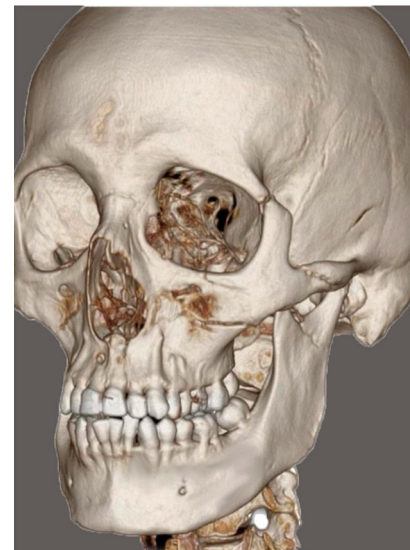


Figure (1): Radiographic picture of preoperative 3D Computed-Tomography Scan.

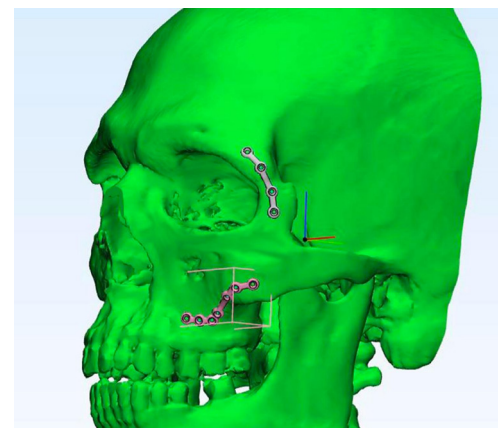


Figure (2): Photographic picture demonstrating preoperative Virtual planning of the titanium implants.

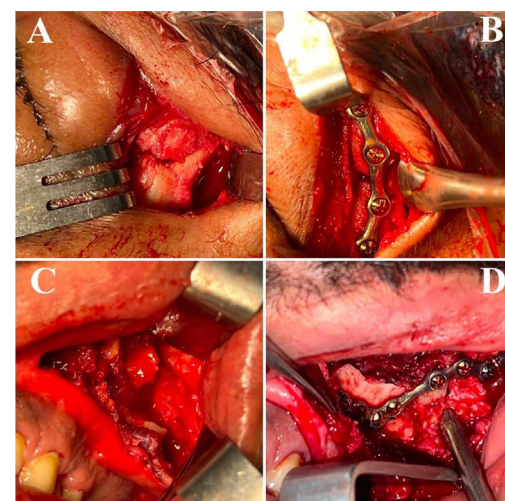


Figure (3): Photograph showing: (A, C), fractured segments. (B, D) fractures reduction and fixations via customized titanium plates.

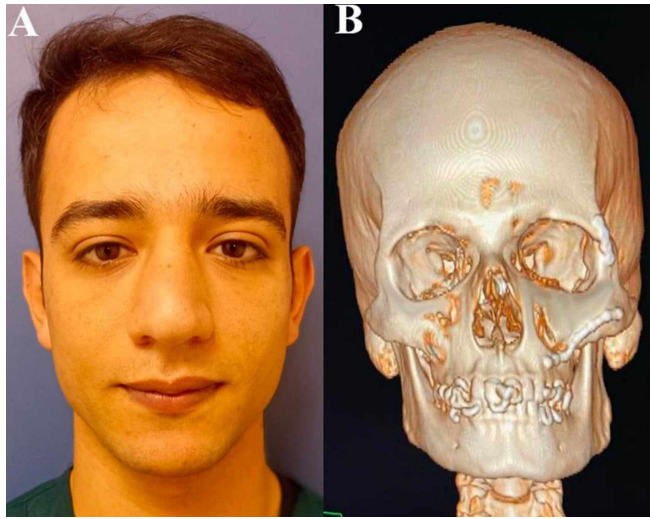


Figure (4): Photograph demonstrate: A, 6 weeks postoperative clinical picture. B, Immediate postoperative 3D Computed-Tomography Scan.

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