Does the use of a customized titanium reconstruction plate for orbital fractures result in better orbital volume and outcomes?

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Protocol

TITLE

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ABSTRACT

Facial fractures are among the most common traumas in level one trauma centers. [1, 2] Approximately 10–25% of facial fractures involve the orbit. [3] Orbital fracture reconstruction is challenging due to the complex bony anatomy and the proximity of adjacent vital structures. In orbital fracture reconstruction, the immediate clinical outcome is challenging to assess due to postoperative edema. Orbital volume measurements remain the only objective method to evaluate reconstruction in the immediate post-operative period.

Studies have shown a linear correlation between post-traumatic orbital volume and enophthalmos. [4] The timely and accurate restoration of orbital volume has been demonstrated to substantially reduce complications including enophthalmos, diplopia, and blindness due to orbital compartment syndrome compared with methods that do not assess orbital volume. [5-7] The use of intra-operative CT scanning and navigation to correctly establish intra-operative orbital volume have been described but are time-consuming and expensive. [8] A patient-specific orbital implant utilizing virtual surgical planning (VSP) has also been advocated. [9] The use of office-based 3-dimensional printers (OB3DP) is evolving, and these inexpensive devices can be used to create a realistic 3D model of the patient's orbital fracture as well as the contralateral healthy orbit. This allows the surgeon to adapt a stock reconstruction orbital plate to the specific injured orbit and to recreate the normal preoperative orbital volume.

The purpose of this study is to answer the following clinical question: among patients with orbital fractures, does the use of pre-adjusted (pre-bend) patient-specific implants utilizing OB3DP technology more accurately reconstruct normal orbital volumes when compared with the use of standard non-adapted orbital implants?

SPECIFIC AIMS AND HYPOTHESIS

Aim #1: To compare orbital volume restoration **at immediate post-operative hour)**

Traditional methods of orbital fractures reconstruction involve intra-operative shaping of orbital implants (titanium mesh). [10] Orbital fracture reconstruction using selective laser-melting patient-specific implants has been found to be superior to traditional reconstruction methods. [8, 11, 12] The challenges with the traditional approach are a significant increase in cost and longer preoperative time (production time). [11, 12] There have been no comparisons published between the traditional approach and pre-adjusted patient-specific orbital implants with respect to orbital volume reconstruction.

- Hypothesis #1: Pre-adjusted patient-specific orbital implants will **more accurately restore the orbital volume** to pre-trauma measures than non-patient-specific orbital implants.

Aim #2: To compare postoperative complications.

The main complications due to orbital fractures reconstruction are 1) enophthalmos and 2) diplopia as a result of inadequate orbital volume reconstruction. The incidence of enophthalmos after the traditional orbital reconstruction approach is 7–27%. [5, 13, 14] This rate is significantly higher than that observed after using the patient-specific approach (3.7%). [12] Again, there are currently no data regarding pre-adjusted, patient-specific orbital floor implants. The incidence of

diplopia after the traditional orbital reconstruction approach is 8–42%, [14-16] which is significantly higher than that for the patient-specific approach (3.2%). [12]

- Hypothesis #2: Pre-adjusted patient-specific orbital implants will **have fewer postoperative complications** than non-patient-specific orbital implants.

Aim #3: To evaluate the length of hospital stay. The typical hospital stay for an orbital floor fracture at Grady Memorial Hospital (GMH) is 1–2 days, depending on the patient's response to surgery.

- Hypothesis #3: Pre-adjusted patient-specific orbital implants lead to a **shorter length of stay**, secondary to improved accuracy of implant design, placement, and reduced need for manipulation. This would be expected to lead to decreased postoperative swelling and pain. Orbital fracture reconstruction could be executed as a same-day surgery (outpatient surgery) when utilizing 3DP.

Aim #4: To compare the overall cost. There are several differences between the two surgical reconstruction methods as outlined in the background. The differences have implications for reducing several factors associated with operative time. The average decrease in operation time for orbital reconstruction with selective laser-melting patient-specific implants is 0.40–3.82 hours. [17]

- Hypothesis #4: The total overall operative cost will be significantly **lower** than for non-patient-specific orbital implants.

BACKGROUND

Facial trauma is among the most common traumas seen in urban trauma centers, [1] and orbital fractures are common in blunt facial trauma. The 3 patterns of orbital fractures are linear, complex, and isolated orbital floor fractures. Linear orbital fractures do not result in a defect. Complex orbital fractures involve extensive facial fractures that affect 2 or more orbital walls and are usually associated with Le Fort II and Le Fort III fractures. Isolated orbital floor fractures affect only one wall, with less than a 2-cm-diameter defect. [18] The incidence of orbital fractures among all facial fractures is approximately 49%; this rate changes depending on the study. Complex orbital fractures represent 66% of all orbital fractures, [19] and 22%–47% are isolated orbital floor fractures. [3, 12]

Over the past two years, GMH has cared for 90 isolated orbital floor fractures. With respect to the **total orbital fractures (complex and isolated types), these numbers increased to 126 cases over the years 2016 and 2017**. Indications for surgery include retrobulbar hematoma, inferior rectus muscle entrapment, enophthalmos larger than 2 mm during the first 6 weeks, fracture involving more than 50% of the orbital floor, and diplopia in the primary field of gaze that fails to resolve after 2 weeks. [3, 7] Titanium mesh is the current recommended material due to its availability, biocompatibility, cost-effectiveness, and low susceptibility to infection. [12, 20]

There are 2 main approaches to orbital fracture management. The traditional approach involves the use of a standard stock orbital plate, which is adapted intraoperatively to the fractured orbit. The advantages of this approach are that the plates are readily available, cheap, and require minimum peri-operative planning. The major drawback of the traditional approach is the inaccurate nature of reconstruction. It is often challenging to restore the orbital volume using this approach, and failure to restore volume results in post-operative enophthalmos. [12] The second approach uses CAD/CAM technology (computer-aided design/computer-aided manufacturing technology). In this approach, a virtual plan is developed based on the patient's

CT scans. A 3D stereolithographic model is then fabricated, and a patient-specific titanium orbital implant is manufactured. These implants are manufactured using a selective laser melting process (KLS Martin, Tuttlingen, Germany). [11, 12] The CAD/CAM technology is currently considered to be the most accurate method of orbital reconstruction. [11, 21] The advantage of this approach is that it is patient-specific and therefore very accurate. However, the CAD/CAM technology is exceedingly expensive (depending on the vendor from $6,995 to $10,956.40 per case) with long production times (7–14 days). Reconstruction of the orbital fracture is time-sensitive to prevent unfavorable long-term sequelae; thus, CAD/CAM technology in orbital fractures has limitations due to production time. The second limitation of this approach is the cost. Fortunately, this technology is available today at a **low cost and high resolution due to office-based three-dimensional printing (3DP).**

In this study, we propose a third approach to manage orbital fractures. This approach involves a **patient-specific pre-adjusted (pre-bend) orbital plate** utilizing an office-based 3DP. The approach is patient-specific because the orbital plate is preoperatively adjusted (pre-bend) to the patient's anatomic model; **this decreases the OR time and increases the accuracy of reconstruction.** The cost of 3D printing the patent's fractured orbital floor in the office is **significantly less than** the cost of utilizing the CAD/CAM technology for one patient. **The 3D printed model will cost at most $1,374.5 ($1.50 printed model + $1,364 for the stock titanium implant) vs. $2,800 for VSP utilizing a stereolithographic model with a patient-specific implant.**

With such a 3D printer, true-to-life anatomic models can be made on-site within hours, and a patient with an orbital fracture can undergo reconstruction with a customized and personalized implant. An important difference compared with the virtual surgical planning (VSP) stereolithographic model is that the titanium implant is not milled on the model in 3DP. We use the over-the-counter titanium plates that are manually adjusted according to the printed model. We then send the plates to sterilization for preparation. Notably, this technology and method are yet to be applied to traumatic orbital floor fractures. Thus, to the best of our knowledge, this study is the first of its kind.

The purpose of this study is to compare (pre-bend) patient-specific orbital implants utilizing an office-based 3-D printer with standard non-adapted orbital implants (traditional approach). We will 1) preoperatively generate a patient-specific model to pre-adapt the titanium mesh to be used in unilateral orbital fractures; 2) accurately restore the orbital volume to the pre-injured measures; 3) prevent post-operative complications in terms of enophthalmos and diplopia; and 4) decrease the operative time, therefore decreasing the overall cost and increasing the value. Our patients greatly benefit from a fast and cost-effective method of reconstructing orbital floors due to the high volume and urban patient population of GMH.

METHODOLOGY

Study Settings and Patients

This is a prospective randomized clinical study with longitudinal follow-up. The study duration is 2 years. It will be conducted at GMH within the Grady Health System. The study targets urban adults suffering blunt facial trauma who are diagnosed with unilateral orbital fracture. Patients will be randomized into one of the following groups:

- Group A: patients who have orbital reconstruction utilizing **pre-adjusted patient-specific** orbital implants with OB3DP **(Treatment Group)**.

- Group B: patients who have orbital reconstruction utilizing **non-patient-specific** orbital implants (traditional approach) **(Control Group)**.

The primary predictor variable is the treatment group (pre-adjusted patient-specific orbital implants utilizing OB3DP vs. non-patient-specific orbital implants).

The primary outcome variable is the orbital volume of the injured orbit compared to the contralateral uninjured orbit as assessed by CT scan with OsiriX medical imaging software (OsiriX MD 8.5.2) **at immediate post-operative hour.**

Accordingly, the primary outcome variable will be classified as:

A. The absolute reduction in orbital volume from the measured post-traumatic volume, as measured by CT.

The secondary outcome variables will be recorded 1 week, 3 weeks, and 6 weeks postoperatively.

The secondary outcome variables include the following:

1- Adequate orbital volume reduction, defined as a reduction of orbital volume to **less than 2 cm^3.**
2- Unsatisfactory orbital volume, defined as a final orbital volume **more than 2 cm^3**
3- Post-operative variables: enophthalmos, infection, infraorbital nerve injury, traumatic pupillary mydriasis, orbital compartment syndrome, extra-ocular motility, and plate contour.
4- Operating time.
5- Length of stay (LOS).
6- Treatment charges.

The following are details regarding secondary outcome variables:

- Enophthalmos as assessed by clinical examination using a Hertel exophthalmometer.
  - A difference of more than 2 mm between the two orbits is diagnostic for enophthalmos.[4]
- Infection
  - As defined by the presence of post-operative pus in the wound, a sinus tract or fistula, or elevated WBC >11.0x10^9/L combined with erythematous skin and swelling on the operated side more than on the un-operated side.
- Infraorbital nerve injury as assessed by clinical examination using neurosensory testing (NST).

i. NST is a standardized methodology designed to objectively evaluate sensory nerve function. [22] The sensory impairment is determined by 3 levels of testing; each level classifies a specific type of sensory nerve injury. [22, 23]
ii. All patients will be assessed for the development of altered sensation of the infra-orbital nerve that:
    A. Did not present prior to the surgery.
    B. B. Did not improve after the surgery.

- Traumatic pupillary mydriases as assessed by pupillary size measurement in millimeters.
  - All patients will be assessed for the development of post-operative traumatic pupillary mydriasis that did not present prior to the surgery.
- Orbital compartment syndrome as assessed through clinical examination using tonometers.
  - Intra-ocular pressure (IOP) > 40 mmHg is diagnostic of orbital compartment syndrome.
- Extra-ocular motility as assessed through clinical examination. The patient should be able to move the eyes through the six cardinal positions of gaze (left, right, up and right, up and left, down and right, down and left). All patients will be examined for the following:
  1. Development of restricted extraocular motility that was not present prior to the surgery.

2. Persistent restriction of extraocular motility after the surgery.

- Plate contour
  - Inability to achieve the normal orbital contour as assessed in the immediate post-operative CT scan.
- Operating time
  - This will be calculated from fracture exposure and identification to the final implant placement and fixation and will be recorded in minutes.
- Length of stay
  1- Isolated orbital floor fracture patients do not require a pre-operative hospital stay. Length of stay will be calculated in terms of post-operative hospital stay (days).
  2- Length of stay in cases of complex orbital fracture will be calculated in terms of pre-operative and post-operative hospital stay (days).
- Treatment charges

This will be calculated with consideration of the following:

1- Facility operating room charges, which include anesthesia time (surgical time multiplied by the facility rate of $33/ minute).
2- Hardware charges (plates and screws).
3- LOS charges (LOS multiplied by the facility daily rate of $1,690/ day).
4- The cost of the 3D printed model including the cost of the 3D printer and filaments ($1.5).

All treatment charges variables will be provided by the GMH Financial Planning and Analysis center. Total treatment charges facility operating room charges, hardware charges, LOS, and the 3D printed model cost will be compared between groups in a manner similar to that outlined by Bouloux et al. [24]

Randomization Sample Size & Calculation

We expect a **sample size of 60** surgical cases, evenly split between the new treatment and control groups, to have a study powered to **detect at least a 1 cm^3 difference in orbital volume** between the groups. The sample size calculation was based on using a two-sample Student's t-test to compare the difference in contralateral orbital volume between the treatment and control groups. We used a **power of 90%,** alpha level of .05, and 1.17 cm^3 standard deviation of orbital volume. The 'normal' orbital volume and standard deviation were estimated from the results of Forbes et al. (1984). Sample size calculations were performed with the 'power.t.test' function in R statistical software based on Cohen (1988).[25] Taking attrition into account, if 25% of our expected patient enrollment numbers are not met for any reason, **our study would still retain a power of 80%**. Additionally, in the event of attrition from loss-to-follow-up alone, our primary outcomes variable and the bulk of the secondary outcomes variables, including the reduction of orbital volume to less than 2 cm^3, operative time, traumatic pupillary mydriasis, orbital compartment syndrome, extra-ocular motility, and plate contour, will be successfully obtained on immediate post-operative hour. **Attrition at these stages will have no effect on the above variables.**

Randomization & Statistical Analysis

Cases will be randomized to the treatment or control arms using a pre-generated block randomization scheme with a **block size of 4** and stratified according to surgeon/specialty. In essence, each surgeon will receive their own list of randomized cases to simplify the logistics of the trial. **The block randomization guarantees that at no point during the trial will there be more than a 3-case difference between the treatment and control arms for each individual surgeon**; thus, it is possible but unlikely that there will be a maximum 9 case difference at some

point (sizes will be equal at completion). The randomization scheme has been pre-generated by a statistician, and the resulting trial arm for each case will be placed in envelopes to be revealed at the time of patient enrollment. The treatment will not be blinded to the physician or the patient; it is not practical to keep knowledge of the procedure concealed.

The success of the randomization will be evaluated at the start of the analysis by comparing patient characteristics. Differences between the treatment and control arms that do not reach statistical significance using appropriate tests (likely t-tests and chi-square tests) that are smaller than 20% for all characteristics will mean that the groups are 'balanced' in our criteria and will be evidence of randomization success. Assuming that standardization is successful, all outcomes will be compared using standard two-sample comparisons. For binary outcomes, such as complications and CT use, Chi-square tests or Fisher's exact tests will be used depending on the prevalence of the outcome. Two-sample t-tests or Wilcoxon-Mann-Whitney tests (if data are non-parametric) will be used to compare mean orbital volume differences and operative times. Differences in length of stay and costs are likely to be analyzed with two sample t-tests on a log scale (thus, a comparison of geometric means will be made). Finally, logistic regression or other multivariable analyses may be performed to identify risk factors for developing complications or deviations from the normal recovery course.

Statistical Support

Support for statistical analyses will be provided by Sebastian Perez, MSPH, a trained biostatistician, working for the Department of Surgery at Emory University Hospital. All analyses will be conducted or supervised by Perez. Perez has 15 years of experience in data analysis and 7 years of experience working as the department statistician for surgery. He has over 40 peer-reviewed publications to his name and experience with outcomes and health services research as well as basic science research. In the past, he has assisted in the design and analysis of similar trials at Emory University. Regarding the cost-effective analysis, Gary F. Bouloux is the primary mentor. He is an experienced researcher and participated in cost-effective research in GMH by comparing the cost effectiveness of 2 types of mandibular fracture treatment. [24]

Inclusion & Exclusion Criteria

- The following subjects will be included in the study:
  1- Agreed to be enrolled in the study.
  2- Indications for surgical repair of orbital floor and/ wall fractures are dependent on several factors:
     a. Correction or prevention of cosmetic deformity (enophthalmos or inferior dystopia; disruption of greater than 50% of the orbital floor is likely to cause cosmetically apparent enophthalmos.
     b. Correction of unresolved diplopia (7 to 11 days) in the sitting of soft tissue prolapse with a positive forced duction test.
     c. Immediate correction of diplopia in the sitting inferior rectus muscle incarceration and a positive forced duction test.
     d. Immediate correction in a symptomatic patient with orbital floor (trapdoor) fracture that has elicited the oculocardiac reflex.
  3- At least 18 years of age.
  4- Unilateral orbital floor fracture.
  5- No history of orbital trauma.
  6- Healthy contralateral orbit.

7- Underwent orbital reconstruction.
8- Admitted to GMH.
9- Returned for the 6-week follow-up.

- Subjects will be excluded from the study enrollment if they:
  1- Refuse study enrollment.
  2- Are younger than 18 years.
  3- Pregnant women.
  4- Prisoner
  5- Unable to obtain consent (cognitively impaired)
  6- Are admitted to hospitals other than Grady Memorial Hospital.

Preoperative Assessment

- All patients, regardless of the group into which they are randomized, will receive a full history and physical examination as part of their admission, including past ocular history.
- A detailed ocular examination will be performed by the same ophthalmology team (Joon Kim, ophthalmology attending, or Andrew Anzeljc, ophthalmology fellow). The ophthalmology team will be blinded to the treatment group.
- This examination will include an evaluation of the following: visual acuity, intraocular pressure, extraocular motility, confrontation visual fields, pupil examination, external examination including Hertel exophthalmometer to document the degree of enophthalmos, slit lamp/penlight exam, dilated fundus exam, and binocular diplopia. These components make up the standard ophthalmologic examination performed for all orbital floor fractures. These data will be abstracted from the medical record before analysis.
- Maxillofacial non-contrast CT scans.
- **The additional workup for group A (treatment group) will include:**
  1) The Digital Imaging and Communications in Medicine (DICOM) image of the pre-op CT scans will be processed using the 3DP computer software to create mirror imaging of the un-injured bony orbit over the fractured orbit. This imaging will be utilized to print a 3D anatomical model. The 3D printing for the enrolled subjects will be performed by Dina Amin and Daniel Maxwell. This will ensure accuracy and limit bias. Amin and Maxwell are trained to operate the 3D printer software and will follow a standardized approach.

     The standardized approach to 3D printing:

     a- A 3D slicer. This is the first software used. Its functions are:
        - Identify the area of interest.
        - Segment the CT DICOM image.
        - Convert the DICOM file into an STL file.

     b- Meshmixer is the second software used. Its functions are:
        - Clean up the printed image.
        - Convert the image to a solid format to facilitate the 3D printing process.
        - Plane cuts and image mirroring.

     c- The third software is the printer's designated software. It facilitates the printing process.

2) Once an anatomical model is created, a titanium mesh will be pre-adjusted to the anatomical model. This is step will be performed by the designated surgical team and supervised by one of the following attending (Dina Amin for OMFS, Oswaldo Henriques for ENT, or Angela Cheng for Plastic Surgery). To optimize standardization and reduce bias, the surgical team will standardize the type of orbital plate by using one vendor (Stryker) and will follow the following guidelines to bend the orbital plates:
    - Identify the fracture dimension and location on the printed model.
    - Chose the titanium plate according to the defect dimension.
    - Start bending the plate from the lateral to medial direction. Doing this ensures that defects in the edges overlap and that the fractured bone (defect) is adequately covered.
    - The defect edges are overlapped by 2 mm of the titanium plate.

3) The pre-adjusted titanium mesh will be sent to the sterile processing department to be utilized in surgery.

Intra-operative Assessment: Procedures & Treatment

- All operations will utilize general anesthesia.
- A forced duction test of the injured eye will be performed after induction and before extubation in all cases to ensure no entrapment of extra-ocular muscles as the standard of care indicates in these cases.
- All isolated orbital floor fractures will be exposed and identified via a transconjunctival approach.
- Complex orbital fractures will be exposed and identified via a transconjunctival approach in combined with lateral cantholysis if needed to improve access.
- To record and compare the operative time between the two groups, a stopwatch will be utilized. The time in minutes will be recorded from fracture exposure and identification to final implant placement and fixation.

Postoperative Assessment

During post-operative care, all patients will undergo the following:

1) Maxillofacial non-contrast CT scans according to the protocol will be obtained as part of the standard of care in managing orbital fractures.
2) The PI will evaluate the orbital volume using OsiriX (medical software). Orbital volume measurements will be obtained to compare the injured and uninjured (contralateral) orbital volumes. OsiriX MD offers advanced processing techniques and has the ability to precisely measure orbital volume. It utilizes the DICOM data from the immediate post-operative CT scans.
3) All patients, regardless of the group into which they are randomized, will receive their post-operative assessment by the designated team resident under the supervision of one of the following attendings: Dina Amin for OMFS, Oswaldo Henriques for ENT, or Angela Cheng for Plastic Surgery.
4) All patients, regardless of the group into which they are randomized, will receive their post-operative ocular assessment by Joon Kim, ophthalmology attending and Co-PI, or by her fellow Andrew Anzeljc.

Follow-Up

- All patients will be regularly assessed at 1 week, 3 weeks, and 6 weeks postoperatively.

This is a standard post-operative follow-up schedule for craniomaxillofacial fracture patients. It is also an adequate duration for edema to resolve, which will assist in the accurate evaluation of enophthalmos. The following will be evaluated and recorded by the surgical team at each follow-up visit: enophthalmos, infection, infraorbital nerve injury, traumatic pupillary mydriasis, orbital compartment syndrome, and restricted extra-ocular movement.

- In terms of data collection and data extraction from Epic: PI Dina Amin, co-PI Daniel Maxwell and an assigned research coordinator will be involved.

Patient Compensation

All patients enrolled in the study will be compensated with $100 for their time and to encourage compliance. Their compensation includes the costs of participation in the study ($50) and the completion of the follow-up visits at week 6.

Data Collection & Analysis

Data	**Time**
Age, sex, race, DOB	Pre-operative (pre-op)
Mechanism of injury, time from injury to admission	Pre-op
Type of orbital fracture and other injuries	Pre-op
Indications for surgery	Pre-op
CT scans results (fracture size & location)	Pre-op
Extra-ocular motility indicating which gaze	Pre-op
Level of infraorbital nerve injury	Pre-op
Traumatic pupillary mydriasis	Pre-op
IOP (Intra-ocular pressure)	Pre-op
Enophthalmos (Hertel exophthalmometer measurement)	Pre-op
The use of 3D printed models	Pre-op
The time needed to print the model	Pre-op
Orbital and ocular exam results	Pre-op
Time from admission to surgery	Pre-op
Date of surgery	Pre-op
Length of surgery (minutes)	Operative
Approach	Operative
Intra-operative complications	Operative
Post-operative orbital volume comparison (OsiriX)	Post-operative
Dates of post-operative visits	Post-operative, weeks 1, 3, and 6
Extra-ocular motility indicating which gaze	Post-operative, weeks 1, 3, and 6
Level of infraorbital nerve injury	Post-operative, weeks 1, 3, and 6
Traumatic pupillary mydriasis	Post-operative, weeks 1, 3, and 6
IOP (Intra-ocular pressure)	Post-operative, weeks 1, 3, and 6
Infection	Post-operative, weeks 1, 3, and 6
Enophthalmos (Hertel exophthalmometer measurement)	Weeks 1, 3, and, 6

Overall cost	Post-operative
Need for second surgical procedure	Post-operative, weeks 1, 3, and 6

SIGNIFICANCE AND INNOVATION

This project will test two new and evolving methodologies in the medical world: 1) an office-based 3D printer and 2) pre-adjusted patient-specific implants. These two methodologies have yet to be applied together in orbital fracture reconstruction. Additionally, this study focuses on low-income patients and will be the first of its kind serving this population. Several other benefits include potential savings related to total overall cost, a reduced operative time and postoperative course, and a subsequent increase in both the quality of care and the value of care, especially in the underserved patient population cared for at GMH. We expect the results of this study to be applicable at most major urban trauma centers across the USA and abroad. The results of this study can be used in future studies as a model or pilot study.

FUTURE PLANS

VSP and patient-specific implants represent the imminent future of the standard of care in surgery. The associated cost is a major hindrance, which is remarkable in a high-volume trauma setting that serves an underserved population (GMH). The proposed study tests the application of these technologies in an underserved population and correlates its use with a reduction in the overall health care cost.

This project will add significant value to the literature in this area. It will aid in the PI's development as a young craniomaxillofacial trauma researcher with an interest in an underserved population. This grant will also represent a vital step in the PI's career development toward an independent investigator based full-time at Grady Health System.

MENTORING PLAN

As the PI (Dina Amin) is in her early research career and this will be her first prospective study, she will have guidance from the following mentors:

1- Gary Bouloux MD, DDS, MDSc, FRACDS, FRACDS (OMS), FACS.
2- Steven Roser DMD, MD, FACS.

Dr. Bouloux is the primary mentor. The PI will meet with him regularly for detailed research mentoring. Dr. Bouloux has wide-ranging research experience, particularly in facial trauma at GMH, where he conducted 2 EMCF-funded prospective studies in Grady (one of which was trauma-related). This experience will be valuable when mentoring for issues related to the conduct of facial trauma research at GMH. The PI will continue to meet with Dr. Bouloux at least monthly for 2 hours for focused mentoring and the discussion of all aspects of the ongoing study.

The PI will also meet with Steven Roser. Dr. Roser will be the secondary mentor and is an eminent national and international figure in the field of oral and maxillofacial surgery. Dr. Roser is an established educator and is widely known in oral and maxillofacial surgery. The PI will meet with him monthly to discuss research progress and future directions. Dr. Roser will also review and collaborate on all manuscripts prepared using this dataset.

HUMAN SUBJECT PROTECTIONS

The following strategies will be used to protect the subjects:

1. All patients with orbital fracture will be offered the opportunity to participate in this study. If they decline, they will still receive the same care and treatment provided by the study.
2. All patients will have the protocol and study rationale explained to them. They will be asked to vocalize their understanding by explaining the same protocol and rationale back to the interviewer.
3. All subjects will sign consent and HIPAA forms.
4. All data will be collected by the residents within oral and maxillofacial surgery, the ENT or plastics training program, or by the PI or co-PIs.
5. All consent, HIPAA, and data collection forms will be stored in a locked office. Data will be entered into a research-designated laptop within the same office, which is password-protected.
6. Patient confidentiality will be maintained in part because no forms or documentation pertaining to study participation are included in the patient's medical record.
7. All data will be scrubbed to remove identifiers after study completion.
8. Patient monitoring will be performed by the PI and the Research Assistant.
9. All adverse events (AEs) will be graded as to their attribution (unrelated to protocol, or possibly, probably, or definitely related to protocol). AEs will be reported to either the PI, co-PI, research assistant, or residents by a study subject or by medical staff caring for the subject. No adverse events are expected in this pilot study. Observed as well as serious AEs will be recorded and reported per IRB and ROC standard protocols. Serious AEs are predefined as any experience that suggests a significant hazard, such as events that: a) are fatal, b) are life-threatening, c) result in permanent disability, d) require inpatient hospitalization or e) involve cancer, a congenital anomaly, or drug overdose.

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