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Predictors of Intraoperative Difficulty and Postoperative Exam Abnormalities in 164 Orbital Operations

Authors
Govind, Akshay
Demirel, Shaban
Lee, Kristin
et al.

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Corresponding Author:	Akshay Govind, DMD, MD, MPH University of California San Francisco San Francisco, California UNITED STATES
First Author:	Akshay Govind, DMD, MD, MPH
Order of Authors:	Akshay Govind, DMD, MD, MPH
	Shaban Demirel, OD, PhD
	Kristin Lee, DDS
	Melissa Amundson, DDS, MPH
	Richard Bryan Bell, MD, DDS
	Eric J Dierks, MD, DMD
Abstract:	Background: Although orbital fractures are common, prediction of outcomes in orbital surgery can be quite challenging. Purpose: We aim to identify predictors of intraoperative difficulty, operating time, and postoperative examination abnormalities in subjects undergoing posttraumatic orbital reconstructions. Study design, setting, and sample: This is a retrospective cohort study of all consecutive orbital operations performed at a private, Level 1 trauma center in Portland, Oregon, USA over an 82-month period. All subjects that underwent exploration of the internal orbit for traumatic indications during the study period were included in the cohort. Predictor variables: Four plating styles, surgical approach (transorbital vs transantral), days from injury to first surgery, fracture size (approximated as a rectangle using linear measurements from CT scans), anteroposterior fracture position, and medial wall involvement were examined. Outcome variables: The primary outcome variable was intraoperative difficulty (defined as requiring revision after intraoperative imaging or return to the OR). Secondary outcome variables included operating time and postoperative examination abnormalities. Covariates: Age and sex were included. Analyses: Chi-square and regression analyses were performed using a significance level of $p < 0.05$. Results: One-hundred-sixty-four orbital operations were performed (90 isolated injuries and 74 combined orbital/midface injuries) on 155 subjects (73% male, mean age 39.8 years, SD 16.7). In subjects with isolated orbital fractures, medial wall involvement was associated with intraoperative difficulty ($p=0.01$). When using a transantral approach, intraoperative difficulty was more likely in more anterior fractures ($p=0.02$). Plating style was associated with operating time ($p=0.03$), with median times from 81 to 105 minutes (range 21 to 248 minutes). Postoperative examination abnormalities were more likely in the transorbital approach group ($p=0.01$). Neither days to first surgery nor intraoperative difficulty were associated with postoperative examination abnormalities. Postoperative eyelid changes were seen in 13.6% of transorbital approaches and 0% of transantral approaches. Correction of gaze restriction and enophthalmos were more likely than correction of diplopia ($p<0.01$). Conclusions and Relevance: Medial wall involvement is associated with intraoperative difficulty in orbital surgery. Anteriorly positioned fractures are better treated transorbitally, while posterior fractures may be amenable to transantral repair, thus avoiding risk of lower eyelid changes.

January 26, 2023

To the Editors of the Journal of Oral and Maxillofacial Surgery,

The following is the final installment in a series of papers I have written from data collected during my fellowship now five years ago! It took years to sort through the data and create a meaningful path for the reader to follow, and I am very proud of the knowledge we have been able to share through this project. I am eager to hear what comments you may have.

Title:
Predictors of Intraoperative Difficulty and Postoperative Exam Abnormalities in 164 Orbital Operations

Akshay Govind, DMD, MD, MPH; Shaban Demirel, OD, PhD; Kristin Lee, DDS; Melissa Amundson, DDS, MPH; R Bryan Bell, MD, DDS; Eric Dierks, MD, DMD

Corresponding author: Akshay Govind
Health Sciences Clinical Assistant Professor – University of California San Francisco
Residency Program Director – Highland Hospital
Former Fellow – Head and Neck Institute, Portland, Oregon
Oral and Maxillofacial Surgery
1411 E 31st St, Oakland, CA 94602
office phone: 510.535.7498
fax: 510.535.7362
Akshay.govind@ucsf.edu

Disclosures: No funding was received for this paper. Dr. Dierks is a paid consultant for KLS-Martin. Dr. Bell is a paid consultant for Stryker.

Thank you,
Akshay Govind

Revision 4 Cover Letter

08/22/2023

Dear Dr. Dodson and Reviewers,

Please see the following notes regarding this revision of the attached manuscript. I truly appreciate your help in making this paper as strong as it can be.

Citation style has been updated with superscripts.

Abstract:
Background: Recommended verbiage was adopted.
Study design, setting, and sample: I condensed the inclusion and exclusion criteria into the most succinct statement I could.
Predictor variables: I could not come up with a way to include specifics about the four plating styles in the abstract without using too many words. It seems reasonable to me for the reader to go to the body of the manuscript and figures for this information, especially because there is not universal language to describe these plating styles. The requested clarifying language has been added to fracture size and anteroposterior fracture position.
Results: Days from injury to first surgery was removed from the parenthetical description of the cohort and replaced with the SD of the age distribution. Negative findings were removed from the abstract. A statistical test was added to compare rates of correction of diplopia to gaze restriction/enophthalmos (also described in the body of the manuscript).

Body of manuscript:
Specific aims: I have added clarifying language around Specific Aims to demonstrate the gap in the existing literature and how the current study looks to address it.
Covariates: I removed the word biologic, and spelled out male and female.
Variables: the words (binary, categorical, etc.) have been removed from the descriptions of the variables.
Associated midface fracture pattern: I've simplified the language here, and rather than list all seven patterns in parentheses, I've referred the reader to figure 2.
Study design/study sample and Data collection/data analysis sections: I modified the inclusion/exclusion criteria section to keep it focused on which subjects are in the cohort. I moved the detail on how we collected information and what kinds of analyses were done to the data collection and data analysis sections, respectively.
Data analysis: I've made the level of statistical significance clearer and added the verbiage around descriptive and bivariate analyses, describing the statistics calculated for each variable in the body of the text.
I have removed the heading labeled Conclusion and modified language at the end of the discussion to close the paper.

Tables:
Table 1 was modified as follows:
Replaced word "Gender" with "Sex"
I added rows for all the data that were collected: Approach, Days from Injury to First Surgery, and Follow-up time. Where appropriate, the n was added to the row.

The added rows are also described in the corresponding section of the Results (Descriptive Statistics of the Study Sample).

What was formerly Table 2 has been split into Tables 2A – 2D, so that each outcome studied has its own table. P-values have been updated to round to the nearest hundredth.

In order to improve the formatting of Table 3 without changing the margins, I found it most effective to change that page to a landscape layout in this manuscript. I believe the font and margins used by the journal will allow this to fit on the page in portrait layout, but I will certainly defer to the copy and/or proof editors for the best ways to display this table.

Sincerely,

Akshay Govind

Predictors of Intraoperative Difficulty and Postoperative Exam Abnormalities in 164 Orbital Operations

Author 1: Akshay Govind, DMD, MD, MPH – Corresponding author
Health Sciences Clinical Assistant Professor – University of California San Francisco
Residency Program Director – Highland Hospital
Former Fellow – Head and Neck Institute, Portland, Oregon
Oral and Maxillofacial Surgery
1411 E 31st St, Oakland, CA 94602
office phone: 510.535.7498
fax: 510.535.7362
Akshay.govind@ucsf.edu

Author 2: Shaban Demirel, OD, PhD
Director of Clinical Research
Legacy Research Institute, Portland, Oregon

Author 3: Kristin Lee, DDS
Former Resident
Highland Hospital, Oakland, CA

Author 4: Melissa Amundson, DDS, MPH, FACS
Clinical Assistant Professor – Florida State University College of Medicine. Maxillofacial Trauma, Tallahassee Memorial Hospital.

Author 5: Richard Bryan Bell, MD, DDS
Physician Executive and Director, Surgical Oncology, Providence Cancer Institute
Former Faculty – Head and Neck Institute, Portland, Oregon

Author 6: Eric Dierks, MD, DMD
Faculty Emeritus – Head and Neck Institute, Portland, Oregon

Predictors of Intraoperative Difficulty and Postoperative Examination Abnormalities in 164 Orbital Operations

Abstract

Background: Although orbital fractures are common, prediction of outcomes in orbital surgery can be quite challenging.

Purpose: We aim to identify predictors of intraoperative difficulty, operating time, and postoperative examination abnormalities in subjects undergoing posttraumatic orbital reconstructions.

Study design, setting, and sample: This is a retrospective cohort study of all consecutive orbital operations performed at a private, Level 1 trauma center in Portland, Oregon, USA over an 82-month period. All subjects that underwent exploration of the internal orbit for traumatic indications during the study period were included in the cohort.

Predictor variables: Four plating styles, surgical approach (transorbital vs transantral), days from injury to first surgery, fracture size (approximated as a rectangle using linear measurements from CT scans), anteroposterior fracture position, and medial wall involvement were examined.

Outcome variables: The primary outcome variable was intraoperative difficulty (defined as requiring revision after intraoperative imaging or return to the OR). Secondary outcome variables included operating time and postoperative examination abnormalities.

Covariates: Age and sex were included.

Analyses: Chi-square and regression analyses were performed using a significance level of $p < 0.05$.

Results: One-hundred-sixty-four orbital operations were performed (90 isolated injuries and 74 combined orbital/midface injuries) on 155 subjects (73% male, mean age 39.8 years, SD 16.7). In subjects with isolated orbital fractures, medial wall involvement was associated with intraoperative difficulty ($p=0.01$). When using a transantral approach, intraoperative difficulty was more likely in more anterior fractures ($p=0.02$). Plating style was associated with operating time ($p=0.03$), with median times from 81 to 105 minutes (range 21 to 248 minutes). Postoperative examination abnormalities were more likely in the transorbital approach group ($p=0.01$). Neither days to first surgery nor intraoperative difficulty were associated with postoperative examination abnormalities. Postoperative eyelid changes were seen in 13.6% of transorbital approaches and 0% of transantral approaches. Correction of gaze restriction and enophthalmos were more likely than correction of diplopia ($p<0.01$).

Conclusions and Relevance: Medial wall involvement is associated with intraoperative difficulty in orbital surgery. Anteriorly positioned fractures are better treated transorbitally, while posterior fractures may be amenable to transantral repair, thus avoiding risk of lower eyelid changes.

Introduction

Orbital fractures have an incidence of 10-25% in patients who sustain facial fractures, with 60-70% of those involving the orbital floor.[1,2] Fractures of the orbit may be seen as isolated injuries or in combination with other midface fractures, and left untreated, sequelae may be either functional or esthetic. Functional complications include binocular diplopia, gaze restriction, or oculocardiac reflex.[1,3] Esthetic complications are typically related to changes in globe position secondary to an altered orbital volume, and may include enophthalmos or vertical dystopia.[3,4]

Absolute indications for immediate orbital surgery are entrapment of the periorbita or the presence of a new oculocardiac reflex. However, the indications for delayed surgical intervention are frequently more subtle, requiring the surgeon to assess findings such as diplopia and/or enophthalmos over time. Orbital surgery may have functional or esthetic complications of its own; even a well-executed surgery may not result in complete resolution of diplopia, gaze restriction, or enophthalmos, and depending on the approach taken, there may be changes to the appearance of the eyelid. Less frequently, there may be infection or inflammation of the orbit or maxillary sinus, and even less frequently, changes that lead to a decrease in or loss of vision.

The goals of surgical repair are to restore synchronous movement of the eyes in all directions and normal projection of and support for the eyes in vertical, anteroposterior, and mediolateral dimensions. This is only possible if the remainder of the midface is correctly positioned. As a result, orbital floor fractures are frequently treated as the final step in larger midface fractures, and this may be done at the same time or in a delayed fashion, depending on the individual case or surgeon's preference.

Conventionally, repairs of orbital floor fractures were performed transorbitally (using incisions either through the lower conjunctiva or lower eyelid), and following surgery, a clinical exam in the recovery unit and CT scan were performed to determine whether reconstruction was acceptable. Our group has previously described multiple techniques and proof of concept for repairing orbital floor fractures transantrally without need for an endoscope,[5] and use of intraoperative CT scanning for orbital reconstruction has been advocated for over 20 years.[6,7,8]

Kwon et al[9] have suggested that large, non-trapdoor and posteriorly located orbital floor fractures are more efficiently treated using a transantral approach, while smaller, trap-door and anterior orbital fractures may be better treated using a transorbital approach. Kwon's group is referring to the intraoperative experience most facial trauma surgeons have faced, specifically that sometimes reconstructing an orbit can be simple and satisfying, while other times it can be fraught with difficulty and hardship. Thus, the specific aim of the current study is to explore this gap in the literature about what factors, related to both injury patterns and surgeon choices, may contribute to intraoperative difficulty.

The purpose of the study is to identify variables associated with intraoperative difficulty and postoperative examination abnormalities in the operative management of orbital fractures, as well as to compare operating times of various plating styles and approaches. Our hypothesis was that there would be factors related to demographics, injury patterns, and surgical technique that may predict these outcomes.

Methods

Study Design/Sample

Prior to collection of data, this study was submitted to the Legacy Health Institutional Review Board under Study 1563, and approval was subsequently granted. A retrospective cohort study of all consecutive orbital trauma reconstruction surgeries performed between May 19, 2011 and March 27. 2018 at a private Level 1 Trauma Center in Portland, Oregon, USA was conducted. The source of the sample was the electronic health record (EHR) operating room schedule for the oral and maxillofacial surgery service from the time of the EHR's implementation to the time the data were collected. At this institution, all facial trauma is treated by the oral and maxillofacial surgery service, with a total of 8 attending surgeons in the practice during the study period. Our sample included subjects with isolated orbital injuries as well as those with orbital injuries combined with other midface fractures. The sample reflected use of four different plating techniques through both transorbital and transantral approaches, largely with the aid of intraoperative 3-D imaging.

Inclusion and Exclusion Criteria

Subjects were included in initial screening if they had a surgery posted to the EHR operating room schedule under one or more of the 8 OMFS attending surgeons during the study period. Subjects were then included in operative report review if the initial screening included a procedure name as documented by the nursing staff that involved any mention of repair of fractures of the midface (orbit, Le Fort, zygomaticomaxillary complex, nasoorbitoethmoid, nasal, frontal sinus, panface, gunshot wounds). Subjects were excluded from this step if their surgeries were performed for non-traumatic indications (e.g. pathology, orthognathic surgery, temporomandibular disorders, etc.), if their bony trauma was isolated to the mandible, or if the injury involved soft tissues only.

Subjects were then included in the cohort for analysis if their surgery involved an exploration or reconstruction of the internal orbit. Subjects were excluded at this step if their midface reduction did not require exploration of the contents of the internal orbit (e.g. inferior orbital rim used as a landmark in reducing a zygomaticomaxillary complex fracture without exploring the orbital floor itself). The entire cohort included those with isolated orbital injuries as well as those with combined orbital/midface fractures, although these groups were analyzed differently (described in the data collection and analysis sections below). All inclusion and exclusion criteria were applied by the primary author (AG) to yield our final samples.

Variables

Predictor Variables

The predictor variables were composed of a set of heterogeneous groups, including:

- **Days from Injury to First Surgery:** This variable was defined as the number of days between the reported injury and the first orbital surgery. The date of injury was obtained from chart review, as reported in the history and physical examination. Dates of surgery were obtained from the operating room schedule. If a subject was operated on more than once, only the first date of surgery was utilized for this calculation.
- **Plating style:** Postoperative CT scans were reviewed by the primary author (AG) and compared with operating room implant logs and operative reports to place the orbital

implant into one of four categories. The four major designs utilized in our cohort are described below and can be visualized in Figure 1.

- Transorbitally-placed flat plate (Figure 1a)
- Transorbitally-placed anatomic plate (with a wing-like extension that climbs more than 2 mm up the medial wall of the orbit – Figure 1b)
- Transantrally-placed flat and broad plate (Bell-style – Figures 1c and 1d)
- Transantrally-placed linear and narrow plate (Dierks-style – Figures 1e and 1f)

- **Approach:** This variable was defined as transorbital (including transconjunctival, transcaruncular, or transcutaneous through the lower eyelid), transantral (through a maxillary vestibular incision and anterior maxillary antrostomy), or mixed (using a combination of approaches from above and below the orbital floor). The approach for each case was ascertained from the operative report.

- **Medial wall involvement:** Preoperative maxillofacial CT scans with ≤1 mm cuts were reviewed by the primary author (AG) in coronal, sagittal, and axial views using PACS (Picture Archiving and Communications System). In coronal views, medial wall involvement was recorded as present if a displaced orbital floor fracture continued medially to cross the midpoint of the transition between the horizontal contour of the orbital floor and the vertical contour of the medial wall. Non-displaced fractures of the lamina papyracea that did not affect orbital volume were recorded as not having medial wall involvement.

- **Anteroposterior position of the fracture:** In sagittal views of the preoperative CT scans, the distance from the inferior orbital rim to the anterior edge of the fracture was measured and recorded in mm.
- **Size of fracture:** In coronal and sagittal views of the preoperative CT scans, the largest dimensions of the orbital floor fractures were measured in mediolateral and anteroposterior dimensions, and the area (in mm^2) was approximated as a rectangle. If the medial wall was involved, the medial-most point of the fracture was approximated at the midpoint of the transition between the horizontal contour of the orbital floor and the vertical contour of the medial wall.

Outcome Variables

The primary outcome of our study was intraoperative difficulty, which was recorded as either present or absent. Intraoperative difficulty was defined as significant manipulation of the reconstructive material after intraoperative 3-D imaging or a return to the operating room due to an unacceptable postoperative result. In our isolated orbital injury group, we also evaluated the outcomes of operating time and postoperative examination abnormalities. Operating time was recorded in minutes from the operating room log, from the time marked "Procedure Start" until the time marked "Procedure End." Postoperative examination abnormalities were recorded by reviewing postoperative progress notes and/or photographs included in subjects' charts and included eyelid changes, globe position changes, changes in vision, diplopia, and gaze restriction. Subjects with orbital fractures combined with other midface fractures were excluded from postoperative analysis due to the heterogeneity of injury patterns.

Postoperative examination abnormalities were recorded as present if any of the postoperative records mentioned esthetic abnormalities (enophthalmos, exophthalmos, or eyelid changes such as entropion, ectropion, or changes in scleral show), oculo-functional abnormalities (diplopia, gaze restriction, or visual changes), or any other complications (sinusitis, palpable plate, hematoma, neuropathic pain, or interference with the inferior rectus muscle). There was no calibration to how chart notes were written at the time of the patient encounters.

Covariates and other variables collected

The covariates assessed in our cohort were age at time of surgery and sex (male (M)/female (F), as recorded in the subjects' demographic information). Other variables collected from a combination of chart review and CT scan review included laterality of fracture (left, right, or bilateral), use of an endoscope (yes/no), use of intraoperative navigation (yes/no), use of intraoperative 3-D imaging (CT, C-arm, none), and associated midface fracture pattern, if applicable (see Figure 2 for complete list).

Data collection

Data collection began by reviewing the operating room log for any procedures listed as reconstruction or open reduction internal fixation of the orbits or midface (Zygomaticomaxillary complex, Le Fort level fractures, or Naso-orbito-ethmoid complex). Operative reports were then reviewed, and subjects were included if the operative reports described any surgical exploration of the internal orbit. For included subjects, demographic information, pre and post-surgery CT scans, history and physical examination notes, operative reports, implant logs, clinical follow-up notes, and any clinical photographs were reviewed by the primary author (AG).

The cohort was divided into two main groups: those with isolated orbital injuries and those with combined orbital/midface fractures. In order to be included in combined orbital/midface fracture category, the internal orbital fracture needed to be contiguous with the associated midface fracture such that reduction of the latter would influence intraoperative assessment of the former. Subjects with internal orbital fractures and non-contiguous injuries (nasal fractures, alveolar fractures, soft tissue lacerations) were included in the isolated orbital injury group.

Data analyses:

All statistical analysis was performed on R (R Core Team 2021) using a significance level of p-value < 0.05. The entire cohort was included in the descriptive analysis as well as analysis for the primary outcome of intraoperative difficulty. Among those with associated midface fractures, only the subgroup with a diagnosis of zygomaticomaxillary complex fracture was large enough to evaluate for a relationship between approach to the orbital floor (transorbital vs transantral) and our primary outcome of intraoperative difficulty (using chi-square analysis). The following predictor variables were analyzed to explore their bivariate relationship with our primary outcome of intraoperative difficulty: days from injury to first surgery (logistic regression), distance from inferior orbital rim to anterior edge of fracture (logistic regression), size of fracture (logistic regression), medial wall involvement (chi-square), surgical approach (chi-square), and plating style (chi-square).

Secondary outcome analyses were performed only on the group with isolated orbital injuries. Subjects were included in the analysis for operating time only if their internal orbital exploration and reconstruction was the sole procedure performed during their operation. Analysis for postoperative examination abnormalities was performed only if subjects had greater than five days of follow-up, due to the interference of acute surgical edema on postoperative outcome analysis.

The secondary outcome of operating time was explored using the predictor variables of plating style (linear regression + ANOVA) and surgical approach (linear regression). The secondary outcome of postoperative examination abnormalities was explored using the following predictor variables: days from injury to first surgery (logistic regression), medial wall involvement (chi-square), surgical approach (chi-square), and plating style (chi-square). Next, analysis was performed to see if encountering intraoperative difficulty was associated with having a postoperative examination abnormality (chi-square). Covariates of age and sex were analyzed with each of the outcomes of interest. The additional variables collected were used to descriptively characterize the cohort.

Lastly, the incidence of specific postoperative examination abnormalities was recorded using simple proportions; presurgical and postsurgical incidence of diplopia, enophthalmos, and gaze restriction were then compared using a proportions test.

RESULTS

Descriptive Statistics of the Study Sample

The entire study sample consisted of 155 subjects who underwent 164 orbital operations. Ninety of these surgeries were performed on 87 subjects with isolated orbital fractures, during which intraoperative difficulty was encountered in 30 cases (33.3%). Seventy-four surgeries were performed on 68 subjects with orbital fractures combined with midface fractures, and intraoperative difficulty was encountered in 31 cases (41.9%). The sample was predominantly male (73%), had a mean age of 39.8 years (SD 16.7 years, Range 4.7 - 81.7 years), and nearly even laterality of injuries. An endoscope was used in 5.5% of cases, navigation in 8.6% of cases, and intraoperative 3-D imaging in 82.8% of cases. A transorbital approach was used in 71.2% of cases, transantral approach in 22.1% of cases, and a mixed approach in 6.7% of cases. Among the isolated orbital injury group, the median time from injury to first surgery was 13 days (IQR 5- 21 days, range 0 – 160 days). For the 74 subjects included in post-operative analysis, median follow-up time was 27 days (IQR 15.25 - 65.25 days, range 6 – 1,152 days). Descriptive statistics of the cohort are outlined in Table 1.

Combined Orbital/Midface Fractures

Of the 74 orbital operations performed on 68 subjects with associated midface fractures, the frequency of each injury type is demonstrated in Figure 2. As a group, numbers were too small and injury patterns too heterogeneous to make comparisons across different injury patterns. However, we were able to analyze the largest subgroup with orbital injuries combined with zygomaticomaxillary complex fractures (n=40) for our primary outcome of intraoperative difficulty using approach as a predictor variable. We found a trend toward greater intraoperative difficulty in the group treated with transorbital approaches (14/32) compared to those treated with transantral or mixed approaches (1/8), although our sample size was too small to reach formal statistical significance (p=0.10).

Isolated Orbital Injuries

The majority of our statistical analysis focused on the group with isolated orbital injuries**,** where we examined 90 surgeries on 87 subjects; these results are outlined in Tables 2A - 2D and are further described in the following text. Typically, patients were first operated on within 3 weeks of their injuries (median 13 days, IQR 5 to 21 days, range 0-160 days).

Primary outcome analysis

Intraoperative Difficulty:

The following were not associated with intraoperative difficulty: days from injury to first surgery (p=0.69), plating style (p=0.36), approach (p=0.82), size of the fracture (p=0.38 for transantral and p=0.33 for transorbital). Numbers were too small to analyze for the effect of use of adjuncts such as an endoscope or navigation, and routine use of intraoperative 3-D imaging prevented us from isolating its effect in this cohort.

Medial wall involvement was associated with intraoperative difficulty (p=0.01) in all approaches and plating styles. When using a transantral approach, distance from the inferior orbital rim to the anterior edge of the fracture was associated with intraoperative difficulty. Specifically, the more posterior the fracture, the less likely we were to encounter intraoperative difficulty using the transantral approach (coefficient = -0.406, p=0.02 using logistic regression). The anteroposterior position of the fracture was not associated with intraoperative difficulty using a transorbital approach (p=0.74). The data did not support a particular "cutoff point" in anteroposterior fracture position to guide decision-making in choice of approach. These results are tabulated in Table 2A.

Secondary outcome analysis

Operating time:

Operating time was examined to compare and contrast the different surgical techniques (four major plating styles using transorbital and/or transantral approaches) utilized in this cohort. Operating time was calculated in the 74 operations where the orbital repair was the only injury addressed during the operation. In the 16 operations that were excluded from this analysis on subjects classified as having isolated orbital fractures, something else like a laceration repair or treatment of dental or nasal trauma contributed to operating time but did not change the classification of the orbital trauma.

In the four major plating styles employed in our cohort, median operating times were between 81 and 105 minutes, with a range from 21 to 248 minutes. Plating style and surgical approach were analyzed as predictors of operating time: We found a significant effect of plating style on operating time (p=0.03), with median times in ascending order from shortest to longest: Bell-style transantral (81 minutes), anatomic transorbital (89 minutes), flat transorbital (94 minutes), and Dierks-style transantral (105 minutes) plate designs. Surgical approach (transantral/mixed vs transorbital) was not found to be a significant predictor of operating time ($p=0.47$). These results are tabulated in Table 2B.

Postoperative examination abnormalities:

Subjects were included in postoperative analysis if they had more than 5 days of follow-up from the date of surgery. Of the 87 subjects who had surgery on isolated orbital injuries, 13 had follow-up time 5 days or less and were thus excluded from our analysis of postoperative examination abnormalities. This left 74 subjects in the postoperative analysis with a median follow-up of 27 days (IQR 15.25 - 65.25 days).

Patients operated on using transorbital approaches were more likely to have any postoperative examination abnormality ($p=0.01$) and an oculo-functional ($p<0.01$) postoperative abnormality compared to those treated using a transantral or mixed approach. There was no significant effect from time from injury to first surgery in predicting postoperative examination abnormalities ($p=0.25$ for any abnormality and $p=0.13$ for oculo-functional abnormalities). Intraoperative difficulty ($p=0.90$) was not found to be associated with postoperative examination abnormalities. There was a trend toward a large effect of medial wall involvement predicting an oculo-functional postoperative abnormality (45% vs 25%) but did not reach statistical significance in our sample size ($p = 0.17$).

There is a complex relationship between plating style and post-operative examination abnormalities ($p<0.01$). If the medial wall is not involved, use of the anatomical plate that climbs the medial wall is more likely to result in a postoperative examination abnormality ($p=0.02$). Although the use of an anatomical plate shows a trend towards more postoperative examination abnormalities, its use is confounded by medial wall fracture involvement. If the medial wall is involved, reconstructing it with an anatomical plate decreases the likelihood of having post-operative enophthalmos and may justify reconstructing the medial component. However, if the medial wall is not fractured, there is no benefit to using a plate that climbs the medial wall. Predictors of having any postoperative examination abnormality are tabulated in Table 2C, and predictors of having a postoperative oculo-functional examination abnormality are tabulated in Table 2D.

Eyelid changes:

Postoperative eyelid changes were seen in 13.6% of subjects who underwent transorbital approaches, while none were seen in our transantral or mixed approach groups. Examples of eyelid changes seen in our cohort include changes in scleral show, ptosis, entropion, and scar contracture.

Diplopia, enophthalmos, and gaze restriction:

Diplopia, enophthalmos, and gaze restriction are common findings in orbital injuries that may be found prior to surgery and may persist after surgery as well. The presence of any of these findings preoperatively is thought to put one at risk for having these findings postoperatively, and the many variables discussed in the patterns of injury and reconstruction influence these risks as well.

The likelihood that these abnormalities were present before surgery and no longer present after surgery were as follows: 51.3% for diplopia, 84.4% for enophthalmos, and 85.0% for gaze restriction, and the improvements in outcomes for enophthalmos and gaze restriction combined were statistically significantly better than those for diplopia ($p<0.01$). Conversely, in subjects who did not have these conditions preoperatively, there was a 11.8% likelihood of postoperative diplopia, a 12.2% likelihood of new globe position change, and a 7.5% likelihood of new gaze restriction after surgery. Figure 3 demonstrates the frequency with which ocular examination abnormalities were resolved by or newly found after orbital surgery. Table 3 outlines the frequency of the specific postoperative examination abnormalities encountered, stratified by approach.

Covariate analysis

Bivariate regression analyses were performed analyzing the relationships between age and sex and our outcomes, and the potential covariates were not found to exert a significant effect on any of the outcomes analyzed (included in Tables 2A-D). Therefore, there was no need to adjust the rest of our analyses for covariates.

Discussion

The current study provides a thorough retrospective analysis of factors maxillofacial trauma surgeons must consider while evaluating and treating orbital fractures in the era of access to intraoperative three-dimensional imaging. Our hypothesis was that we would find factors related to demographics, injury patterns, and surgical technique that may predict operating time, intraoperative difficulty, or postoperative examination abnormalities. We found medial wall involvement to be a predictor of intraoperative difficulty and that more anterior fractures predicted intraoperative difficulty in the transantral approach. Plating style had a significant effect on operating time, and both plating style and approach had effects on incidence of postoperative examination abnormalities, with lower overall and oculo-functional abnormality rates seen in the transantral approach.

Our sample size 155 subjects reflects a demographic of mostly younger males, as is common in the facial trauma literature. Intraoperative 3-D imaging was utilized in 82.8% of cases, and while our group has published previously on the use of intraoperative 3-D imaging in midface trauma,[8,10] the current study describes more fully our advocacy for intraoperative image-guided decision-making. This is captured in our primary outcome measure of “intraoperative difficulty.” In our cohort, intraoperative images were obtained either when the surgeon felt the reconstruction was complete or when he/she felt the next maneuver was not easily made by clinical evaluation alone. In our research protocol, Intraoperative Difficulty was recorded as present if either the reconstructive material needed to be removed and repositioned based on intraoperative imaging or if the patient needed to return to the operating room because of an unacceptable postoperative result.

Orbital Injuries Combined with Other Midface Fractures

For our 74 orbital operations combined with other midface fractures, zygomaticomaxillary complex fractures were the most common (n=40) and the most comparable. Le Fort, NOE, blast, or pan-facial fractures were too heterogeneous to give more specific guidelines, however, the principle of reducing and fixating the framework of the midface and then re-evaluating the orbital fractures remains sound. For operative zygomatico-orbito-maxillary complex (ZOMC) fractures, patients will almost always already have a maxillary vestibular incision, and thus it makes sense to evaluate whether a transantral repair of the orbital floor can be done successfully to avoid an additional incision. Further, intraoperative difficulty was encountered more frequently in the ZOMC fracture pattern when using a transorbital approach, but sample size was not large enough to reach statistical significance. The current authors advocate that after fixation of the zygoma, the orbital fracture should be assessed, repaired transantrally if possible, and if not, repaired by a transorbital or mixed approach. Given the retrospective nature of the current study, it is possible surgeons in our cohort chose the transantral approach on more straightforward cases, so future researchers should consider designing prospective studies on ZOMC fractures where the initial approach to the orbital floor component is randomized.

Isolated Orbital Injuries

Among the 87 subjects who underwent 90 surgeries for isolated orbital injuries, our study compared four major plating styles using transorbital, transantral, or mixed approaches, evaluating for operating time, intraoperative difficulty, and postoperative examination abnormalities. Indications for surgery were in line with standard teachings on orbital repairs, with three subjects (3.4%) undergoing surgery for true acute entrapment and the remainder undergoing surgery to address diplopia (53%), gaze restriction (28.7%), and/or enophthalmos (42.5%), noting that a single subject may have had more than one indication for surgery. Although a statistically significant difference was found in operating time by plating style, all plating styles had marked ranges, highlighting the multitude of factors that influence the challenge of orbital reconstruction.

Our cohort was treated with the following reconstructive materials: Titanium (81.1%), Porous Polyethylene-coated Titanium (7.8%), Resorbable plate or film (6.7%), bone (3.3%), and Porous Polyethylene (1.1%) using the four major plating styles illustrated in Figure 1. Our material choices reflect an overall preference for using screw fixation to secure the reconstructive material. We did not find that one plating style, material, or approach reigned supreme in terms of intraoperative difficulty across all injury patterns, and we found no relationship between the size of the fracture and the likelihood of encountering intraoperative difficulty. We did find that when using a transantral approach, intraoperative difficulty was encountered more frequently the more anterior the fracture was. Thus, a transantral approach is more likely to be the right choice for a posteriorly positioned floor fracture, whereas a fracture that is more anterior or requires reconstruction of the medial wall is better approached transorbitally. Our findings are consistent with prior literature from Kwon,[9] although neither Kwon nor we found a single cutoff value for distance from the inferior orbital rim that should dictate the choice of approach. Our group has previously shown that orbital volume can be restored in simple orbital floor fractures using either transorbital or transantral approaches.[11] Size of the fracture influences how likely a patient is to suffer entrapment (small fractures) or enophthalmos (large fractures), but this was not predictive of intraoperative difficulty or postoperative examination abnormalities in our sample.

Our study shows that there are characteristics of the injuries themselves that influence how challenging an orbital repair will be. Specifically, involvement of the medial wall complicates both the dissection and the reconstruction. In all approaches and plating styles, medial wall involvement was associated with intraoperative difficulty and showed a trend toward postoperative oculo-functional abnormalities, and this should guide surgeons to schedule more OR time and consider having intraoperative 3-dimensional imaging available to guide surgery, if they do not already use it routinely. It is well known that the transconjunctival incision can be extended to the medial orbit to join with a transcaruncular incision, but some surgeons hesitate to extend medial to the lower lid punctum, for fear of disrupting the lacrimal sac. While we do not have data to say if inadequate exposure contributed to intraoperative difficulty in our cohort, we reiterate the principle of optimizing surgical exposure to facilitate full appreciation of relevant landmarks for reconstruction. Over the past several years, plating companies have offered preformed orbital plates with approximated orbital anatomy. These often have a wing-like extension meant to climb the medial wall of the orbit. One key finding of our study is that use of such a plate, which requires more medial dissection, increases the risk of postoperative examination abnormalities. Thus, zealous medial dissection and use of an anatomic plate is only advocated if the medial wall is actually fractured and in need of reconstruction.

Our analysis offers a nuanced report of postoperative outcomes in orbital surgery that can help direct anticipatory guidance given to patients. Complication rates in published literature on orbital surgery vary wildly, ranging from 3.0% to 85.5%.[4] We chose to report even the most subtle postoperative examination abnormalities described in our clinical notes; among those with more than 5 days of follow-up (n=74), some detectable examination abnormality was present in 54.1% of subjects with a median follow-up time of 27 days. Diplopia, gaze restriction, and eyelid changes were more common in transorbital approaches while enophthalmos was more common in in the transantral approach.

Prior studies on complications following orbital surgery are outlined below:

Gosau et al[4] found a 19% complication rate among 189 subjects who underwent orbital surgery (including both isolated fractures and those mixed with other midface fractures). In this cohort, 50% of subjects were operated on by the 3rd day after injury. All approaches were transorbital, using approaches such as midlid (66.1%), infraorbital (22.2%), subciliary (6.9%), and either transconjunctival or existing wounds (4.8%). This study used primarily PDS (70.5%) and Ethisorb Dura (23.3%) sheets. Titanium mesh was used 6.2% of the time. Baumann et al,[12] in a cohort of 32 subjects undergoing orbital surgery, showed a perioperative complication requiring take-back to the OR in 3 subjects. Additional postoperative findings were enophthalmos 22.6% of the time, and diplopia in 61.3% at 1 week, 35.5% at one month, and 32.3% at 6 months. Of the 10 subjects with diplopia at 6 months, two were significantly impaired by the diplopia. Brucoli et al[13] found in a cohort of 40 subjects, that diplopia was seen in 17/40 subjects and enophthalmos in 11/40. Eyelid changes were not documented. Nam et al,[14] using largely a subciliary approach in 405 cases, reported 5.4% with enophthalmos and 1.5% with diplopia with a mean follow-up time of 8 months. This low rate of diplopia is due to their definition of double vision within 30 degrees of primary gaze, thus excluding many who experienced diplopia in more extremes of gaze. Notably absent is any comment on eyelid changes. Holtmann et al[15] reported on 507 subjects who underwent orbital surgery, primarily using PDS-foil for smaller fractures and titanium mesh for larger fractures. They report on a lower complication rate in the PDS group, but the size of the PDS group was more than 20 times the size of the titanium mesh group (470 vs 22). Nevertheless, this study does show improvement in rates of diplopia in patients with small orbital fractures treated with PDS-foil. Our study's findings on postoperative exam abnormalities are in line with findings from past literature, reminding the reader that orbital surgery, at least in the weeks to months following surgery, comes with a high rate of imperfection.

Recommendations in the literature vary on optimal timing for orbital repair. Some advocate for early operations on the grounds that there will be less soft tissue scarring, making surgery easier and lowering postoperative complication rates. Others advocate for delayed evaluation to minimize unnecessary operations on people who would not develop hard indications for surgery.[16] Our median interval between between injury and first surgery was 13 days, with an upper quartile of 21 days. While we did not find a relationship between this interval and intraoperative difficulty or postoperative examination abnormalities in our sample, it is important to recognize that our data do not answer the question of whether delayed operations (months after the injury) are more difficult or have more complications than those done in the acute period. Further, the development of enophthlamos and the persistence of diplopia cannot be reliably predicted by the radiographic and clinical findings in the first few days after an orbital injury. As such, a practice of immediate operation may lead to unnecessary surgeries, and some proportion of those can be expected to have postoperative abnormalities. Therefore, the current authors favor waiting for resolution of acute edema in non-emergent cases, giving both the patient and the surgeon data over time to make a careful decision about whether to pursue surgery. Currently, the role of 3-D printing to create patient-specific templates or hardware for orbital surgery is emerging. Case reports and series have been published demonstrating the safety of the technique, but due to a lack of controlled studies, it remains unclear what contribution 3-D printing alone makes to outcomes in orbital surgery.[17]

For many patients, a modest amount of enophthalmos will be less bothersome than diplopia, gaze restriction, or a change in appearance of the eyelid. In our sample, those with documented pre-operative gaze restriction and enophthalmos had complete resolution of these findings in 84.4% and 85% of cases, respectively. Resolution of diplopia was much more difficult to predict, as only 51.3% of subjects with preoperative diplopia had absolutely no postoperative diplopia. Our median follow-up time was 27 days, and we did find cases where diplopia was still present at 1 or 2-week follow-up visits that eventually resolved by several weeks out. Some of our subjects who only followed up for a short period of time were recorded as having diplopia, thus likely overestimating the incidence of this outcome long-term.

Using this very sensitive definition, our cohort showed an overall postoperative exam abnormality rate of 54.1%, which is within the range of what has been described in prior literature. Interestingly, intraoperative difficulty was not associated with postoperative exam abnormalities, but we did find a higher rate of postoperative examination abnormalities in the transorbital approach group than the transantral or mixed approach group. We believe eyelid changes are among the most significant findings of this report, as even a well-placed transconjunctival or mid-lid incision may lead to subtle but noticeable changes in the eyelid. It has been well established that the subciliary incision is not appropriate for trauma[18] due to increased risk of ectropion, and this approach was not used in our cohort. We advocate for counseling patients to expect some ongoing challenges with the operated eye in the short-to-medium term.

Critics of our study will rightfully mention the limitations of its retrospective nature, particularly the fact a systematic protocol was not followed as surgeons decided on the specifics of surgery: the approach, the plating style, and the assessments of the intraoperative images and suitability of reconstruction. Our findings that favor the transantral approach could be due to case selection, highlighting the need for prospective studies in this field. Another limitation of our study is that our subject list was generated using an operating room log, meaning we did not capture the courses of subjects who had similar injuries and did not undergo surgery. Additionally, because the vast majority of our cohort was operated on within the first three weeks after the injury, we do not answer the question of whether operating on orbital fractures in the acute period is any more or less favorable than a delayed approach (months later).

Follow-up times in our cohort are quite variable, thus likely overestimating our rates of postoperative abnormalities; however, this did not affect our analysis for our primary outcome of intraoperative difficulty. Lastly, one must consider the problem of having run multiple comparisons, thus increasing the likelihood of achieving statistical significance by chance alone. The authors accept that this retrospective study was meant to explore multiple variables to generate hypotheses to test more robustly in prospective studies. Future studies should consider using standardized photographs (preoperative and postoperative), calibrated use of a Hertel exophthalmometer, and/or videos of eye movement with evaluators blinded to the surgery status of subjects, rather than relying on chart notes, often written by multiple providers without any calibration. Creation of a Likert scale for intraoperative difficulty might also be useful to correlate with the binary definition used in the current study.

Nevertheless, our study highlights many important considerations in treatment of orbital fractures in the era of intraoperative 3-D imaging. Medial wall involvement is associated with increased incidence of intraoperative difficulty; anterior fractures are better treated transorbitally, while posterior fractures may be better suited to transantral repair. The major advantage of the latter is avoidance of changes to the lower eyelid. Preoperative findings of enophthalmos and gaze restriction are far more predictable to correct with surgery than diplopia. Time from injury to first surgery was not associated with intraoperative difficulty or postoperative exam abnormalities, and therefore surgeons should consider allowing acute edema to subside before deciding with their patients whether to pursue surgery in non-emergent cases of orbital trauma.

Table 1. Descriptive Statistics of 164 Orbital Operations in 155 Subjects

Descriptive Statistics **n=155**			
Age (years)	Mean 39.8	SD 16.7	Range 4.7 - 81.7
Sex	27% F	73% M	
Laterality	47.2% R	50.3% L	2.5% Bilateral
Use of Endoscope	5.5% Yes	94.5% No	
Use of Navigation	8.6% Yes	93.4% No	
Use of intraoperative 3-D Imaging	67.5% CT	15.3% C-Arm	17.2% None
Approach	71.2% Transorbital	22.1% Transantral	6.7% Mixed
Intraoperative difficulty encountered	30 of 90 isolated orbital surgeries (33.3%)	31 of 74 combined orbital/midface surgeries (41.9%)	
Days from Injury to First Surgery (Isolated orbital injuries n=87)	Median 13 days	IQR 5 – 21 days	Range 0 – 160 days
Follow-up time (for those included in post-operative analysis n=74)	Median 27 days	IQR 15.25 - 65.25 days	Range 6 – 1152 days

Tables 2A – 2D: Predictor-Outcome Analyses for Subjects with Isolated Orbital Injuries

Table 2A: Predictors of intraoperative difficulty

Outcome	**Predictor**	**p-value**
Intraoperative difficulty	Days from injury to first surgery	0.69
	Plating style	0.36
	Approach	0.82
	Medial wall involvement	**0.01**
	Size of fracture (transantral)	0.38
	Size of fracture (transorbital)	0.33
	Anteroposterior position of fracture (transantral)	**0.02**
	Anteroposterior position of fracture (transorbital)	0.74
	Age	0.64
	Sex	0.43

Table 2B: Predictors of operating time

Outcome	**Predictor**	**p-value**
Operating time	Plating style	**0.03**
	Approach	0.47
	Age	0.38
	Sex	0.15

Table 2C: Predictors of any postoperative examination abnormality

Outcome	**Predictor**	**p-value**
Postoperative examination abnormality (any)	Days from injury to first surgery	0.25
	Medial wall involvement	0.62
	Plating style	**<0.01**
	Approach	**0.01**
	Intraoperative difficulty	0.90
	Age	0.62

	Sex	0.50

Table 2D: Predictors of postoperative oculo-functional examination abnormality

Outcome	Predictor	p-value
Postoperative examination abnormality (oculo-functional)	Days from injury to first surgery	0.13
	Medial wall involvement	0.17
	Plating style	0.09
	Approach	**<0.01**
	Age	0.78
	Sex	0.38

Table 3: Frequency of postoperative examination abnormalities by approach (n=74 subjects with more than 5 days of follow-up)

Approach	Diplopia	Eyelid changes	Enophthalmos	Gaze Restriction	Visual changes	Sinusitis	Other	Any Irregularity	Oculo-functional Irregularity
Transorbital n=44	43.2%	13.6%	11.4%	11.4%	0.0%	4.5%	2.3%	65.9%	45.5%
Transantral n=26	15.5%	0.0%	15.5%	7.7%	0.0%	11.5%	7.7%	38.5%	15.5%
Mixed n = 4	0.0%	0.0%	25.0%	0.0%	0.0%	0.0%	25.0%	25.0%	0.0%

Eyelid changes refers to entropion, ectropion, or changes in scleral show. Oculo-functional Irregularity refers to diplopia, gaze restriction, or visual changes. Any Irregularity refers to any post-operative irregularity found on exam.

Figure Legends:

Figure 1: Four major orbital plating style designs reflected in our cohort (a – f)
1a: Transorbital flat plate
1b: Transorbital anatomic plate
1c: Bell-style arrowhead transantral plate (photograph)
1d: Bell-style arrowhead transantral plate (sagittal radiograph)
1e: Dierks-style linear transantral plate (photograph)
1f: Dierks-style linear transantral plate (3-D radiograph)

Figure 2: Frequency of Associated Midface Fractures with Orbital Involvement (N=74)

Complex orb = Complex orbital fractures, LF2 = Le Fort II fractures, GSW = gunshot wound, NOE = nasoorbitoethmoid fractures, PAN = panfacial fractures, LF3 = Le Fort III fractures, ZMC = zygomaticomaxillary complex fractures

Figure 3: Frequency of Ocular Examination Abnormalities After Orbital Surgery

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Figure 1a

Click here to access/download;Figure;(1a) Transorbital flat plate.jpg

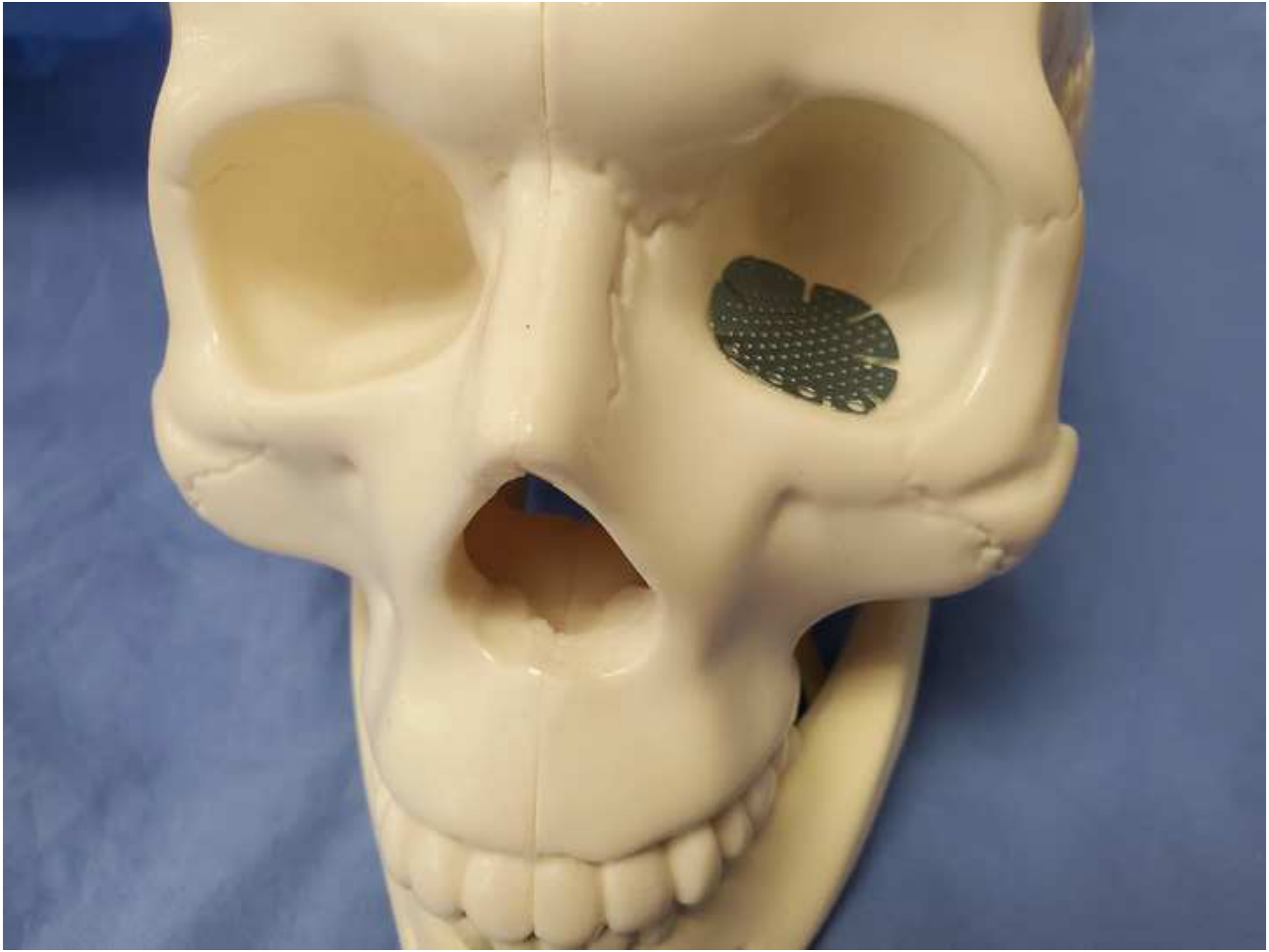

Figure 1b

Figure 1c

Click here to access/download;Figure;(1c) - Bell-style Arrowhead plate.jpg

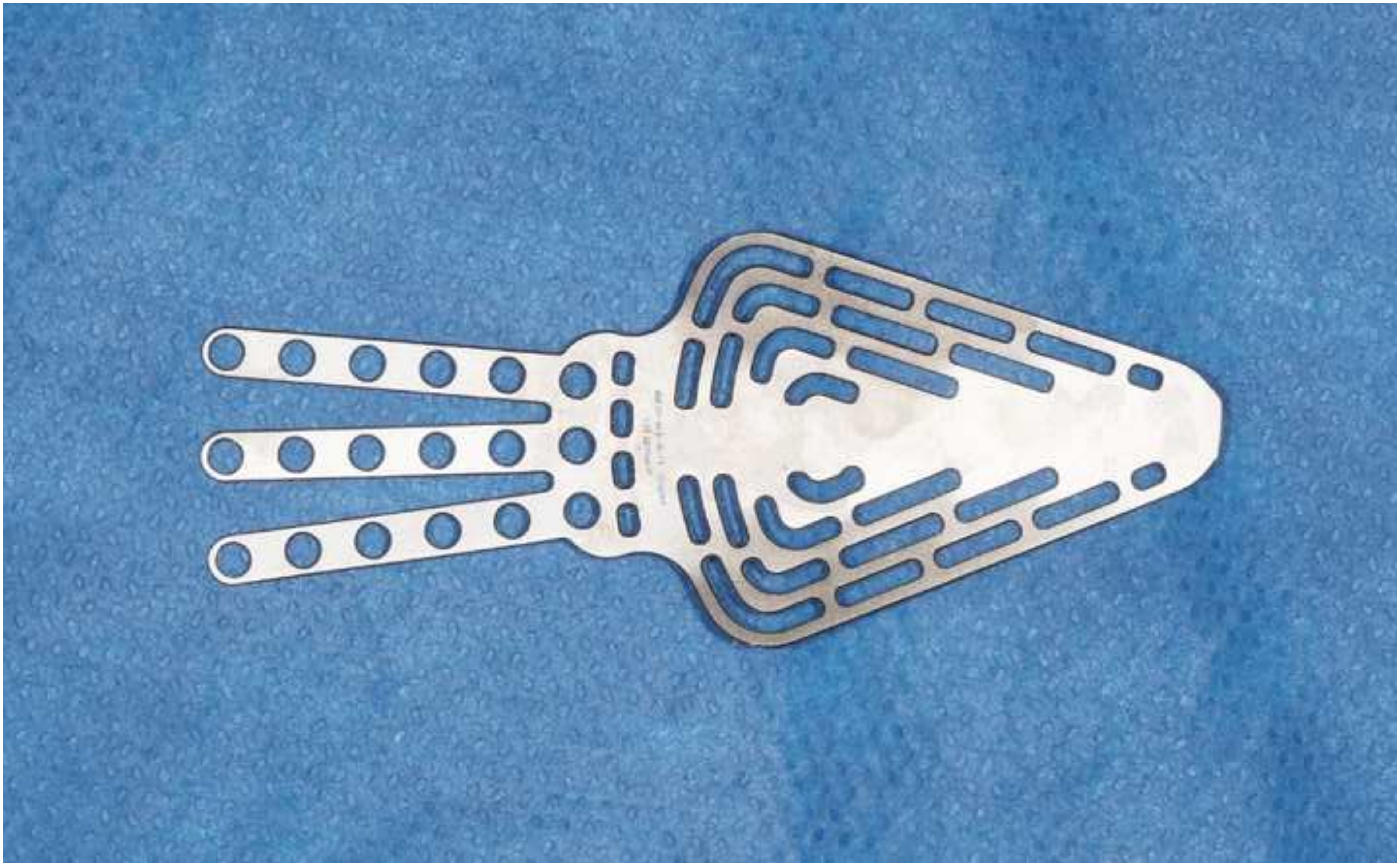

Figure 1d

Click here to access/download;Figure;(1d) Bell plate sagittal xray with arrow.jpg

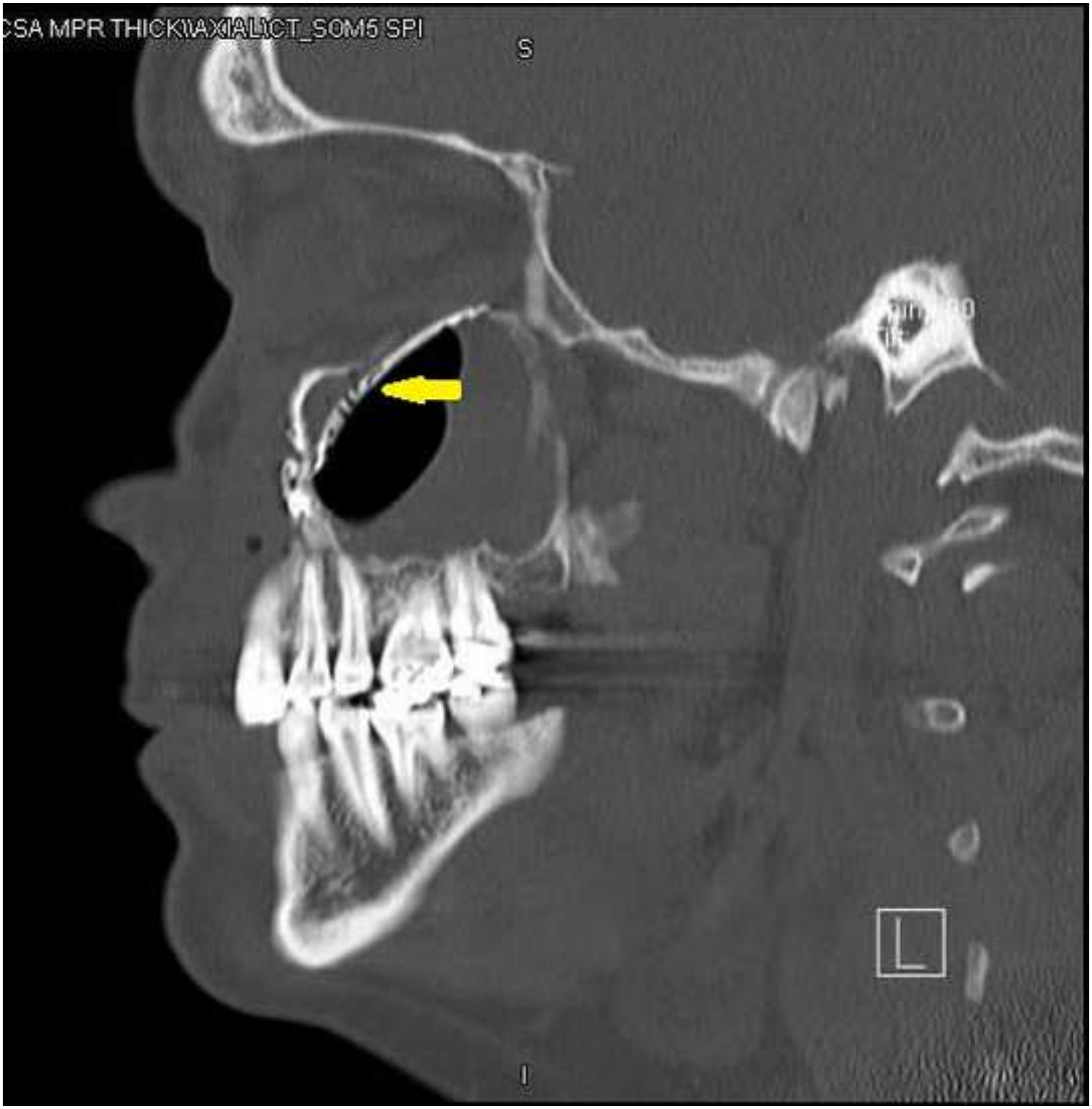

Figure 1e

Click here to access/download;Figure;(1e) - Dierks plate.jpg

Figure 1f

Click here to access/download;Figure;(1f) - Dierks plate lateral xray with arrow.jpg

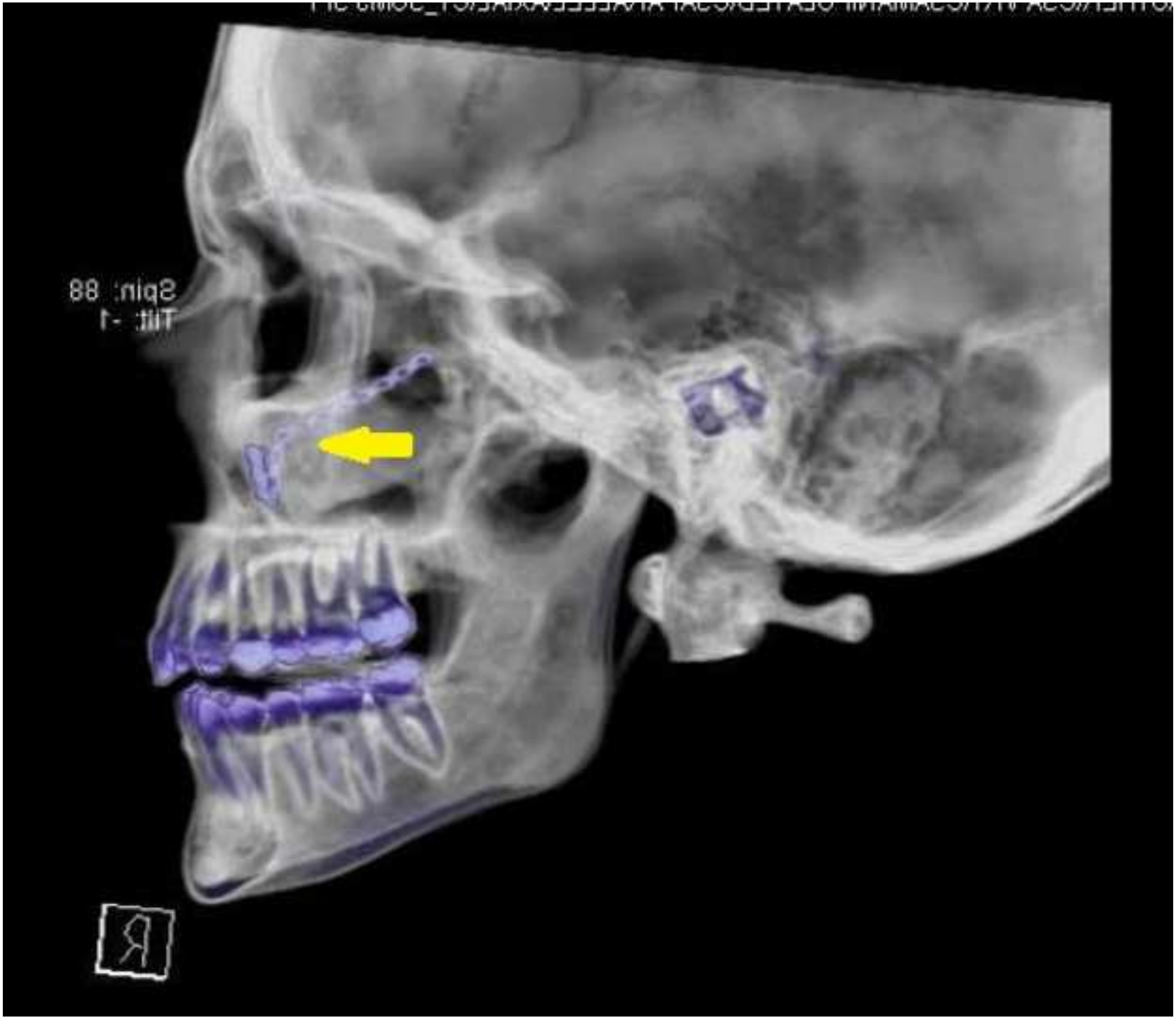

Figure 2

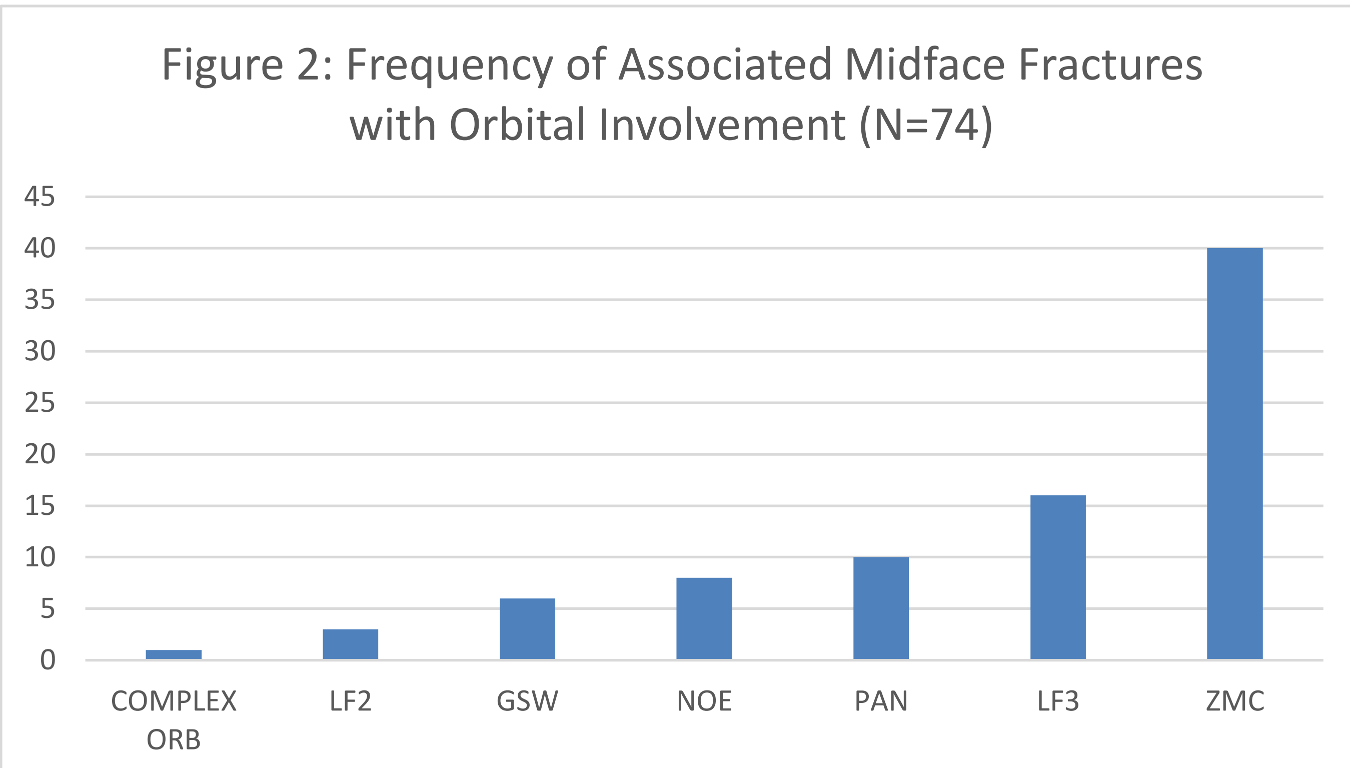
Figure 2: Frequency of Associated Midface Fractures with Orbital Involvement (N=74)
45
40
35
30
25
20
15
10
5
0
COMPLEX ORB
LF2
GSW
NOE
PAN
LF3
ZMC

Figure 3

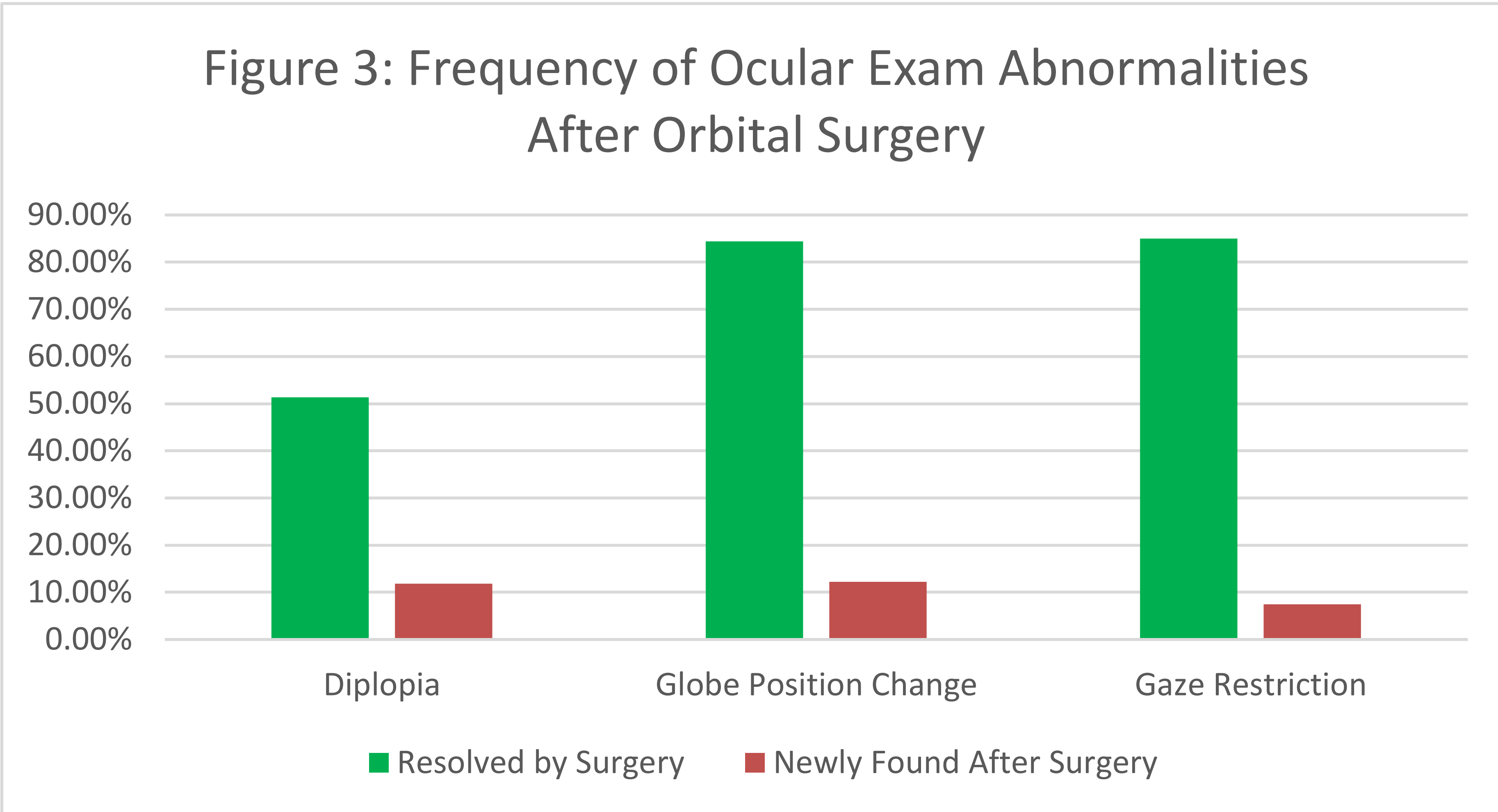
Figure 3: Frequency of Ocular Exam Abnormalities After Orbital Surgery
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
Diplopia
Globe Position Change
Gaze Restriction
Resolved by Surgery
Newly Found After Surgery

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☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐

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Commercial Interest(s) (any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.)	**Research Grant (including funding to an institution for contracted research)**	**Speakers' Bureau**	**Stock/Bonds (excluding Mutual Funds)**	**Consultant**	**Other (Identify)**
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐

___ 3rd Co-Author (if applicable)

Name: ________Melissa Amundson______________________________ ____

DISCLOSURE OF FINANCIAL RELATIONSHIPS WITHIN 12 MONTHS OF DATE OF THIS FORM

__X__ **NO**—Neither I, nor any member of my 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.

OR

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*	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐

___ 4th Co-Author (if applicable)

Name: ___Richard Bryan Bell____
____

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☐	☐	☐	☐	X	☐
☐	☐	☐	☐	☐	☐

___ 5th Co-Author (if applicable)

Name: _______Eric Dierks____
____

DISCLOSURE OF FINANCIAL RELATIONSHIPS WITHIN 12 MONTHS OF DATE OF THIS FORM

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☐	☐	☐	☐	X	☐
☐	☐	☐	☐	☐	☐

___ 6th Co-Author (if applicable)

Name: ____ ______________________________________

DISCLOSURE OF FINANCIAL RELATIONSHIPS WITHIN 12 MONTHS OF DATE OF THIS FORM

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*	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐