Outcomes of zygomatic fractures: a cross-sectional study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint injuries
Study type	Observational invasive

Summary

ID

NL-OMON57464

Source
ToetsingOnline

Brief title
ZY-PROM

Condition

- Bone and joint injuries
- Fractures

Synonym
cheekbone fracture, zygomafracture

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Quality of life, Satisfaction, Symmetry, Zygoma

Outcome measures

Primary outcome

Patient satisfaction and quality of life using:

- FACE-Q: Tevredenheid over uiterlijk van gezicht

- FACE-Q: Tevredenheid over resultaat

- FACE-Q: Psychisch welzijn

- FACE-Q: Sociaal functioneren

- FACE-Q: Impact herstel kort na behandeling

Secondary outcome

Functional outcomes

- Ocular motility

- Cutaneous sensory function

- Range of motion/mouthopening

Symmetry

- Degree of residual displacement and asymmetry in both hard and soft tissues

post-treatment

Study description

Background summary

Facial trauma represents a significant event in a patient*s life, often resulting in physical deformities and potential psychological consequences. In

facial trauma cases, fractures occurring in the zygomatic bone area are prevalent due to the distinctive shape and positioning within the face. These fractures can disrupt the facial symmetry, which plays a role in the perceived aesthetics and functionality of the human face, impacting not only physical appearance but also psychological well-being and social interactions.
The zygomatic bone, a critical component of the midfacial skeleton, contributes to the contour and width of the face, supports the orbit and has a functional role as the origin of one of the masticatory muscles, the masseter muscle. Therefore, fractures in this region can lead to a variety of complications including diplopia, enophthalmos, sensory disturbances and mastication problems. Treatment aims not only to restore function and aesthetics but also to prevent long-term deformities.
Despite advancements in surgical techniques and imaging modalities, postoperative complications such as residual deformity, asymmetry of hard and soft tissue, and dissatisfaction with facial appearance remain remain concerns that warrant further investigation. Even when bone symmetry is achieved, patients may still report perceived asymmetry. Current literature, primarily focused on hard tissue symmetry, indicates the necessity of including both soft and hard tissues in future symmetry analyses.

Study objective

This study aims to create a detailed database of patients treated for zygomatic fractures at Erasmus MC from 2008 to June 2023. By leveraging data from electronic patient records, we intend to gather extensive demographic, clinical, and treatment-related information. Following this, patients will be invited to undergo additional evaluations including Cone Beam Computed Tomography (CBCT) scans, which offer precise imaging to assess for any residual displacement and asymmetry. For soft tissue, 3D facial photography will be used to objectively measure facial asymmetry, offering a comprehensive view of both functional and aesthetic results post-recovery. Patient satisfaction and quality of life post-treatment will be assessed through validated questionnaires (FACE-Q), providing insights into the psychological and social impacts of these injuries. Functional tests will be conducted to evaluate ocular motility and cutaneous sensory function.

Through this multifaceted approach, the study aims to identify factors contributing to optimal outcomes and those that may predispose patients to poorer prognoses. The findings will not only enhance understanding of zygomatic fractures but also inform future clinical practices, ensuring improved patient care and satisfaction through better expectation management.

Study design

This study aims to create a detailed database of patients treated for zygomatic fractures at Erasmus MC from 2008 to June 2023. By leveraging data from

electronic patient records, we intend to gather extensive demographic, clinical, and treatment-related information. Following this, patients will be invited to undergo additional evaluations including Cone Beam Computed Tomography (CBCT) scans, which offer precise imaging to assess for any residual displacement and asymmetry. For soft tissue, 3D facial photography will be used to objectively measure facial asymmetry, offering a comprehensive view of both functional and aesthetic results post-recovery. Patient satisfaction and quality of life post-treatment will be assessed through validated questionnaires (FACE-Q), providing insights into the psychological and social impacts of these injuries. Functional tests will be conducted to evaluate ocular motility and cutaneous sensory function.

Study burden and risks

Cone Beam Computed Tomography (CBCT) is an advanced imaging modality utilized for high-resolution three-dimensional (3D) visualization of the maxillofacial region. It employs a rotating C-arm apparatus to project a cone-shaped X-ray beam through the patient's head, yielding detailed images with minimal distortion. CBCT is pivotal in the diagnosis and assessment of maxillofacial conditions, including zygomatic fractures, while ensuring low radiation exposure. Over the past two decades, CBCT has been extensively integrated into dental and maxillofacial imaging, with numerous studies substantiating its efficacy and safety in clinical contexts. It serves as a cornerstone in orthodontic, implantological, and trauma evaluation, supported by a substantial body of evidence validating its ability to delineate bone structures and identify fractures. Human exposure to CBCT has demonstrated a robust safety profile, characterized by radiation doses lower than those of conventional CT scans, thus imparting negligible additional risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients who sustained a zygomatic fracture and were treated at Erasmus MC from January 2008 to June 2023.
- Patients aged 18 years and older at the time of the initial treatment.

Exclusion criteria

- Subsequent facial trauma: Patients who experienced additional facial trauma after the initial zygomatic fracture, which could affect the outcomes and complicate the assessment of the initial treatment.
- Solitair zygoma arch fracture: Patients who have a zygomatic arch fracture. This will nog influence the asymmetry or physical appearance.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2025
Enrollment:	90
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-05-2025
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL87280.078.24