

## EVALUATION OF VIRTUAL PLANNING AND CUSTOM-MADE TITANIUM PLATES IN TREATMENT OF UNILATERAL ZYGOMATICO- MAXILLARY COMPLEX FRACTURES - ONE YEAR PROSPECTIVE CLINICAL AND RADIOGRAPHIC STUDY

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### ABSTRACT

**Aim:** To evaluate the application of mirror imaging, computer guided design and custom made titanium plates in the treatment of unilateral zygomaticomaxillary complex fractures and its role in accuracy of restoration of facial symmetry .

**Method:** Fifteen patients with unilateral zygomaticomaxillary complex fractures were included in this study and chosen from the department of oral and maxillofacial surgery Alahrar teaching hospital. Preoperative CT scans were made for each patient, DICOM files were transferred to Mimics Medical 19.0 software for virtual planning in which mirror image of the unaffected side was used to perform virtual reduction of fractured bone and designing surgical guides and custom-made plates. Surgical guides were used intraoperatively for reduction of fractured bone, and custom-made plates were used for fixation of fractured bone taking in consideration anatomical features and suitable sites for screws. All patients underwent CT scans, DICOM files were transferred to Mimics Medical 19.0 software for postoperative evaluation of displacement and rotation of Zygomatic bone.

**Results:** The use of surgical guides and custom-made plates improved the reduction accuracy and reduced intraoperative surgical time. Measurements of the treated displacement of the zygomaticomaxillary complex proved that facial symmetry of all patients was improved, accuracy of reduction increased, and all patients were completely satisfied with the obtained treatment results.

**Conclusion:** As with limits of current short-term prospective study, the use of surgical guide and custom-made plates is considered an effective surgical treatment in reducing and stabilizing one-sided complex zygomaticomaxillary fractures, hence, it improves outcomes of clinical relations, radiological findings, as well as outcomes related to patient-based findings after 12 months of surgery.

**KEYWORD:** Virtual planning, Zygomaticomaxillary complex fractures, Surgical guides, custom made plates

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## INTRODUCTION

Zygomatic bone is an important bone of the facial skeleton which shares mainly in the profile of the face of any person. It has three surfaces and 4 projections which articulate with other bones such as Frontal bone by frontal zygomatic suture, Temporal bone by zygomatic temporal suture, Maxillary bone by zygomatic maxillary suture, and Sphenoidal bone by zygomatic sphenoidal suture.<sup>1,2</sup>

It contributes in the formation of lateral orbital bone and infra orbital rim as well as in the formation of zygomatic arch with temporal bone. It also gives origin and insertion for facial muscles that are responsible for the movement of the jaw and facial expressions.<sup>3,4</sup>

Zygomatic fracture is a common type of facial fracture that usually results from high energy impact trauma because it is the most prominent point of the facial skeleton. It may have different patterns according to direction and type of trauma.<sup>5</sup>

Zygomatic complex fracture is one of the most common fractures of the facial skeleton, it represents about 25% of facial skeleton fractures and about 40% of mid face fractures. It can be categorized as the second most common fracture of the facial skeleton after nasal fractures.<sup>6,7,8</sup>

Zygomatic fracture leads to a change in the orbital volume, which may affect movement of the globe causing its limitation, produce bi-vision (diplopia), external eye globe bulging (exophthalmos), and internal fall of eye globe (enophthalmos). It may also affect the movement of the mandible when zygomatic arch is fractured and displaced inward toward the path of the condyle of the mandible.<sup>9-11</sup>

The most common problem of zygomatic complex fractures is loss of facial symmetry and facial disfigurement because it contributes in mid-face width and protrusion. The esthetic defects caused by ZMC fractures affect patient confidence and social communication, and thus, the reduction

of zygomatic complex fracture is challenging to restore facial symmetry.<sup>12-14</sup>

Traditional methods for zygomatic complex fracture reduction depend on operator skills and experience, so accurate anatomical reduction is difficult to achieve. Moreover, when there is a comminuted ZMC fracture, it is very difficult to get accurate reduction even if the surgeon is skillful and experienced.<sup>15</sup>

Emerging computer technology created a lot of computer-assisted designing (CAD) methods in diagnosis, virtual planning of surgery (VSP) as well as fractures management in the field of maxillofacial.<sup>16,17,18</sup>

These methods, which include VSP, 3D models of fast prototyping, navigation of surgery, personal templates of surgery as well surgeries by robotics, had been used in fractures treatment of zygomaticomaxillary complex in recent era.<sup>19</sup> These recent technology and 3D printing benefit both the patient and the surgeon as it increases the accuracy of the surgery and decreases intraoperative time and tension.<sup>20</sup>

In case of unilateral zygomatic complex fracture, virtual reduction and mirror imaging help us to get accurate reduction and achieve facial symmetry enabling us to evaluate zygomatic sphenoidal angle which is the indicator for accurate reduction.<sup>21,22</sup>

The software helps us to design and print surgical guides which are used intraoperatively to achieve accurate reduction and save time. It is also used in designing and fabricating custom-made plates specific for each patient to act as a fixation tool and gives chance to place plates in the accurate site.<sup>23-25</sup>

Custom-made plates are designed and fabricated using CAD/CAM technologies and are 3D printed from medical titanium grade 4 with a 2 mm profile. This thickness gives it enough rigidity and strength making it non-bendable saving its design and shape. It is designed to fit each patient's special anatomy

and follow fracture patterns to get the best fit and fixation.<sup>26,27,28</sup>

Mirror imaging is crucial in surgical planning for those patients who have unilateral ZMC fractures by using the unaffected side to produce 3-D models that help in the treatment of those cases by aiding in designing the surgical procedure preoperatively, simulating the reduction and fixation before surgery, and so achieve better therapeutic effects, osteotomy, fractured segments movement, besides the presurgical manufacturing of repositioning templates or personalized pre-shaped implants in an aim to decrease the operative time and reduce subsequent therapeutic potential complications.<sup>8-15</sup>

## PATIENT AND METHODS

### Patient selection:

Fifteen patients were selected from department of oral and maxillofacial surgery at Alahrar teaching hospital, Zagazig, Alsharqia, Egypt. All included candidates were males and have a mean range of age-life 18-60 years. The fracture causes were RTA and interpersonal violence. All patients were medically free and fit for general anesthesia. They had unilateral zygomatic complex fractures with no fractures at TMJ region or other facial side and were treated within 10 days post trauma.

All the patients were informed about the protocol and objectives of this study before obtaining informed consents. The study protocol was approved by the local ethical committee of the faculty of Dentistry, Delta university under the issue number: 014/2024.

### Preoperative phase

#### Patient assessment:

First aid measures were applied on the patients' arrival to the emergency room and routine work-up for trauma was performed. Consultation of neurosurgeons, ophthalmologists and general

surgery specialists and medical clearance was essential.

### Data collection

Facial CT (axial, coronal, sagittal, and 3D) was performed for all patients with slice thickness 1mm at the department of radiology, AlAhrar teaching hospital. CT data was then transferred to Mimics Medical 19.0 software (Materialise NV, Technologielaan 15, 3001 Leuven, Belgium) to delineate of reference planes and marker points, for detection of displacement and rotation of fractured zygomatic bone and for designing of guides and plates.

### Planes

Four selective points had chosen to fix the planes reference:

- A. The left condyle Center point.
- B. The right condyle Center point.
- C. Prior- nasal.
- D. Point in Mid-way a long A and B.

Three planes of reference were used for fracture displacement evaluation:

**Plane of sagittalis (SP):** plane a long D and vertical to AB

**Plane of coronalis (CP):** plane a long D and vertical to CD

**Plane of horizontalis (HP):** plane a long A, B, and C

### Marked used points

- 1. ZM [superior point of ZM suture on infra orbital rim]
- 2. ZF [utmost lateral site of zygomatico- frontal suture]
- 3. ZS [utmost prominent site at zygoma]
- 4. ZT [utmost lower site at suture of temporo-zygomatic]

### Measurement of fracture displacement:

In mirror imaging by using 3-D computerized tomography the four marked points (ZM,ZF,ZS,ZT) are demarcated for both affected and non-affected sides, then the distance between each point and the three reference planes (sagittal, coronal, horizontal) for non-affected, and affected sides was measured. By comparison of these measurements for each point on both sides, this can aid pre-operatively in detecting the deviation displacement of each point in three directions (inward, backward, upward). When these measurements were repeated postoperatively, it showed the degree of symmetry of both sides in facial width. Surface deviation analysis among virtual surgical planning and post-interference CT scans assessed the three-dimensional effect on zygomatic complex reduction.

### Designing and manufacturing of Surgical guides and plates

Using Mimics Medical 19.0 software, CT data of all patient are used to design guide for reduction of fractured bones and plates for fixation of fractured part adequately.

**First step:** is doing segmentation to define hard tissue fracture in CT data then separate unaffected bone from fractured segments.

**Second step:** is drawing mid sagittal plane and get mirror image from unaffected side to the fractured side.

**Third step:** is to perform virtual reduction on fractured segments according to mirror image from the unaffected side taking in considerations fractured zygomatic bone articulations.

**Fourth step:** is to draw the plate on the reduced segments by making screw sites on bone with adequate thickness and away from vital structures and gaps which detect the shape of the plate.

**Fifth step:** is to move fractured segments to its place before virtual reduction with screw marks on it then draw guide according to screw marks. So we get guide on fractured bone to detect screw sites and guide reduction and plates to fix fracture on its reduced place.

The data are processed and transferred in form of STL files, The exported STL file for the surgical guide is 3D-printed using the Anycubic Photon Mono X (MSLA) 3D printer (Hongkong Anycubic Technology Co., Ltd. 101-501, Building 11, Yinhai Industrial City, Shenzhen, China) using Clear Photopolymer resin.

The exported STL files for custom made plates are fabricated using mill star milling machine (JIUH-YEH PRECISION MACHINERY CO., LTD.No.195, Rd.11, Ta-Li Industrial Park, Ta-Li Dist, Taichung City, Taiwan.R.O.C.) using medical titanium grade 4.

All manufacturing process of custom-made plates and Surgical guides were done by (ARAB ENGINEERS company, Cairo, Egypt.)

### Operation method:

Custom-made plates and guides are sterilized in the sterilization department, and at the operating room, all patients received general anesthesia. Antiseptic iodine\* solution was used to clean up and disinfect the surgical field before surgery. Surgical guides and custom-made plates were used for reduction and fixation of unilateral zygomatic complex fractures through intraoral vestibular incision and lateral eyebrow incision.

### Postoperative phase

After the surgical operation, the patient stayed under observation for 24 hours until the patient is fully conscious and completely stable.

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\* Mundidone Betadine solution of 10%, concentration: manufactured by Nile Co. for Chemical Industries & Pharmaceuticals, Egypt.

Postoperative facial CT scans were done for all patients at the department of radiology, AlAhrar teaching hospital using the same preoperatively used device to get the same CT data. The CT data was then transferred to the software for the evaluation of results and the comparison with results of the unaffected side to assess symmetry.

Prolene\*\* sutures of extra oral skin flap were removed after one week and intra oral vicryl\* 000sutures were left to resorb. Antibiotic Sulbactam combined with Ampicillin in the form

of Ampules\*\*\* of concentration 1.5gm was given two times per day for a week. Analgesic as well non-steroidal anti-inflammatory as diclofenac sodium\*\*\*\* was given 2 times a day for 14 days.

All patients followed up weekly in the first 45 days till they were completely stable and able to get full mouth opening and clear globe with full eye movement in all directions and no diplopia or enophthalmos. All patients were followed up afterwards at six months and at one year.

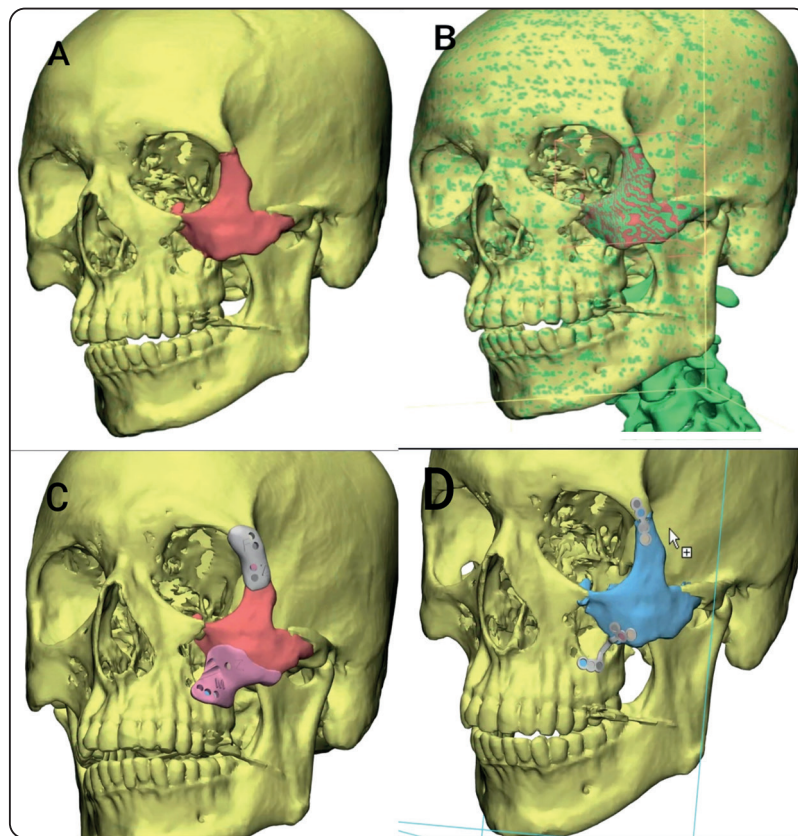


Fig (1) Showing steps of virtual planning and designing of surgical guides and custom made plates.

\* 000, Resorbable suture Vicryl of Ethicon, Company of Johnson & Johnson,

\*\* Ethicon, Non-resorbable suture for Company of Johnson & Johnson,

\*\*\* Unasyn in form of Ampules, by Pfizer of Egypt (S.A.E. Egypt),

\*\*\*\* Voltaren of 75mg concentration in form Ampule, manufactured by Pfizer of Egypt (S.A.E.Egypt).





Fig (2) Showing Surgical guides and custom made plates

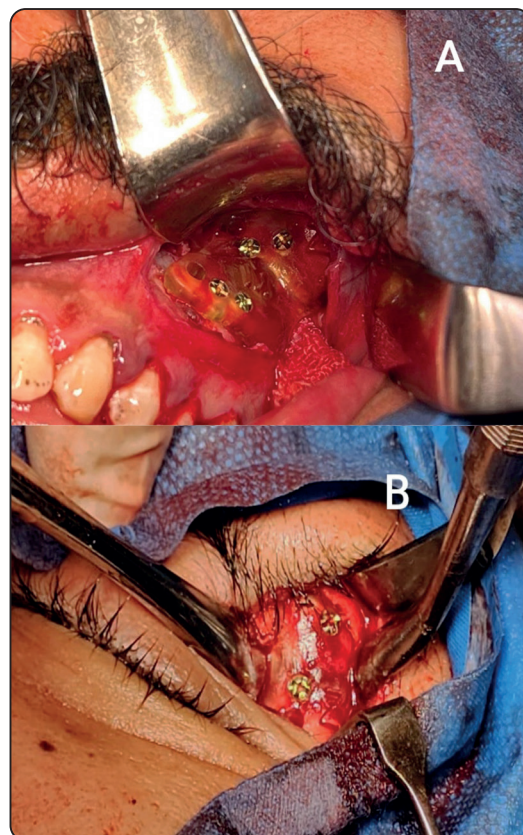


Fig (3) Showing surgical guides in place fixed with screws

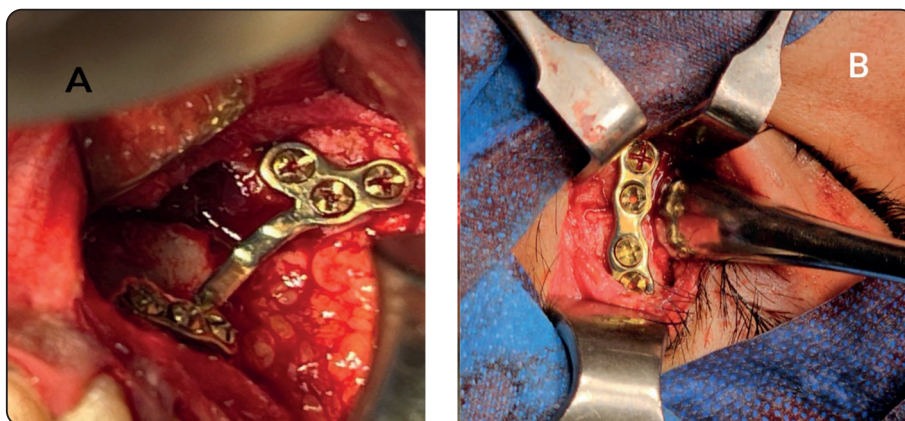


Fig (4) Showing fractured bone reduced and fixed using custom made plates

### Analysis of Statistics

The data had been analyzed using SPSS® software version 25 (SPSS Inc., Chicago, IL, USA). The resultant data had been parametric and hence met normal distribution. Comparison of change in Zm, Zs, Zt, and Zf between directions (inward,

downward, and backward) and observations (preoperative, and post operative) were performed by repeated measures of ANOVA succeeded by Bonferroni test for multiple comparisons. Graphical presentation to data was made using clustered bar charts. Significance of P-values was considered if lower than 0.05.

## RESULTS

### Effect of Direction

A comparison of change in Zm, Zs, Zt, and Zf landmarks between directions (inward, downward, and backward) is presented in Table 1. For both observations, there was a significant difference in Zm, Zs, Zt, and Zf landmarks (in mm) between directions (repeated ANOVA,  $p < .001^*$ ). For both observations, backward recorded the highest Zm, Zs, and Zt (in mm), followed by inward, and the downward recorded the lowest Zm (in mm). For preoperative observations, inward recorded the highest Zf (in mm), followed by backward, and downward recorded the lowest Zf (in mm). For postoperative observations, the backward recorded the highest Zf (in mm), followed by the downward, and the inward recorded the lowest Zf (in mm). Multiple comparisons of Zm (in mm) between directions is applied in suchlike table form. For both observations, there had a difference significance among each double direction.

### Observation effect

A comparison of change in Zm, Zs, Zt, and Zf landmarks between observations (preoperative, and post-operative) is presented in Table 1. For all directions, there was a significant difference in Zm, Zs, Zt, and Zf (in mm) between observations (paired samples t-test,  $p < .001^*$ ). For all directions, postoperative observation recorded significantly lower Zm, Zs, and Zt (in mm) (in mm), than preoperative observation; for inward directions, postoperative observation recorded significantly lower Zf (in mm), than preoperative observation. While, for backward, and downward directions, preoperative observation recorded significantly lower Zf (in mm), than postoperative observation.

### Patient satisfaction, facial symmetry, and wound healing

Comparison of mean percentage of patient satisfaction, facial symmetry, and wound healing between observations (preoperative and postoperative) is presented in table 2. Post operative patient satisfaction was significantly higher than preoperative patient satisfaction (paired samples-

TABLE (1) Comparison of change in different landmarks (in mm) between Directions and observations

|          |                         | Inward |      | Backward |      | Downward |      | Repeated ANOVA<br>(p value) |
|----------|-------------------------|--------|------|----------|------|----------|------|-----------------------------|
| Landmark |                         | XI     | SDe  | XI       | SDe  | XI       | SDe  |                             |
| Zm       | Preoperative            | -2.39a | .12  | 2.74b    | .096 | 2.21c    | .059 | <.001*                      |
|          | Postoperative           | .806a  | .043 | 2.04b    | .045 | -.230c   | .046 | <.001*                      |
|          | Paired t-test (p value) | <.001* |      | <.001*   |      | <.001*   |      |                             |
| Zs       | Preoperative            | -.820a | .057 | 4.65b    | .079 | 2.41c    | .068 | <.001*                      |
|          | Postoperative           | .122a  | .022 | 1.24b    | .037 | .298c    | .041 | <.001*                      |
|          | Paired t-test (p value) | <.001* |      | <.001*   |      | <.001*   |      |                             |
| Zt       | Preoperative            | -1.10a | .036 | -2.064b  | .051 | -1.17c   | .080 | <.001*                      |
|          | Postoperative           | .302a  | .028 | 1.78b    | .030 | -.678c   | .041 | <.001*                      |
|          | Paired t-test (p value) | <.001* |      | <.001*   |      | <.001*   |      |                             |
| Zf       | Preoperative            | 1.15a  | .041 | .344b    | .037 | -.078c   | .041 | <.001*                      |
|          | Postoperative           | .530a  | .046 | .810b    | .026 | -.608c   | .037 | <.001*                      |
|          | Paired t-test (p value) | <.001* |      | <.001*   |      | <.001*   |      |                             |

XI; mean, SDe; Standard deviation; \*p has significance at level of 5%. Diverse letters at suchlike raw showed a difference significance among each double directions (test of Bonferroni,  $p$  more than .05). Similar letters in suchlike raw revealed non- difference significance among each double directions (Bonferroni test,  $p$  more than .05)

t- test,  $p < .001^*$ ). Postoperative Facial symmetry was significantly higher than preoperative Facial symmetry (paired samples- t- test,  $p < .001^*$ ). Postoperative wound healing was significantly lower than preoperative wound healing (paired samples- t- test,  $p = .002^*$ )

TABLE (2) Comparison of mean percentage of patient satisfaction, facial symmetry, and wound healing between observations

| Patient satisfaction            |          |           |
|---------------------------------|----------|-----------|
|                                 | <i>X</i> | <i>SD</i> |
| Preoperative                    | 9.00     | 8.94      |
| Postoperative                   | 96.60    | 4.22      |
| Paired samples t-test (p value) | <.001*   |           |
| Facial symmetry                 |          |           |
|                                 | <i>X</i> | <i>SD</i> |
| Preoperative                    | 9.00     | 8.94      |
| Postoperative                   | 96.60    | 4.22      |
| Paired samples t-test (p value) | <.001*   |           |
| Facial symmetry                 |          |           |
|                                 | <i>X</i> | <i>SD</i> |
| Preoperative                    | 9.00     | 8.94      |
| Postoperative                   | 96.60    | 4.22      |
| Paired samples t-test (p value) | <.001*   |           |

*X*; mean, *SD*; standard deviation; \**p* is significant at 5% level.

## DISCUSSION

Males are more frequently exposed to high-risk exertions as well as occupations, as riding of motorcycles in addition to working at extreme heights, which contribute to a higher prevalence of injuries. Etiology of zygomaticomaxillary complex (ZMC) fractures include accidents of road jam, massive fall from height, assaults, as well sports-related incidents. In our study, the primary causes were accidents of road jam accidents (66.67%),

fall from high (16.67%), as well assault violence (9.25%). These findings align with those of a recent local study that also identified road traffic accidents as the leading cause of maxillofacial fractures.<sup>29-31</sup>

Different populations may exhibit varying etiologies for ZMC fractures due to differences in socioeconomic status, vehicle preferences, and lifestyle factors. This variability underlines the need for population-specific data to better understand and address the mechanisms of injury.<sup>31</sup>

ZMC has an irregular 3D shape and a complex anatomical structure, forming the lateral wall of the orbit and surrounded by various muscles. ZMC fractures increase the risk of functional and aesthetic defects, making the treatment more challenging. The primary goal of managing ZMC fractures is to restore the midfacial contour, whereas accurate reduction is the cornerstone of the treatment.<sup>32,33</sup>

Successful reduction heavily relies on the surgeon's expertise, as inexperienced surgeons may struggle to achieve precise anatomical alignment. Therefore, achieving accurate reduction of comminuted ZMC fractures can be a significant challenge, which was in contrast to this study, owing to the usage of virtual planning and surgical guides which gave surgeons the ability to perform the operation preoperatively on a software by mirror imaging and virtual planning and create guides for intraoperative reduction guaranteeing perfect reduction of fractured bone, and providing the excellent obtained results.<sup>34,35</sup>

Several studies suggested that surgical navigation may address the issue of fracture reduction and enhance its accuracy. However, its effectiveness can be impacted by several factors, including errors related to conversion and reformation of images, software as well as hard-ware limitations, data entry and saving, system vulnerabilities, displacement in soft-tissue, and intra-surgical methods. This was in contrast to this study, as its application appeared to be simple and not sophisticated, assuring its facilitated use with optimistic gained results.<sup>36-39</sup>



The planning for virtual surgery and procedures of navigation involve extra time, financial costs, and needs equipment for surgery navigation of extreme cost. Furthermore, the successful application of navigation systems requires specialized training of surgeons, and thus limiting its usability, particularly in hospitals of first aid. Moreover, the irregular shape of the zygomaticomaxillary complex leads to the rely of reduction verification on very few numbers of unreliable points. On the other hand, in the current study, the used surgical guides were of low cost, more applicable, and didn't require special training. Moreover, it was not affected by soft tissue displacement while easily following the irregular shape of zygomaticomaxillary complex compared to surgical navigation, and accordingly, we get better results and increased reduction accuracy along with fast, easy, and simple technique.<sup>36,37</sup>

Patient-specific surgical guides are being increasingly utilized in multiple branches in the surgical field of maxillofacial, as to help in operating orthognathic procedures, surgical reconstruction following tumor removal, or temporomandibular joint surgery. New advancements in computer-assisted technology as well as surgical planning have progressed over time, and through the results of the current study, after the use of mirror imaging, surgical guides, and custom-made plates, it was noticeable that computer-assisted surgery showed an efficient role in diagnosis and treatment of unilateral zygomatic-maxillary complex fractures, which was in agreement with multiple other studies. 38-40

Some surgeons may use personal-specific surgical guides for reduction as well as stabilization of complex zygomatic fractures. However, in some other studies previous designs of surgical guides were fabricated on 3-D skull models from acrylic resin that were bulky, thick, constructed in multiple pieces for each patient, and applied intra-operatively through multiple facial incisions. these guides were difficult in its use, application intra-operatively

carried extreme harm and morbidity to facial tissues through multiple facial incisions that were used, in addition to non-satisfactory obtained results. These results were in contrast to results of the current study as in this study 3-D models of zygoma were used in virtual planning to construct thin surgical guides formed from clear photopolymer resin, of not more two pieces that were not connected to each other so were easily applied intra-operative through either trauma cut wounds, old skin scar at affected region, or small incisions without any deterioration of facial tissues. So, in this study by the usage of small surgical guides designs that were easily applied intraoperatively to fractured bone, gave proper reduction, and hence more better results were obtained with less effort and minimal damage to tissues in comparison to some other studies.<sup>41,42</sup>

Some studies used virtual reduction and mirror imaging to create 3D model for the skull of the patient. The 3D printed skull has the fractured side reduced using VSP, on which the surgical guide was created using self-cure acrylic resin and mini plates were pre-shaped to be used as a fixation tool and guide intraoperatively. This method gave accepted results, but it wasn't easy to adapt acrylic guide because it was large and didn't take in consideration the nature of fractured bone as well as the pre-shaped mini plates. Results in the current study gave better reduction through use of thin clear photopolymer resin in guide construction in addition to excellent fixation results due to the use of custom-made mini-plates which were fabricated to each individual to follow fine details and anatomical features of the fractured bone. This led to accurate, easy and safe fixation without endangering surrounding tissues, which was in contrast with other studies which used pre-shaped mini-plates which were not self-designed that led to harm to anatomical structures during their application through either its length and/or thickness. Additionally, it was not adapted fitly to all surfaces of fractured bony segments, and hence, the more favorable fixation results of the current study.<sup>15</sup>

Researchers used virtual reduction and Surgical guides in reduction of unilateral ZMC fractures and they got good results, which was in line with the results of this study. However, the main difference was the use of hemi-coronal flap by these studies to gain access to the affected side for reduction and fixation of the bone, which was too aggressive incision, traumatic, and time-consuming that resulted in obvious ugly scars in their results. This was in contrary to the gained results of the current study in which small surgical guides were applied to their sites through small lateral eye-brow incision and hidden intra-oral vestibular incision. This led to minimal scar formation, better esthetic results, and high degree of patients-satisfaction. Thus, in favor to our study, better results were obtained in reduction and fixation by simple, easy, little time consuming, non-aggressive maneuver with minimal resultant scar and proper aesthetics.<sup>43,44</sup>

In the current study, using mirror imaging from non-fractured side for virtual surgical planning and reduction of unilateral ZMC fracture led to proper designing of two fitted and thin surgical guides for each patient which were applied to the patients through minimal or hidden incisions followed by the use of custom-made self-individual plates for fracture fixation. All the previous steps together, led to the optimistic better results of this study in contrast to other studies which attained success but at a lower-level.<sup>15,41</sup>

## CONCLUSION

As with limits of current short-term prospective study, the use of surgical guide and custom- made plates is considered an effective surgical treatment in reducing and stabilizing of one-sided complex zygomaticomaxillary fractures, hence it improves outcomes of clinical relations, radiological findings, as well as outcomes related to patient-based findings after 12 months of surgery.

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