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ORIGINAL ARTICLE

C-arm as intraoperative control in reduction of isolated zygomatic arch fractures: a randomized clinical trial

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Abstract
Purpose Isolated zygomatic arch fractures (IZAFs) are habitually reduced at a distance, via a temporal approach. Open reductions are not recommended due to the associated morbidity and complications. However, performing closed reductions makes it difficult to determine whether it was done satisfactorily. This study aims to determine whether the acquisition of intraoperative images with a C-arm to evaluate IZAF reductions is a useful technique in treating such fractures.
Methods Our hypothesis is that acquiring intraoperative images with a C-arm reduces the need for a second surgery. Between 2009 and 2012, 50 patients who were diagnosed with IZAF requiring surgery were randomly distributed into two groups: 25 patients were in the experimental group, where fracture reduction was performed and immediately corroborated intraoperatively for an adequate result using a C-arm, and 25 patients were assigned to a control group where the fracture reduction was controlled with post-surgery imaging.
Results The results did not reveal significant differences between both groups ($p = 0.5$). Nevertheless, the experimental group had the advantage of being able to immediately reduce the fracture again if the result was unsatisfactory.
Conclusions Despite the fact that the results are not statistically significant ($p = 0.5$), the authors recommend undertaking an intraoperative imaging analysis in areas where we are not certain of the reduction.

Keywords Zygomatic arch fracture · C-arm · Intraoperative imaging

Introduction

Isolated zygomatic arch fractures (IZAFs) correspond to approximately 14 % of all zygomatic fractures [1]. Typically, the reduction is done at a distance via a Gillies temporal approach or the supraorbital approach described by Dingman and Natvig in 1964 [2–4]. Other approaches and treatments with open reductions must be reserved for combined or panfacial fractures; they are not recommended as a first choice because they can cause higher levels of morbidity and high complication rates compared to closed treatment [2, 5]. Meanwhile, there are increasing reports of successful reduction using assisted-endoscopic methods [6–8].

According to the AO Foundation principles, the challenge of closed treatment lies with the fact that it is difficult to affirm that an adequate and stable reduction has been achieved [4]. In addition, it has the disadvantage of not affording a direct view of the fracture or the reduction obtained. Lastly, there is a risk of causing lesions to soft tissue because of the reduction instrument's poor placement [6].

All of these inconveniences have prompted specialists to use different forms of intraoperative imaging like computer tomography (CT) [9], ultrasound [10], endoscopic assistance [6–8], and others to manage and control these fractures [11]. However, the infrastructure or the technology to guarantee these procedures in the operating room are not always available in developing countries, which means that the responsibility lies with the surgeon's experience.

The purpose of this study is to determine whether the acquisition of intraoperative images with a C-arm (a mobile image intensifier system) to evaluate the reduction of pure

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zygomatic arch fractures is a useful technique in treating such fractures. Our hypothesis is that acquiring intraoperative images with a C-arm reduces the need for a second surgery. The specific objective is to contrast the surgeon's subjective clinical evaluation upon completing the reduction with the objective evaluation of radiographic control.

Material and method

The authors undertook a randomized clinical trial approved by the hospital ethics board, which complies with the Helsinki Declaration and in conformance with CONSORT. The sample for this study was selected from the population of patients referred to the Maxillofacial Surgery Service at our level 1 trauma center in Santiago, Chile, for surgical treatment of IZAF between 1 January 2009 and 31 December 2012 due to functional or esthetic limitations.

The inclusion criteria were as follows: (1) patients over the age of 18, (2) isolated zygomatic "M-type" arch fractures, (3) functional and/or esthetic limitations caused by fracture, and (4) treated with Gillies distance approach..

The exclusion criteria were as follows: (1) fractures that extended to other skeletal structures, (2) other types of approach, and (3) comminuted fractures.

The patients accepted for this study approved and signed an informed consent. A pre-operative CT scans were done to all patients using a Siemens® Somatom Sensation model, year 2010, with 64 channels, a 1-mm cross-section, a 20 % overlap, 120 Kv, 120 mA, and using a bone reconstruction algorithm (Fig. 1). A single surgeon, under general anesthesia performed

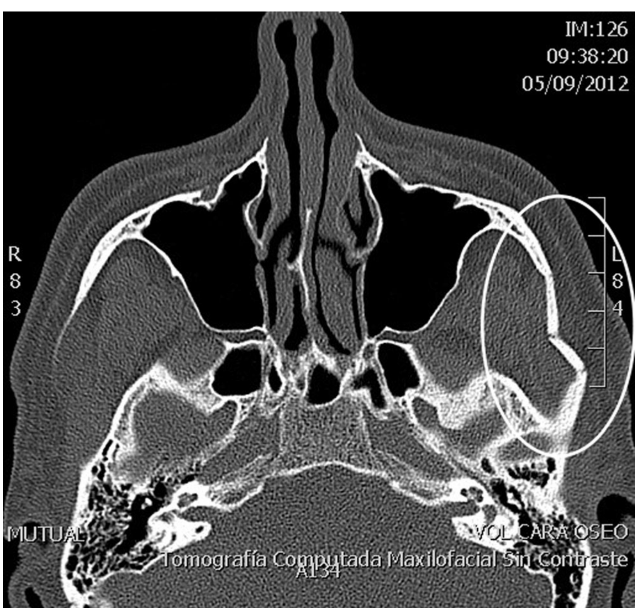

Fig. 1 Pre-operative craniofacial non-contrast CT. Axial cross-section. "M-shaped" isolated zygomatic arch fracture of the left side

in an operating room, treated all patients acutely. To reduce the fractured segment, a Gillies distance approach was made and a Dingman elevator was inserted under the fracture, reducing the segments without fixation. Closure was performed using continue 4–0 non-reabsorbable suture. Patients were randomly assigned by an author with no clinical involvement in the trial, using a permuted block design with computer random number generator, to one of two treatment groups: (1) the "control" group, in which the reduction of the zygomatic arch was evaluated with postoperative imaging, and (2) the "experimental" group, where the fracture reduction was evaluated intraoperatively using images obtained with the C-arm. Blocked size randomization—to 25 patients for each group—was used to ensure that comparison groups will be generated according to a ratio 1:1. According to the work algorithm that we designed for this study (Fig. 2), upon completing the arch reduction on patients in the experimental group, the surgeon had to respond to the question: Was the fracture reduction a success? If the response was affirmative, then an intraoperative image was taken. If there was no reduction or it was insufficient upon evaluating the intraoperative imaging, then the reduction was repeated and the question asked again (Fig. 3). The algorithm continues until a proper reduction can be observed in the intraoperative image (Fig. 4). For the subjective evaluation, the reduction was considered a success if the surgeon perceived an adequate facial width, without a palpable bony step-off or a limitation in the mandibular opening during intraoperative evaluation. Additionally, an instrument was used to roll under the arch to detect bony steps. For the objective evaluation, the reduction was considered a success if a correct reduction could be visualized, with an adequate zygomatic arch contour, without a gap, overlapping, or displacement of fragments. All patients were followed for at least 6 months.

The intraoperative image for the experimental group was done with a mobile C-arm (Siemens© ARCADIS Varic, USA). According to the algorithm, once the reduction was completed, the patient was placed in supine decubitus position with the neck hyperextended. The C-arm was subsequently positioned. The central X-ray was aimed at a 45° angle with regard to the zygomatic arch on the fractured side—similar to a submental vortex projection—with image intensifier located cranial to the patient's head. The intraoperative image was obtained using pulse acquisition (dose 55 to 60 kV, 2 to 2.5 mA). In our experience, positioning the patient and removing the mobile C-arm from the operating room takes approximately 10 min. For their part, the postoperative radiographic controls for the control group were taken within 4 h post-surgery, using the same submental vortex technique described above but with a conventional X-ray equipment (dose 70 to 75 kV, 10 mAs). In both groups, measures were taken to prevent patients from leaning on the affected area post-surgery.

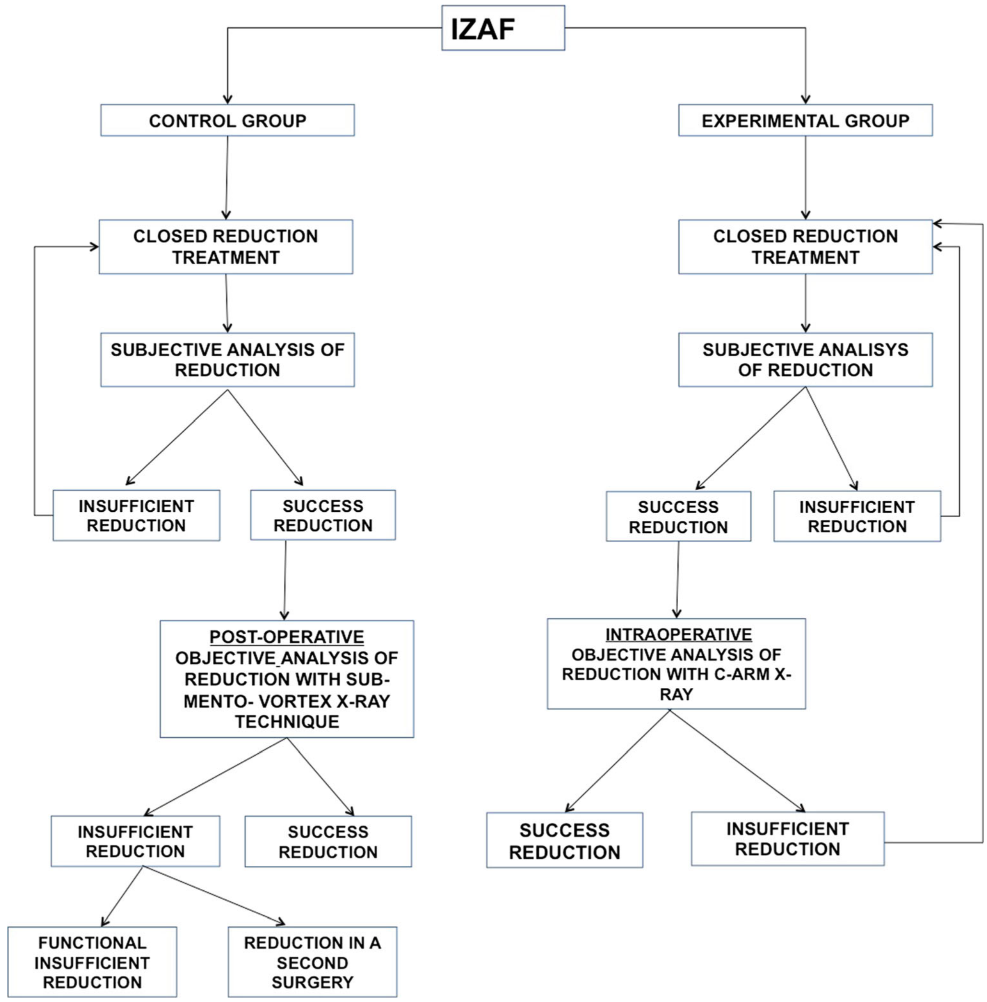

Fig. 2 Algorithm used in this study. In the "control group," insufficient reduction at first surgery required a second surgery to correct alterations, unless a functional and esthetically acceptable reduction was achieved. For their part, in "experimental" group, if there was no reduction or it was insufficient upon evaluating the intraoperative imaging, reduction was repeated at the same surgery

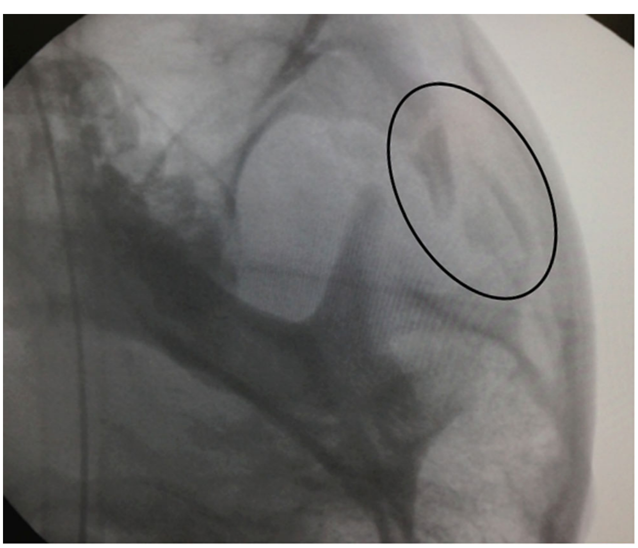

Fig. 3 Intraoperative C-arm image. An insufficient reduction in left arch fracture is observed. The technology allows surgeons to react immediately in the intraoperative phase

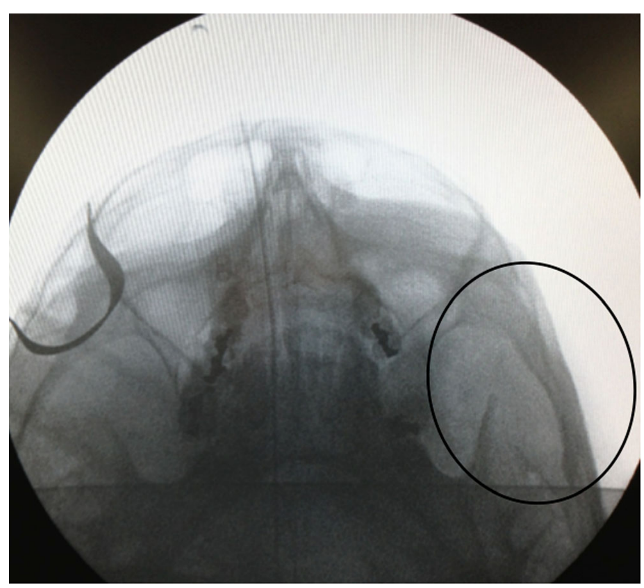

Fig. 4 Objective successful reduction of the isolated zygomatic left arch fracture of patient in Fig. 3 evaluated with intraoperative C-arm image

The primary predictive variable analyzed was the time of the radiographic control in the reduction (obtained intraoperatively with the C-arm versus postoperatively). The primary outcome of interest studied was the need for a second intervention. Another variable studied was the surgeon's subjective clinical evaluation upon completing the reduction. The surgeons affirmed according to his or her perception whether the reduction had been success achieved or not. This variable was contrasted with the objective evaluation produced by the control radiography. Objective or subjective success was defined above.

Stata® software was used for the statistical analysis. Difference in proportions test was used to determine whether there were significant differences between the two groups. A value of $p < 0.05$ was established as a significant difference.

Results

Between January 2009 and December 2011, a total of 109 patients (96 men and 13 women) with zygomatic complex fractures were treated at our center. Of the total, 50 patients (44 men and 6 women) diagnosed with isolated zygomatic M-type arch fractures who received surgical treatment in the form of a distance reduction using a Gillies approach were included in this study, of which 25 patients were randomly assigned to the control group and the remaining 25 to the experimental group. Average patient age was 45 years (range 18–79 age). The primary analysis was intention-to-treat and involved all patients who were randomly assigned. Fifty-eight patients were excluded from the study because they had fractures that extended to other skeletal structures (zygomaticomaxillary fracture mainly). The other patient who was excluded had a comminuted fracture of the zygomatic arch and was treated openly.

Of the patients in the control group, 21 had satisfactory reductions, both subjectively as well as objectively (with postoperative control imaging). In three patients where a clinically adequate reduction was thought to have been achieved, postoperative radiographic control revealed that the reduction had been unsatisfactory. However, the reduction was functional and esthetically acceptable in these three patients, meaning that a second surgery was unnecessary. The remaining patient in this group required a second surgery to correct alterations, as the reduction was insufficient. (Table 1).

For their part, in the experimental group, the intraoperative images revealed an unsatisfactory reduction in four patients, who therefore required two or more reduction attempts in the same operative act. A satisfactory reduction was achieved on the first try in 21 patients from this group (Table 1). In addition, none of the patients in this group required a second surgery as a correct reduction was achieved intraoperatively in all of them.

Our group's experience is that there is no significant difference ($p = 0.5$) when the need for a second intervention upon using postoperative radiography to control reduction is compared with the intraoperative acquisition of images in the difference in proportions test.

Discussion

In line with the objectives of this study, we determined the usefulness of obtaining intraoperative images to control the reduction of IZAF, based on the hypothesis that using a C-arm in the intraoperative evaluation would reduce the need for a second surgery. In addition, we contrasted the surgeon's subjective evaluation after completing the reduction with the objective evaluation of the radiographic control.

The results of this study allow us to confirm the hypothesis that acquiring intraoperative images with a C-arm reduces the need for a second intervention. However, when the results are compared with those of the control group, we did not find a significant difference in terms of the success or failure of the reduction when compared to the use of a conventional postoperative control imaging. In addition, both groups achieved 84 % satisfactory reductions on the first try. Considering these results, we can affirm that the distance reduction of an IZAF by an experienced surgeon will habitually be successful with or without intraoperative images. However, despite the fact that the results are not statistically significant, we recommend using intraoperative radiographic images obtained with a C-arm or with other radiographic methods as a way to control the

Table 1 Closed reduction of isolated zygomatic arch fracture

Control group		Experimental group	
Success reduction at first surgery	21 patients	Success reduction at the first attempt	21 patients
Insufficient reduction at first surgery	3 patients[a]	Success reduction in 2 or more attempts	4 patients
Need for second surgery	1 patient	Need for second surgery	0

[a] Insuficient reduction at radiographic control. However, the reduction was functional and esthetically acceptable in these three patients, meaning that a second operation was unnecessary

reduction of IZAF. The technology allows surgeons to react immediately in the intraoperative phase when an insufficient reduction is detected. In this way, a success rate of close to 100 % in the first operation can be achieved, reducing the need for a second intervention. Furthermore, if an intraoperative imaging method is available in the operating room, it can replace the postoperative control imaging.

The use of intraoperative images is not yet a routine procedure in maxillofacial traumas [9]. Intraoperative radiographic controls are described with increasing frequency in the literature, though the need for them is not yet widely acknowledged [9, 11–13]. The arguments against include the high doses of radiation emitted (usually 0.01–0.03 mSv for plain X-rays vs approximately 2–2.3 mSv for CT scans) and the cost [14]. Though the C-arm does emit radiation, using this radiographic technique (not cone beam), only low-dose nonfluoroscopic views are used and the reductions can be completed with no more than five images. Thus, the accumulated dose is ultimately considerably less than what is emitted by a maxillofacial CT scan [14]. Regarding the cost, the issue is not just economic but also medical. When the need for a second surgical intervention or more is eliminated, the operation room's operational costs are reduced and these can correspond to 30–40 % of the hospital's total costs [12, 14]. Thus, in the case of the use of the C-arm, the cost argument becomes support for its use. In addition, the armamentarium required to acquire this type of images is widely available even in developing countries.

At our level 1 trauma center, a traumatic event in maxillofacial territory is evaluated using a CT scan when indicated. If there is an IZAF with surgery indicated, the reduction is controlled with a two-dimensional image to reduce the radiation that the patient is subjected to, as described in the literature [4, 5]. However, if other structures are compromised, such as the zygoma, then our protocol indicates control with multiplane imaging. We believe it is necessary to undertake an intraoperative imaging analysis using X-rays, CT, via endoscopy, ultrasound, etc. in areas where we are not certain of the reduction. However, anatomical complexity of the maxillofacial skeleton causing significant structural overlap and difficulties in interpretation, in contrast to the long bones, should be considered. Despite the fact that the statistics in our study show that there is no significant difference between an interaoperative control and a postoperative one, obtaining an optimal result on the first intervention, with minimal radiation; reducing the need for a second intervention, and also economic, medical, and morbidity costs, all back the recommendation that intraoperative images be obtained with a C-arm.

Compliance with ethical standards This study was approved by the hospital ethics board, which complies with the Helsinki Declaration.

Fundings Neither authors nor any member of our immediate family has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

Informed consent The patients accepted for this study approved and signed an informed consent.

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