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Accuracy of Virtual Surgical Planning in Reduction of Zygomatico-Maxillary Fractures
A Randomized Clinical Controlled Study

A Thesis Protocol
Submitted for partial fulfillment of the requirements of the Master degree
In dental science

Oral and Maxillofacial Surgery

Research code: **HE-11**
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"Thesis Research Protocol"

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1. Abstract

Introduction: The zygomaticomaxillary complex (ZMC) is particularly susceptible to trauma, often resulting in noticeable midfacial deformities and asymmetry. Accurate fracture reduction is crucial for restoring facial aesthetics and minimizing long-term psychosocial impacts. Virtual surgical planning, along with the use of prebent miniplates on surgical guides, enhances precision by allowing detailed 3D visualization and manipulation of fracture fragments for optimal reconstruction. This improves the facial symmetry and patient satisfaction after surgery.

Aim: To investigate the accuracy of virtual surgical planning (VSP) and prebending of conventional miniplates in management of zygomaticomaxillary complex (ZMC) trauma.

Methodology: This study will be conducted on 20 patients with zygomaticomaxillary complex fracture sites. The patients will be divided into two groups (Group I and Group II) randomly and equally via www.randomizer.org Group I: Ten patients with zygomaticomaxillary complex fracture undergo open reduction and internal fixation will be managed with virtual planning and prebending surgical guide, Group II: Ten patients with zygomaticomaxillary complex fracture undergo open reduction and internal fixation will be managed without virtual planning and prebending surgical guide. Postoperative evaluation clinically inflammation, facial symmetry and eye movement using 2D photos and radiographically for CT discrepancy and bone formation using postoperative C.T after 3 months.

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2. Introduction and Background

The zygomaticomaxillary complex (ZMC) is one of the facial regions most prone to trauma due to its prominent position. Patients with ZMC fractures regularly suffer from deformity and asymmetry of the midface, since the zygomatic bone plays a key role in defining midfacial width, height, and projection **(Dubron et al., 2022)**

The zygomatic bone, with its articular processes, accounting for 30–50% of all fractures of the facial massif **(Committeri et al., 2023)**

The zygomatic bone articulates with the frontal, sphenoid, temporal, and maxillary bones, composing the zygomatic complex with those adjacent structures. The zygomatic complex strongly contributes to midfacial width and protrusion, thus playing a vital role in facial contour **(Bitter, Huber and Schmid, 2021).**

The origin of maxillofacial fractures includes traffic accidents, physical assaults, falls, and sports-related trauma. These causes vary by region and population, influenced by economic, cultural, and environmental factors **(Mittal *et al*., 2020).**

If untreated, they can cause both functional (diplopia, enophthalmos, limitation of mouth opening) and cosmetic (facial asymmetry, loss of zygomatic projection) impairments **(Longeac *et al*., 2021).**

Correct anatomical reduction of the ZMC is the keystone for functional and cosmetic restoration. **(Boffano et al., 2013).**

Therefore, accurate reduction of ZMC fractures is imperative in restoring the anatomical contour of the face and its aesthetic appearance. Failure to re-establish facial contour will cause asymmetry of the midface and may lead to poor self-esteem and low quality of life **(Dubron *et al*., 2022).**

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Virtual surgical planning (VSP) is a rapidly advancing technology that has revolutionized the field of craniofacial surgery. This technique allows surgeons to use advanced computer software to simulate surgical procedures and plan the optimal approach for treating complex facial fractures, such as those of the zygomaticomaxillary complex **(Committeri *et al*., 2024).**

Currently, the correction of maxillofacial fractures can be simulated virtually with surgical repositioning of fracture fragments and complex rotations. This virtual approach to surgical planning allows the surgeon to visualize the entire facial skeletal deformity and its surrounding structures to manipulate the 3D anatomy and plan the desired reductions more precisely. The development of virtual surgical planning techniques has led to major advances in repair of facial fractures while limiting the size of surgical access, thus rendering the surgery less invasive. **(Thakker et al., 2019).**

Because of the ZMC structure shape, traditional radiographic ways for the evaluation of ZMC symmetry are subjected to distortion. On contrary, 3D computed tomography (3D-CT) techniques provide accurate measurements and provides accurate reads of different anatomical structures. Moreover, the 3D-CT technique avoids the distortion caused by improper head position. Thus, the accurate quantification of ZMC symmetry can be done with 3D-CT. **(Farida *et al*., 2020).**

The need for digital planning before surgery is increasing but there is a continuing concern about its accuracy. **(Jansen et al., 2018).**

Virtual planning significantly improves the accuracy of zygomaticomaxillary complex fracture reduction compared to conventional techniques, resulting in better symmetry and anatomical restoration. **(Wang et al., 2021).**

Recent studies have demonstrated that this approach can significantly improve surgical outcomes. For instance, **Longeac et al. (2021)** reported that VSP and 3D-printed guides allowed for precise reduction and fixation of complex ZMC fractures. The use of these technologies enables surgeons to preoperatively simulate the reduction, design patient-specific guides, and precontour plates, thereby reducing intraoperative decision-making and improving efficiency.

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Xue et al. (2019) found that this method not only improved accuracy but also reduced operative time. Furthermore, **Bao et al. (2019)** quantitatively assessed symmetry recovery in ZMC fracture reduction, revealing that computer-assisted techniques resulted in more accurate outcomes compared to traditional methods. The integration of VSP, 3D-printed guides, and prebending of conventional miniplates offers a synergistic approach that leverages advanced technology while utilizing familiar fixation materials, potentially facilitating wider adoption of these precision-enhancing techniques in maxillofacial trauma surgery.
So the aim of this study is to determine the accuracy of virtual surgical planning (VSP) and 3D-printed surgical guides, combined with prebending of conventional miniplates, in zygomaticomaxillary complex (ZMC) fracture reduction and comparing outcomes clinically and radiographically to traditional surgical method.

3. Research Q (RQ):

In patients with zygomaticomaxillary facture what is the difference between virtual planning and traditional surgery clinically regarding facial symmetry, presence of intra or postoperative complications and bone formation?

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4. Research Hypothesis, Aim, Objectives & Expected Outcomes

a. Hypothesis

Null Hypothesis: there is no significant difference between virtual planning and traditional surgery clinically regarding facial symmetry, presence of intra or postoperative complications and bone formation.

Alternative Hypothesis: there is significant difference between virtual planning and traditional surgery clinically regarding facial symmetry, presence of intra or postoperative complications and bone formation.

b. Aim

To investigate the accuracy of virtual surgical planning (VSP) and prebending of conventional miniplates in management of zygomaticomaxillary complex (ZMC) trauma.

c. Objectives

Clinical Outcomes:

1- Presence of intra or postoperative complications via clinical examination.
2- Contour and symmetry of the face via measurements of clinical facial reference points.
3- Eye movement through clinical examination of eye movements and absence of diplopia in all gazes.
4- Presence or absence of enophthalmos, diplopia, ectropian and wound dehiscence through clinical examination.
5- Duration of the surgery by recording of start and end time from the beginning of incision.

Radiographic Outcomes:

1- Healing Process through post-operative CT.
2- Cost of virtual planning and 3d printed surgical guide.

d. Expected Outcomes

Virtual surgical planning and prebending of miniplates may provide more accurate reduction of zygomaticomaxillary fractures and improve function and facial esthetics.

5. Research Design and Methods

1- Materials :

Brand name	Composition	Company
Miniplates	Titanium	Anton Hipp
Screw	Titanium	Anton Hipp

- Software: Slicer 3D, Blender and Cloud Compare.

2- Methods:

- Study Design:
  Randomized clinical study via www.randomizer.org

- Study Setting:
  This study will be conducted on twenty patients with zygomaticomaxillary fracture.

- Patient Selection and Grouping:
  Patients will be selected from the outpatient clinic of the Oral and Maxillofacial Surgery department in the Faculty of Dentistry, Suez Canal University and Mataryah Teaching Hospital. All patients will be informed with all the details of the surgical procedures, complications and the whole study schedule. Then, each patient will sign an informed consent.
  Patients participating in the current study will have to fulfill the following eligibility criteria:

Inclusion Criteria:

1. Confirmed ZMC fracture. Patients must have a confirmed diagnosis of a ZMC fracture based on clinical and radiological evaluation (e.g., CT or cone-beam CT). **(Farida *et al.*, 2020)**
2. Age above 18 years. Adult patients are typically selected to avoid the variability of growth in pediatric patients. **(Dubron *et al.*, 2022**)
3. Ability to undergo pre- and post-operative imaging **(Jansen *et al.*, 2018)**

Exclusion Criteria:

1. Systemic diseases affecting bone healing (e.g., osteoporosis, cancer, long-term corticosteroid use) **(Bitter *et al.*, 2021**)
2. Non-compliance or inability to follow-up post-operatively includes patients with cognitive impairments, psychiatric illness, or lack of consent. **(Dubron *et al.*, 2022).**
3. ASA IV, V and VI

Grouping:

Only 20 patients with zygomaticomaxillary fracture the patients will be divided into two groups (Group I and Group II):

Group I: Ten patients with zygomaticomaxillary complex fracture undergo open reduction and internal fixation will be managed with virtual planning, 3D printed guide and prebending of conventional miniplates.

Group II: Ten patients with zygomaticomaxillary complex fracture undergo open reduction and internal fixation will be managed by traditional surgery without virtual planning 3D printed guide and prebending of conventional miniplates.

Workflow:

Preoperative CT data will be segmented to generate three-dimensional (3D) models of the zygomaticomaxillary complex fracture. Virtual reduction will be performed on these models to achieve anatomical alignment, followed by 3D printing of the model to facilitate prebending of titanium miniplates. These prebent plates will subsequently be used for intraoperative fixation.

Postoperatively, CT scans will be reconstructed into 3D models and superimposed onto the preoperative virtually reduced models using specialized alignment software. This process will enable quantitative assessment of discrepancies between the planned reconstruction and the achieved surgical outcome.

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I. Preoperative evaluation:

- Clinical examination (check facial symmetry, occlusion, eye movement, sensation).
- Imaging: CT scan (3D preferred) to assess fracture lines and displacement.
- Virtual surgical planning, 3D printing and preplating of surgical miniplates

II. Surgical protocol:

- **Anesthesia and Preparation (Dubron, K. *et al.*, 2022)**
  1. General anesthesia is the standard.
  2. Prophylactic antibiotics are administered pre-incision.
  3. Patient is draped to allow access to both intraoral and periorbital regions.

- **Surgical Approach (Committeri, U. *et al.*, 2024)**

1. Lateral eyebrow (zygomaticofrontal suture)
2. Subciliary or transconjunctival (infraorbital rim/orbital floor)
3. Intraoral (zygomaticomaxillary buttress)
4. Optional: Gillies temporal approach (zygomatic arch)

- **Fracture Exposure and Reduction (Dubron, K. *et al.*, 2022)**
  1. Carefully expose fracture lines through selected approaches.
  2. Reduce displaced zygoma using bone hooks or elevators.
  3. Confirm anatomical repositioning by assessing orbital rim, malar projection, and zygomatic arch.

- **Fixation**

Perform 3-point or 4-point fixation depending on fracture complexity:

1. Zygomaticofrontal suture
2. Infraorbital rim
3. Zygomaticomaxillary buttress
4. Zygomatic arch (if needed)

Use titanium mini-plates and screws; optionally, prebent using VSP.

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Consider orbital floor reconstruction if herniation or displacement is present.

- **Orbital Floor Reconstruction (if needed) (Jansen, B. *et al.*, 2018)**
  1. If the floor is fractured or herniated, use titanium mesh or resorbable materials to reconstruct.
  2. Avoid over- or under-correction to prevent enophthalmos or diplopia.

- **Closure**

Layered closure of all incisions.

III. Postoperative evaluation: **(Starch-Jensen, T. *et al.*, 2023)**

- **Medication**: Prescribe antibiotics, corticosteroids, and analgesics.
- **Imaging**: Postoperative CT scan with the following machine specifications (model name: GE optima CT 520, software: GE health care volume viewer, power: AC 3-50 Hz, voltage: 75kva) after 24 hours and 3 months to verify reduction, presence of infection, hardware failure and facial symmetry.
- **Follow-up**: Assess for complications—enophthalmos, diplopia, malunion, infraorbital nerve damage.

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IV. Drug prescription protocol:

- Broad-spectrum antibiotics, such as **amoxicillin-clavulanic acid** (625 mg orally every 8 hours for 5–7 days), are commonly prescribed to reduce the risk of postoperative infections, particularly when intraoral incisions are involved **(Farida *et al.*, 2020).**
- In patients with penicillin allergies, **clindamycin** may be used as an alternative **(Lalani and Laskin, 2007).**
- To manage inflammation and swelling, a short course of **dexamethasone** (4 mg once daily for 2–3 days) is often administered **(Anderson *et al.*, 2014).**
- Pain control typically includes a combination of **non-steroidal anti-inflammatory drugs (NSAIDs)** such as **ibuprofen** (400–600 mg every 6–8 hours) and **paracetamol (acetaminophen)** (500–1000 mg every 6 hours), depending on the patient's pain levels and tolerance **(Laskin, 2012).**
- In cases where intraoral incisions are used, **chlorhexidine mouthwash** (0.12%, twice daily for 7–10 days) is recommended to maintain oral hygiene and reduce bacterial load **(Kumar *et al.*, 2015).**

6. Statistical plan

A-Sample Size Calculation:

The sample size for this study was calculated according to **(Arkin 1984).**

$$N = \frac{(Z\alpha)^2 * (S)^2}{(d)^2}$$

N= Total sample size
S = Standard diversion
$Z\alpha$= 1.96 at significant level 95%
d =Different between factors
This sample size is in agreement with another study that tested in smeller subject **(Kholaki O., Hammer D. A et al, .2019).**

Sample size calculation was performed using G*Power version 3.1.9.4 **Faul et al, (2007)** University Kiel, Germany. Copyright (c) 1992-2019.

The effect size f was 5.34 (large) according to the previous studies with alpha (a) level of 0.05 and Beta (B) level of 0.05, i.e., power = 95%; the estimated sample size (n) should be 20 samples and will be divided as follows.

Table, shows the samples distribution in each group

Samples distribution	Type	No. of samples
Group 1	Control	10
Group 2	Study	10
Total samples		20

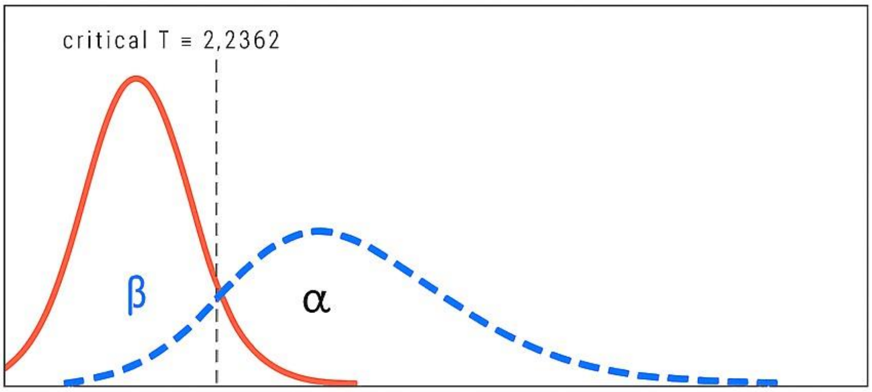

Fig 1, β and α for sample size

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B-Statistical analysis:

All data will be assessed by use of Statistical Package for Social Sciences (SPSS) system.

Experimental design and data analysis

All data will be collected and statistically analyzed using statistical tests as follows:

A normality test will be done to check normal distribution of the sample.

Statistical analysis will be done using the SPSS software at significant levels 0.05 (P- Value ≤0.5

1) Descriptive data:

Descriptive statistics will be used to summarize patient demographics, fracture characteristics, and surgical parameters. Continuous variables (e.g., age, surgical time, 3D discrepancies) will be expressed as means ± standard deviations (SD) or medians with interquartile ranges (IQR), depending on the distribution. Categorical variables (e.g., complication types) will be presented as counts and percentages.

2) F- test

One way ANOVA (parametric or non-parametric) will be used to compare between the two groups for each parameter under study. P value ≤0.05 is considered be statistically significant.

3) T- test

Independent Student's T-test data will be performed for comparing the mean differences between the two groups for each measurement.

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To assess the effectiveness of Virtual Surgical Planning (VSP) in the management of zygomaticomaxillary complex (ZMC) fractures, a comparative analysis will be conducted between two cohorts: one managed with virtual reduction and the other with a traditional surgical approach. The statistical analysis will be focused on evaluating surgical accuracy, operative time, and postoperative complications.

The primary outcome will be the mean discrepancy in 3D alignment, as calculated through the superimposition of preoperative and postoperative CT models. These models will be analyzed using specialized software to quantify the spatial deviation (in millimeters) between planned and achieved bone positions. The discrepancy data will be exported in STL format and aligned using 3D processing tools such as Cloud Compare.

The mean, standard deviation, minimum and maximum values, and root mean square error (RMSE) of discrepancies will be computed for each group. Normality of the data will be assessed using classical tests including Shapiro–Wilk, Anderson–Darling, Lilliefors, and Jarque–Bera, with significance defined at $p > 0.05$ to support the assumption of normal distribution.

The primary statistical test for comparing surgical accuracy between groups will be the independent samples t-test (two-tailed). Where applicable, a Z-test may be used to confirm the results, particularly for standardized mean difference comparisons. A significance threshold of $p < 0.05$ will be applied throughout.

For sample size justification, data were extrapolated from Committeri et al. (2024), in which the VSP (virtual reduction) group showed a mean CT discrepancy of 0.175 mm (SD ± 0.147) compared to 0.875 mm (SD ± 0.112) in the traditional surgery group. Based on these parameters, a power analysis was performed using G*Power 3.1, indicating that a minimum of 1 patient per group would be statistically sufficient to detect a difference with an effect size of Cohen's $d = 5.34$, assuming $\alpha = 0.05$ and power = 0.95. In the present study, 10 patients per group (total $N = 20$) will be included, resulting in a calculated power > 0.999.

Facial symmetry will be assessed by measuring distances between anatomical reference points (such as the zygomatic prominences and infraorbital rims) on both sides of the face, using postoperative clinical photos or 3D facial scans.

Differences greater than **2 mm** will be considered asymmetrical. The mean inter-side difference will be compared between groups using the same tests as above.

Secondary variables, including operative time and complication rates (e.g., oedema, hematoma, bleeding), will be analyzed as follows:

Operative time: Expressed as means ± SD and compared using t-test or one-way ANOVA if multiple subgroups (e.g., different surgeon experience levels) are involved.

Complications: Tabulated as frequencies and compared using Chi-square or Fisher's exact test, depending on distribution requirements.

Where relevant, correlation between surgical experience level and operative time will be analyzed using Pearson's or Spearman's correlation coefficient. Data visualization will include bar graphs, distribution curves, and superimposition colorimetric maps, following the structure of the original study.

All analyses will be conducted using SPSS, GraphPad Prism, and G*Power 3.1.

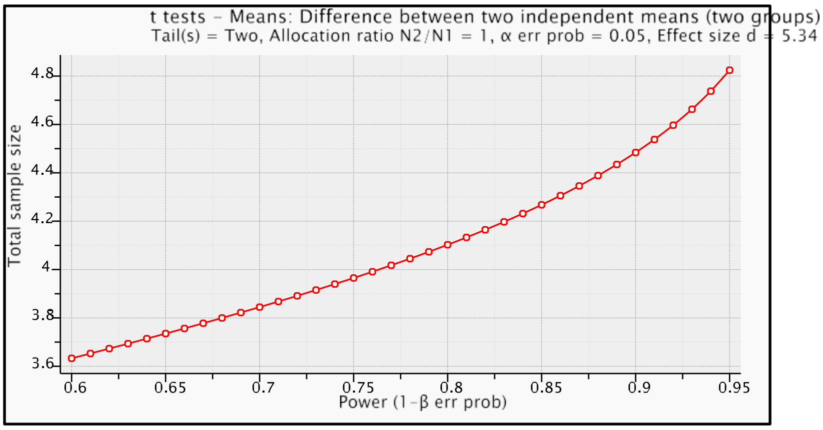
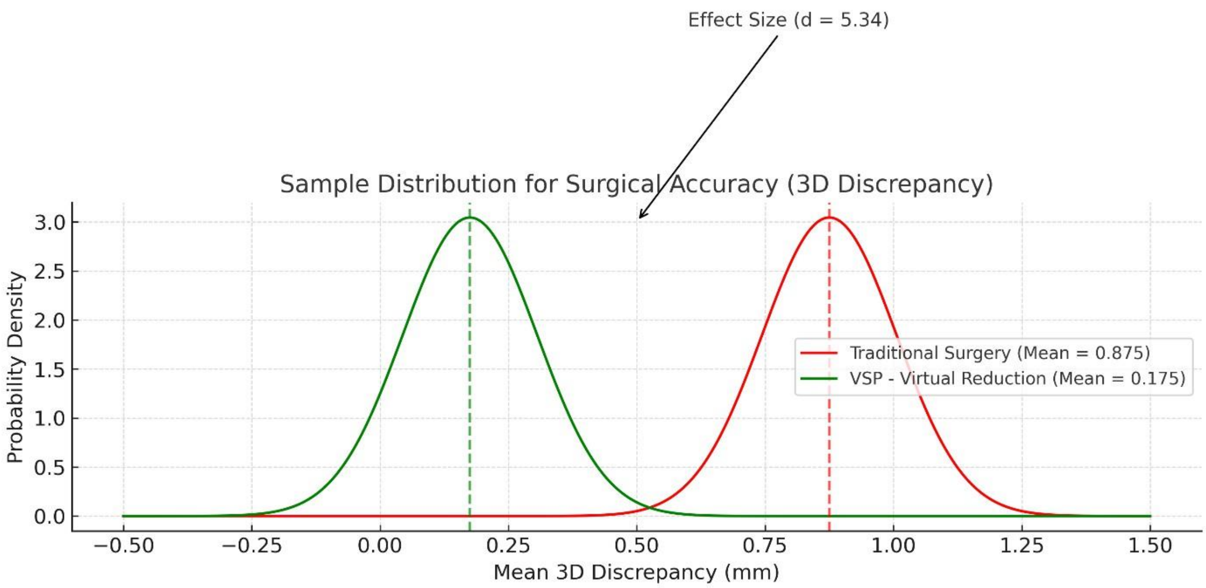
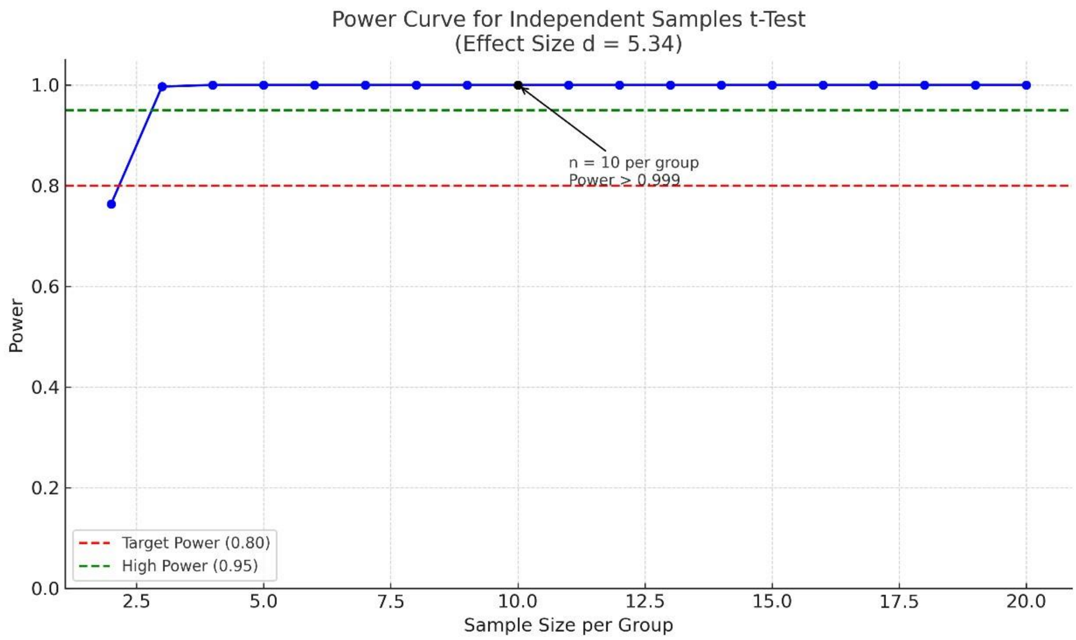


Fig 2, power (1-β err prob) for sample size





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7. Ethics consideration:

The present research will be conducted after the approval of the Research Ethics Committee (REC) of the faculty of Dentistry, Suez Canal University. It will be conducted on twenty patient suffering from zygomaticomaxillary fracture. Ethical considerations regarding patient well-being and confidentiality will be undertaken by the researcher and an informed written consent will be signed by the subjects/ patients before commencing the study explaining all clinical examinations, procedures and follow up.

(Attached appendix)

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8. Time Plan:

Include Grant Chart as following example:

Starting after approval of ethical committee and faculty counsel. **Ending** after 12 months

Aivity/Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Patient selection	☒	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Surgical procedure	☐	☐	☒	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Post-operative evaluation	☐	☐	☐	☐	☒	☐	☒	☐	☐	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Statistical analysis	☐	☐	☐	☐	☐	☒	☐	☒	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Thesis writing	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Publication	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

9. Research Estimated Budget in Egyptian pound

Supplementary					Publications	**Total**
Radiographs	drugs/ Lab chemicals	Lab-investigations	Materials	Others (Instruments)		
CT	Antibiotics, analgesics, anti-inflammatory Drugs	CBC Virology (HBV,HCV,HIV)	Titanium miniplate mesh and screw Lancet#15, Suture silk, Local anesthesia, Saline Softwares 3d printed model	Elevators Syringes Minnesota Muco-periosteal elevator		
10000	2000	10000	35000	5000	3000	65000

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11. Appendices

(Questionnaire / Consent form)

Faculty of Dentistry Research
Ethics Committee (REC)

Investigator Application Form

1- Name of researcher: **Hossam Shaban El Fadly Mohamed**

2- Name of Department: **Oral and Maxillofacial Surgery**

3- Address of researcher: 6th of October city Giza.

a- Email: Hossax20@gmail,com

b- Phone number: +201145007231

4- Name (s) of Co-investigator (s):

Prof. Dr. Mohamed Ahmed Elsholkamy

Prof. Dr. Morres Fekry khalil

Dr. Mohamed Nageh

5- Grade of protocol:

*M.D.Sc. (*) *Ph.D. ( ) *Doctorate degree (D.D.Sc) ( )

*Other ( )

*Domestic ( ) *Multi-Centre within Egypt ( )

*International ( )

6- Title of the research: **Accuracy of Virtual Surgical Planning in Reduction of Zygomatico-Maxillary Fractures A Randomized Clinical Controlled Study**

7- Type of the research:

*Drug trial ( ) *Surgical technique (*) *Investigative technique ( )

*Devise study ( ) *Survey study ( ) *Blood sampling ( )
*Review of old records ( )
Subjects of research:

1- * Children (< 18 years): ( ) *Adults (>18 years) : (*)

*Vulnerable groups
(yes) or no (*)

If yes, please describe:

Tel:01145007231

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