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Patient satisfaction of computer guided reduction of Zygomatico-Maxillary Complex (ZMC) fractures using Patient Specific Guide (PSG) versus conventional reduction: a randomized clinical trial

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ABSTRACT

Background and objectives. This study was conducted to evaluate of the patient satisfaction of computer guided reduction of Zygomatico-Maxillary Complex (ZMC) fractures using Patient Specific Guide (PSG) Versus Conventional reduction.

Materials and methods. In this clinical trial patients were classified into two groups; each group consist of eight patients where the study group represented the use of patient specific guide for reduction and fixation of zygomatic fracture while the Control group represents conventional reduction and fixation of zygomatic fracture. The primary outcome is patient satisfaction while intraoperative time is the secondary outcome.

Results. There was no statistical significancy in the overall satisfaction level between CR and GR, also there was no significancy between time consumed in CR and GR as guided reduction technique could save only about 8 minutes.

Conclusions. Patient-specific guided reduction is an satisfactory technique for the reduction of zygomatico-maxillary complex (ZMC) fractures. Moreover, this technique decreased the operation time without a statistically significant difference from the conventional technique.

Keywords: CBCT, mediopalatine suture, orthodontics

Abbreviations

3D	– Three-Dimensional	CR	– Conventional Reduction	MVA	– Motor Vehicle Accidents
CAS	– Computer-Assisted Surgical	GR	– Guided Reduction	ORIF	– Open Reduction and Internal Fixation
CBC	– Complete Blood Picture	IPV	– Intimate Partner Violence	ZMC	– Zygomatico-Maxillary Complex

INTRODUCTION

Fractures occurring within the zygomatic complex may result in the displacement of both the zygomatic bone and the zygomatic arch, potentially leading to function and aesthetic problems such as restricted opening of the mouth and asymmetry of the face. Prompt reduction and fixation of these fractures during the initial surgical intervention typically address these concerns effectively [1].

Fractures occurring within the facial skeleton exhibit diverse patterns of presentation, influenced by the underlying cause of injury. Typical sources of facial bone fractures encompass traffic incidents (involving motorcycles, automobiles, bicycles, pedestrian collisions), assaults, falls from heights,

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stumbles, sports-related mishaps, industrial/workplace accidents, and other miscellaneous causes such as gunshot wounds, train accidents, and pathological fractures [2].

A fracture of the zygoma holds clinical significance concerning both facial aesthetics and function. The displacement of the malar prominence is pivotal in shaping the overall facial appearance and can lead to alterations in facial contour, resulting in deformities. In displaced fractures, Open Reduction and Internal Fixation (ORIF) are necessary to prevent ophthalmology hazards and mastication problems. The key factors crucial for effective management of malar bone fractures include precise reduction and ensuring three-dimension stability of the fractured segments, aiming for satisfying function and aesthetical outcomes [2].

Advancements in computer technologies have facilitated the emergence of numerous Computer-Assisted Surgical (CAS) modalities for addressing maxillofacial traumatic surgeries. Surgical-designing softwares and computer-fabricated stereolithographic models have enabled surgeons to conduct precise preoperative simulation, resulting in optimal Three-Dimensional (3D) surgical plans [3]. The current technology allows for the fabrication of individually tailored aesthetic implants as well [4]. Yet, the achievement of satisfactory outcomes relies heavily on effectively translating the preoperative virtual surgery to real operation. Prior to the adoption of computer-guided surgery, attaining favorable results was challenging [5].

The implementation of computer-guided surgeries has presented an efficient resolution to this issue. Nevertheless, one of the challenges associated with this approach is the irregularity of malar bone surface and the absence of distinct anatomical landmarks that allow prober repositioning of fractured bony segments in surgery, especially in instances of deferred zygomatic fractures [5].

Although there are a few articles on the use of patient specific guides, they were typically on reconstruction of head and neck, and there is a gap knowledge regarding the success rate of the use of those patient specific guides in reduction and fixation of ZMC fractures for decreasing the intraoperative time and improving the patient satisfaction.

MATERIALS AND METHODS

This study was randomized controlled trial, participant collected from Oral and Maxillofacial Surgery clinic, faculty of dentistry, Cairo University and Misr University for Science and technology from July 2021 to Feb 2023. The research ethics committee of faculty of dentistry, Cairo University has approved the study with Code: 26-7-21. This study enrolled 16 patients who fulfilled the following criteria: zygomatic fracture type III, IV and V according to rowe and killey classification [6], aged from18 to 60 years and had a recent fracture (less than 2 weeks). With exclusion of zygomatic fracture type I, II and VI according to rowe and killey classification) [6], medical compromised patient, patient on radiotherapy, and bone disease.

Patients were classified into two groups; each group consist of eight patients, were randomly assigned to either control or study group in the ratio of 1:1 using random number table by computer generated randomization (www.randomizer.org) which was done by the main supervisor. By using sequentially numbered opaque sealed envelopes, the allocation scheme generated by senior nurse, who was not involved in ascertaining eligibility, performing the surgery, or assessing the outcome. In the study group Guided Reduction (GR) using patient specific guide used for reduction and fixation of zygomatic fracture, while in the control group Conventional Reduction (CR) and fixation of zygomatic fracture was achieved.

Preoperatively, all participants underwent: preoperative laboratory investigations (Complete Blood Picture (CBC), coagulation profile, blood glucose level, liver and kidney functions), anesthesiologist consultation, preoperative antibiotics, consent from the patient or his parent before surgery, and complete information concerning the protocol was provided and simplified to the patient with reasoning of all the steps included as the importance of the follow up visits and home medication.

Regarding study group a 3D model was fabricated while the anatomical reference for reduction was the non-fractured side, then generating a patient specific guide with intimately adapted fitting surfaces aiming to reduce the fractured segments in place. then patient specific surgical guide was 3D printed and sterilized preoperatively using glutaraldehyde 2%. (Figure 1)

All procedures were performed under general anaesthesia with endotracheal intubation, the patients were placed supine with a head ring under the occiput helped in stabilizing the head, hemostatic infiltration; Epinephrine (Adrenaline) saline solution in dilution of 1:200,000 is used for infiltration 5-7 min before the surgery [7]. Fracture sites were exposed through subciliary, lateral eyebrow and maxillary vestibular incisions.

In the study group, the patient specific guide was inserted to allow the reduction of fractured segments as planned pre-surgically on the software, while free hand reduction was done in the control group, then fixation of fractured segments in both groups were done using titanium 2.0 miniplates and screws, closure in layers was performed and the intraoperative time was estimated in hours (Figure 2).

For postoperative management, all patients were given antibiotics for 7 days, while postoperative analgesia was achieved using the nonsteroidal anti-inflammatory drug. Sutures removed after 8 days.

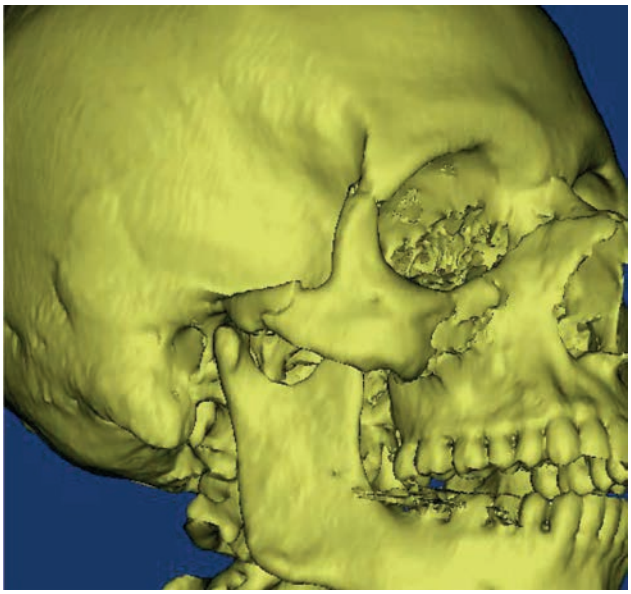

FIGURE 1. Photograph showing a 3D model of the patient's skull was calculated

Both control and study groups were subjected to the same follow up regimen for six months, questionnaire for patient satisfaction [8] was originally developed for the assessment of patients' subjective evaluations of five associated symptoms: deformity, pain, paresthesia, annoyance from incision and trismus after treatment of zygomatic fractures. The satisfaction visual analog scale was used for assessment of each symptom, and this was evaluated one week, 3, 6 months postoperative (Figure 3).

RESULTS

The study was conducted on 16 patients that were equally and randomly allocated to each of groups (i.e., 8 patients each). There were 8 males and zero females in the study group, while there were 6 males and 2 females in the control group. The average age of participants fell within the second and third decades of life. Patient satisfaction level of paresthesia, deformity improvement, pain, incisions and trismus were assessed over 3 periods of time (1 week, 3 and 6 months).

Paresthesia satisfaction level had a continuous elevation over the 3 periods of time between CR and

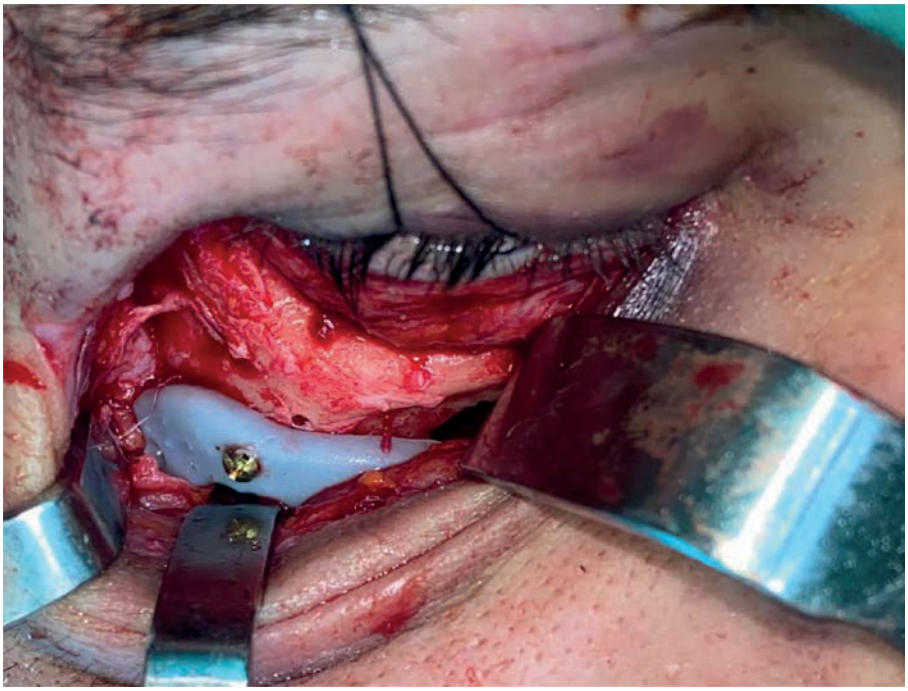

FIGURE 2. Photograph showing reduction of fractured segments using patient specific guid

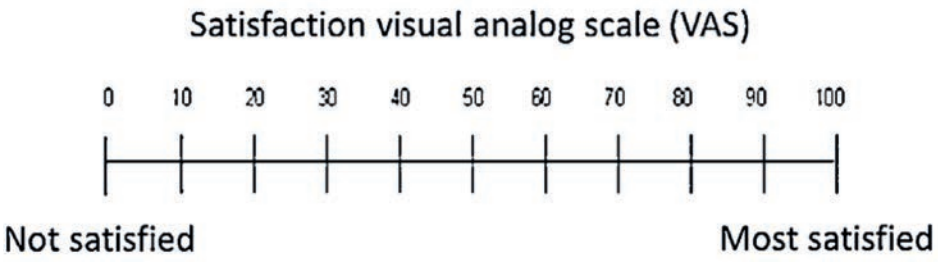

FIGURE 3. Photograph showing satisfaction visual analogue scale [9]

GR groups. where CR group recorded the highest satisfaction level over these time periods as 55±18.52, 80±15.12 and 91.25±11.26 respectively, while 45± 27.26, 71.25±22.95 and 85±15.12 respectively in GR group, with no statistical significancy p>0.05.

Deformity improvement satisfaction level had also a continuous elevation over the 3 periods of times as mentioned between CR and GR groups. The GR group recorded the highest satisfaction level over these time periods as 52.5±13.89, 80±13.09 and 88.75±11.26 respectively, while 45±16.04, 75±9.26 and 88.75±6.41respectively in CR group with no statistical significancy p>0.05.

The pain satisfaction level reveals that there was also continuous elevation over the 3 periods of time between CR group (30±18.52,71.52±11.26 and 91.25± 11.26 respectively) and GR group (40±21.39, 75±10.69 and 88.75±6.4 respectively). where GR group recorded the highest satisfaction level post operatively and after 3 months while CR after 6 months with no statistical significancy between them p>0.05.

Satisfaction level from incisions was continuous over the 3 periods of time between CR and GR groups. The GR group recorded the highest satisfaction level over these time periods 47.5±16.7, 77.5± 11.65 and 90.26 respectively, while 37.5±11.65, 65± 10.7 and 85±9.25 respectively in CR group, with only significancy after 3 months p<0.05.

Trismus satisfaction level was also continuous in elevation in the 3 periods of time between CR (56±25 15.98, 80±9.26 and 93.75±7.44 respectively) and GR (55±28.28, 85±13.1 and 96.25±5.18) groups. Where the CR group recorded the highest satisfaction level at 1 week only while the GR group after 3 and 6 months, with no statistical significancy p>0.05 between them.

The overall satisfaction level between CR and GR groups was continuous elevation in the 3 periods of time. where GR group recorded the highest satisfaction level at 1 week and after 3 months while the CR group after 6 months only, with no statistical significancy p>0.05 between them (Figure 4).

This study reveals that there was no significancy between time consumed in CR which consumed around 2 hours and 40 minutes while the GR takes 2h and 32 min. so guided reduction technique could save only about 8 min. Table (1)

TABLE 1. Mean and SD of time consumed in operation of CR and GR groups

Comparison	Group	Mean ± SD Min	P-value
Time	CR	160.0000 ± 65.03	0.777
	GR	151.8750 ± 45.67	

* Significant p-value ≤0.05

DISCUSSION

Fractures involving the zygomatic bone are frequently observed in individuals experiencing maxillofacial trauma. This prevalence is attributed to the prominent position of the zygoma as a malar eminence in the midface. The surgical correction of zygomatic bone fractures remains vital and poses a significant challenge for contemporary surgeons. This is primarily due to the essential role played by the zygomatic bone in shaping, functioning, and contributing to the aesthetic appearance of the face [10].

The majority of displaced fractures involving the ZMC typically necessitate the use of titanium miniplates for fixation. This is crucial for the resto-

FIGURE 4. Overall satisfaction curve over 3 different intervals time between CR and GR groups

ration of zygomatic projection, facial symmetry, and orbital volume. In recent developments, computer guided surgeries using patient specific guides, prebent plates on 3d models and patient specific plates have shown satisfactory results [11].

Regarding gender in the present study, male predominance was found in both groups in harmony with many studies [12-14], this is due to increased male engagement in activities like Motor Vehicle Accidents (MVA), Intimate Partner Violence (IPV), and work-related accidents. Participants' average age was in their twenties, in agreement with Padmanavam and Mishra [15], specifically 52.1% were aged 16-30. However, Zhou et al. [16] noted peak incidence in the third and fourth decades, likely due to higher social interaction and higher rates of mobility rendering them more susceptible to injuries.

Cheek numbness is one of the most common symptoms in zygoma fracture. Either by the infraorbital nerve entrapment in fractured segments or the surrounding tissue swelling which may cause paresthesia. As well as functional and esthetic deformity induced by trauma to that bone which plays an important role in facial contour and esthetics of the face in the human body [17].

In the current study, there was continuous elevation in the satisfaction level of numbness sensation and deformity improvement over 3 periods of time between CR and GR groups. The CR group recorded the highest satisfaction level over these time periods with no statistical significance. However, Yang et al. [10], recorded that numbness was documented as 57% in navigation group and 42.9% in control group that had residual numbness during follow-up at 3 to 6 months, which is comparable to the literature reported from 10% to 50% [18].

As mentioned in this study The GR group recorded the highest satisfaction level over the 3 time periods with only significancy after 3 months, and a 90% mean for satisfaction level of the incision, which was coincided with Elbarbary [19] Who stated that the postoperative objective grading of the scars by the surgeon in subciliary incision was 100% invisible, and subjective scar grading by the patients was 100% invisible, as well as all patients were completely satisfied with the scar appearance. Although, another study [20] favored the subtarsal incision over subciliary incision for the exposure of inferior orbital rim, as it provided rapid access to the field, higher postoperative esthetics and better patient satisfaction, and state it as a minimally invasive approach that offers sufficient and direct access to fractures of the orbital floor and infraorbital rim, while minimizing the risk of postoperative complications.

On the other hand, impingement zygomatic arch on coronoid process of the mandible induces trismus in patients having ZMC fracture, as well as pain, swelling and inward rotation of zygomatic bone. The current study reveals that there was a continuous elevation in the trismus satisfaction level postoperatively. Patients' satisfaction was elevated from 55% in immediate postoperative to 96.2% in 6 months follow up. Samin et al. [21] observed that 51.2% of ZMC fracture patients complain from trismus associated with various procof ZMCf ZMC, such as infraorbital rim, frontozyomatic and zygomaticomaxillary processes, that was not statistically significant, while it had highly significant with zygomatic arch fracture. Chang et al [22] reported that only 2 patients maintain trismus in follow up periods.

According to this study, there was no significant difference between times consumed in CR which consumed around 2 hours and 40 minutes while the GR takes 2hours and 32 minutes. So, GR technique could save only about 8 min. However, a study done by Li et al. [23] to establish the advantages and efficiency of CAS technique in the treatment of comminuted mandibular fractures compared with conventional technique. A virtual reduction surgery before the operation, made the real surgery carried out based on the preoperative planning, decreases the operative time in comparison with the conventional group.

Montaser et al. [12] stated that the ZMC fracture reduction and fixation intraoperative time in was (68±21) minutes in study group which is less than intraoperative time in control group (109±68 minutes). This can be justified by the fact that the patient specific plate was perfectly adapted on the surface of the bone with no need for any bending; however, there is no difference statistically in intraoperative time.

The current study presented the significance of the use of the computer guided surgery in surgical planning preoperatively, specifically the use of the non-fractured side as a reference that influence satisfactory symmetrical outcomes postoperatively, moreover the surgeon can be aware of the surgery preoperatively by the aid of virtual planning so that difficulties intraoperatively can be expected and easily handled. That was supported by the study that [24] advocated virtual planning and the use of patient specific plates as a reduction guide and fixation device because when surgeons build the virtual operative plan, it facilitates the surgical processes, reducing operating time, and overcome the dependence of the surgeon experience that determine the reduction accuracy in the conventional technique. However, Yang et al. [25] discovered that the utilization of patient specific implants is limited because of their cost, length of surgical planning, time of fabrication and require more equipment and facilities.

CONCLUSION

Patient-specific guid technique for the reduction of ZMC fractures has shown patient satisfactory outcomes. Moreover, this technique helps even the unexperienced surgeon to precisely reduce and fix the fractured segments and minimize the intraoperative time.

Additional multicenter studies are needed to corroborate our findings.

Author's contributions:
Conceptualization, MM and AM; Methodology, AM; Software, AM; Validation, RM, HA, MM; Formal analysis, UED; Investigation, RM; Resources, HA; Data curation, Ragia Mounir; Writing—original draft preparation, Ahmed Morad; Writing—review and editing, Ragia Mounir; Visualization, Hany Amin; Supervision, Ragia Mounir; Project administration, Ahmed Morad.

All authors have read and agreed to the published version of the manuscript.

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Conflict of interest:
Authors declare there is no conflict of interest with respect to the research, authorship, and/or publication of this article.

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