Title:	**Multi-Institutional Validation of the Integrated Modular Patient-Reported Outcome Assessment for Craniomaxillofacial Trauma (IMPACT)**
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ABBREVIATIONS AND DEFINITIONS OF TERMS

UTHSC	University of Tennessee Health Science Center
IMPACT	Integrated Modular Patient-Reported Outcome Assessment for Craniomaxillofacial Trauma
IMPACT-G	General Module of the IMPACT
IMPACT-N	Nasal Module of the IMPACT
IMPACT-O	Orbital Module of the IMPACT
IMPACT-J	Jaw Module of the IMPACT
PRO	Patient-Reported Outcome
PROM	Patient-Reported Outcome Measure
QOL	Quality of Life
IRT	Item Response Theory
MCID	Minimally Clinically Important Difference
IRB	Institutional Review Board
MMF	Maxillomandibular Fixation

ABSTRACT

Context: Maxillofacial trauma literature is dominated by objective, physician-rated outcomes, leaving a gap in our understanding of the patient experience.

Objectives: The primary objective of this study is to validate a novel patient-reported outcome Measure (PROM) for maxillofacial trauma: Integrated Modular Patient-Reported Outcome Assessment for Craniomaxillofacial Trauma (IMPACT).

Study Design: Prospective, multi-institutional survey study.

Setting/Participants: Patients presenting for routine clinic follow-up for maxillofacial trauma at high-volumue trauma centers throughout the United States will be screened. Adults with fractures of the upper face, midface, mandible, and/or facial soft tissue injury within the last 12 months will be included.

Study Procedures, Interventions and Measures: Participants providing informed consent will complete the appropriate IMPACT survey modules based on their fracture pattern: IMPACT-N for involvement of the nasal region, IMPACT-O for the orbital region, and/or the IMPACT-J for the jaw. Patients will also complete the 15 Dimension (15D) QOL survey as a control. Surveys will be collected at two consecutive appointments. Independent variables related to the trauma will be abstracted for analysis.

Main study outcome measures: The primary objective will be to determine criterion validity of each IMPACT module and subscale via correlation with the 15D (Pearon's r). Secondarily, we will analyze internal validity and reliability (via Cronbach alpha and Item Response Theory [IRT] analysis). Consecutive surveys will be compared for reliability. The minimally clinically important difference (MCID) will be calculated using an anchor-based approached. Finally, IMPACT scores will be analyzed across independent variables including sociodemographic variables, trauma details, and management approach.

1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Maxillofacial trauma literature is dominated by objective and physician-rated outcomes, leaving a paucity of patient-reported outcome (PRO) research. In fact, no PRO measure (PROM) has ever been validated in this population, posing a tremendous barrier to our understanding of the patient experience. This project will overcome this barrier by validating a novel PROM: The Integrated Modular Patient-Reported Outcome Assessment for Craniomaxillofacial Trauma (IMPACT). Integrating the IMPACT into future studies may revolutionize the field by providing novel evidence for controversial topics such as maxillomandibular fixation techniques, surgical approaches, adjunctive therapies, and more.

1.2 Relevant Literature and Data

A paucity of patient-reported outcome (PRO) research in the field was first exposed by a brief literature review from the United Kingdom in 2019[1]. More recently, the host institution for this study performed a comprehensive, scoping review of all PRO studies in maxillofacial trauma across some of the largest academic databases between 1999 and 2024, identifying only 88 publications over that 25-year period (data unde review). PRO measures (PROMs) that have been used are heterogenous and not designed for or validated in maxillofacial trauma patients. Most of them focus on psychosocial outcomes and the Hospital Anxiety and Depression Scale (HADS) has been used most frequently. The scarce PRO data we do have repeatedly demonstrates that maxillofacial trauma patients suffer increased rates of mental health disease[2-4]. Feelings of anxiety or depression are driven by unique aspects of each patient's trauma experience, aspects that cannot be understood from imaging or chart review. Unfortunately, there is no validated instrument to study this experience, posing a barrier to our understanding and management of mental health disease in these patients.

1.3 Compliance Statement

This study will be conducted in full accordance with the institutional review board (IRB) for each participating institution. Each institution will obtain full, independent approval to perform this study from their home IRB. As the host institution, The University of Tennessee Health Science Center (UTHSC) Policies and Procedures and all applicable Federal and state laws and regulations will be followed. All episodes of noncompliance will be reported. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

2.1 Primary Objective

The primary objective of this study is to determine the validity of each IMPACT module and subscale for measuring QOL in patients with maxillofacial trauma.

2.2 Secondary Objectives

1. Analyze IMPACT module and subscale scores across baseline sociodemographic, injury, and treatment variables in order to understand which factors influence QOL.
2. Analyze the reliabilty of each IMPACT module and subscales.
3. Determine the sensitivity to change for IMPACT modules and subscales.
4. Calculate the minimally clinically important difference (MCID) for each IMPACT module and subscales.

3 INVESTIGATIONAL PLAN

This study will be a multi-institutional field test for the IMPACT. The survey will be administered to maxillofacial trauma patients presenting for routine clinic follow-up along with a control QOL survey. IMPACT module and subscale scores will undergo psychometric testing to determine validity and reliability.

3.1 General Schema of Study Design

This will be prospective, observational survey study for patients with maxillofacial trauma.

3.2 Study Duration, Enrollment and Number of Sites

3.2.1 Duration of Study Participation

The study duration per subject will be up to 3 months, with 1 day of screening and initial survey completion, then 1 additional follow-up survey at a subsequent appointment. Each survey takes 2-20 minutes to complete depending on complexity of the fracture pattern, for a possible total study commitment of 4-40 minutes for each participant.

3.2.2 Total Number of Study Sites/Total Number of Subjects Projected

The study will be conducted at approximately 10 investigative sites across the United States. Recruitment will stop when 150 subjects have completed each IMPACT Module. It is expected that approximately 500 subjects will be enrolled to yield 150 subjects that are indicated for each IMPACT module.

3.3 Study Population

Participants will be identified from the population of patients presenting to clinics where facial trauma is managed, including otolaryngology, oral and maxillofacial surgery, plastic surgery, and/or ophthalmology clinic(s).

3.3.1 Inclusion Criteria

1) Diagnosis of maxillofacial trauma (fracture of any facial bone[s] and/or soft tissue injury) within 12 months of recruitment date.

3.3.2 Exclusion Criteria

1) Patients presenting to clinic for reasons not related to maxillofacial trauma.
2) Patients with isolated fractures of the cranium or teeth.
3) Patients who cannot read, write, and/or speak English.
4) Patients who are unable to provide informed consent for themselves (including those who are under 18 years old, incapacitated, intoxicated, or cognitively impaired with a legal guardian)

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

This study is observational and will not involve any change to the routine clinical care of participants. The three components of data collection in this study will be the (1) initial visit (screening, informed consent, and initial survey completion), (2) the follow-up visit (follow-up survey completion), and (3) a chart review for independent variables.

4.1 Observational Period

All patients presenting to clinic for maxillofacial trauma will be screened using the inclusion and exclusion criteria above. Patients who satisfy these criteria will be asked to complete surveys at two consecutive appointments during any of their regular clinical follow-up for maxillofacial trauma within one year from the injury.

4.1.1 Procedures: Initial Visit

Informed Consent: Patients will be introduced to the study and asked to complete informed consent. Those who do not wish to participate will not be given the surveys and will undergo the routine clinical care as otherwise scheduled.

IMPACT and 15D Survey Completion: A member of the research team will assign and administer the appropriate IMPACT modules for each patient based their fracture pattern (preferably on a tablet, but may complete on paper if needed). All patients will also complete the 15D QOL survey at each visit.

4.1.2 Procedures: Follow-up Visit

IMPACT and 15D Survey Completion: A member of the research team will assign and administer the appropriate IMPACT modules for each patient based their fracture pattern (preferably on a tablet, but may complete on paper if needed). Alternatively, patients will be

offered the opportunity to provide there email address to complete the follow-up survey at home at a later date.

4.2 Subject Completion/Withdrawal

Patients may choose to discontinue participation at any time without prejudice to their clinical care. For patients that choose to withdraw, no further surveys will be collected.

4.2.1 Early Termination Study Visit

For patients that choose to withdraw, no further surveys will be collected. They will be asked if any previously collected data may still be used anonymously. If yes, that data will be included in the analysis but if not, all prior survey responses and other data will be permanently deleted from the database.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening and Monitoring Evaluations and Measurements

5.1.1 IMPACT Survey

The IMPACT is a PROM with 4 independent modules. The first is a "General Module" for all patients with maxillofacial trauma. The remaining three modules were designed for specific fractures involving nasal, orbital, and/or jaw regions (Table 1). Each module takes 2-5 minutes to complete for a total of 2-20 minutes/survey depending on fracture pattern.

1. General Module (IMPACT-G)
    a. **Target patients**: All maxillofacial trauma patients
    b. **Number of questions**: 21
    c. **Structure**: 5-point Likert Scales (except for a single "pain score" from 0-10)
    d. **Subscales (4):** Overall Facial Appearance, Psychosocial Function, General Symptoms, Pain
2. Nasal Module (IMPACT-N)
    a. **Target patients**: Fractures of the nasal bones and/or sinuses
    b. **Number of questions**: 15
    c. **Structure**: 5-point Likert Scales
    d. **Subscales (2):** Nasal Function, Nasal Appearance
3. Orbital Module (IMPACT-O)
    a. **Target patients**: Fractures of the orbital walls or rim
    b. **Number of questions**: 15
    c. **Structure**: 5-point Likert Scales
    d. **Subscales (2):** Orbital Function, Orbital Appearance
4. Jaw Module (IMPACT-J)
    a. **Target patients**: Fractures of the mandible or upper jaw
    b. **Number of questions**: 20
    c. **Structure**: 5-point Likert Scales
    d. **Subscales (2):** Jaw Function, Jaw Appearance

Table 1: User guide for the Integrated Modular Patient-Reported Outcome Assessment for Craniomaxillofacial Trauma (IMPACT).

IMPACT Modules	IMPACT-G	IMPACT-N	IMPACT-O	IMPACT-J
Facial Soft Tissue Injury	X			
Upper Facial Third Fractures				
Frontal Sinus	X	X		
Superior orbital rim	X		X	
Middle Facial Third Fractures				
Nasal bones and/or septum	X			
Facial sinus fractures	X	X		
Naso-orbito-ethmoid	X	X	X	
Orbital rim and/or wall	X		X	
Zygomaticomaxillary complex (ZMC)	X		X	X
Zygomatic arch fracture	X			X
Upper dentoalveolar or palate	X			X
Le Fort I	X	X		X
Le Fort II/III	X	X	X	X
Lower Facial Third Fractures				
Mandible	X			X
Lower dentoalveolar	X			X

This table identifies the appropriate modules to administer to patients with varying patterns of facial trauma. Modules are designed to be assigned by the research team or trained clinical staff before the encounter. These modules function independently, where one patient may only qualify for the IMPACT (ie. soft tissue injury only) while another may warrant all four modules (ie. Le Fort III or panfacial fractures).

5.1.2 15D Survey

The 15D is a well-established survey to assess QOL over numerous medical and/or surgical patients. It has 15 questions each on unique 5-point Likert scale and all related to some QOL theme. This survey has previously been used in maxillofacial trauma[5-7]. It was choosen as a control for this study given its robust validity for measuring QOL and several individual themes that are specifically related to maxillofacial trauma such as eating, drinking, speech, anxiety, and depression.

5.2 Safety Evaluation

As an observational survey study, there are no expected adverse events; however, patients will be observed per regular clinical care for any adverse event associated with their facial trauma.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

The primary endpoint pertains to the primary objective, determining the validity of each IMPACT module and subscale for measuring QOL in patients with maxillofacial trauma. This will be determined by correlating the IMPACT scores with the corresponding 15D score, controlling for any independent predictors of IMPACT and 15D scores.

6.2 Secondary Endpoints

1. Identification of independent predictors of IMPACT scores including baseline sociodemographic, injury, and treatment variables.
2. Determine the reliability of IMPACT scores.
3. Calculate the change in IMPACT scores at subsequent clinic visit(s).
4. Calculate the MCID for each IMPACT module and subscale.

6.3 Control of Bias and Confounding

As a survey study, selection bias may skew the results if the sample included in the final analysis is not representative of the overall population. We intend to minimize this through a mult-institutional platform with multiple trauma centers around the United States.

In addition, nonresponse bias is a key challenge in PROM research. It is possible that patients choosing to participate differ from those who do. We will strive to overcome this by standardizing the recruitment process and highlighting the low risk nature of the study to optimize our response rate. We will also compare deidentified, baseline characteristics between patients who do and do not choose to participate. To minimize observer bias, we will offer patients privacy to complete the survey alone or with family. To identify confounding, we will analyze all independent variables for correlation with the IMPACT as described above.

6.4 Statistical Methods

All analysis will be performed by the host institution. Effect sizes with 95% confidence intervals (CI) will be provided for every applicable measurement. The analytical plan will be reviewed by professional biostatisticians at the host institution.

6.4.1 Baseline Data

The following chart review variables will be abstracted after informed consent is obtained and the initial survey is completed. This data will be summarized descriptively with average, median, range, interquartile range, and standard deviation, as appropriate. Each variable will then be tested for association with IMPACT scores on univariable analysis. Clinically or statistically significant variables will then be included in subsequent multivariable testing.

- Sociodemographic data: Age, sex, race, ethnicity, marital status, smoking status, payor type (private, medicare, Medicaid, government, none / self-pay, or other), and Social vulnerability index (SVI) values based on home address.
    - SVI: A measure of social vulnerability assigned to each zip code or census track by the Center for Disease Control and Prevention.
- Trauma data: Mechanism, concominant multisystem trauma, airway status, level of care (discharged from emergenct room, floor/stepdown admit, intensive care admit), presenting signs or symptoms (cranial nerve weakness, trismus, malocclusion, visual impairment), description of facial trauma, comprehensive facial injury (CFI) score, and Facial Injury Severity Score (FISS).
    - CFI: An objective scale based on maxillofacial imaging and clinical exam providing an integer that represents fracture severity by correlating it with the operative time for repairing each fracture[8].
    - FISS: An objective scale based on maxillofacial imaging and clinical exam providing an interger that represents the objective severity of facial trauma by correlation with the cost of management[9].
- Management data: Treatment (observation, bedside intervention, or surgical repair), type of surgical repair (closed reduction, open reduction, internal fixation, external fixation, and maxillomandibular fixation [MMF]), hospital length of stay (days), disposition (home versus medical facility)
- Objective complications: Wound injection or dehiscence, Malunion or nonunion, hardware extrusion, or any unplanned return to the emergency department, admission or reoperation related to the facial injury.
- Survey metadata: time from trauma to survey (days), time from intervention to survey (if applicable; days), presence of maxillomandibular fixation at the time of the survey.

6.4.2 PROM Scoring

- IMPACT Scoring: IMPACT modules consist of 8-16 Likert scale questions from 0-4 (5-point). The total module score will be standardized by taking the average of all questions in a module then multiplying x25, giving a total module score of 0-100 with higher scores indicating more worse QOL impairment. The pain scale will be reported separately and the final score will be the patients pain score from 0-10 multiplied by 10 for a final pain score of 0-100. For the initial analysis, partially completed surveys with any number of missing answers will be included. Individual subscales for each module will also be given a "subtotal" score which is the average of the Likert scale answers in that subscale, multiplied by 25 for a standardized score from 0-100.
- 15D Scoring: The 15D is scored using a non-linear, copyright algorithm that accounts for baseline demograpic variability. It is available here: https://15d-instrument.net/15d/ (15D©/Harri Sintonen). The code for this analysis already been released to the host institution for use in the analysis of this study.

6.4.3 Analysis of Primary Outcome of Interest

This validity of the IMPACT in measuring QOL will be determined by calculating Pearson's r between the score from each IMPACT module and subscale with the 15D QOL survey.

Each module or subscale will considered valid if it shows significant ($p>0.05$) and at least moderately-positive correlation ($r>0.4$) with the 15D. All independent variables that influence IMPACT scores will be controlled for in a multivariable regression model.

6.4.4 Analysis of Secondary Outcomes of Interest

1. IMPACT independent predictors: This secondary objective will identify independent variables that are associated with IMPACT scores. Multivariable logistic and linear regression models will be developed for categorical and continuous independent variables, respectively, and tested for association with each IMPACT score. Those independently associated with the IMPACT will be reported and factored into the multivariable regression for the primary endpoint.
2. Internal consistency and reliability will be measured measured by Cronbach alpha testing, item-response theory (IRT), and correlation between initial and followup surveys for patients completing both within one month.
3. The MCID for each module and subscale will be calculated using an anchor-based approach with a single item that addresses each patient's overall satisfaction.

6.5 Sample Size and Power

For PROM development, 4-10 participants per item with an absolute minimum of 100 is often recommended for field testing[10-11]. Therefore, this study will have 150 patients complete each module. Based on a host institution pilot study of 50 patients, the percentage of those being indicated for the IMPACT-N, IMPACT-O, and IMPACT-J were 40%, 30%, and 60%, respectively. Therefore, it is expected that 500 patients with maxillofacial trauma will need to be recruited in order to properly validate the least common IMPACT-O with at least 150 patients. The anticipated nonresponse rate from this pilot study was 33%, so it is expected that a total of 750 patients will need to be invited in order to meet this sample size.

7 SAFETY MANAGEMENT

7.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study; however, this is an observational study that does not involve any medical care procedures so AEs are not expected.

7.2 Adverse Event Reporting

If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study, these will be reported to the institutional IRB where the incident took place.

STUDY ADMINISTRATION

7.3 Data Collection and Management

Data collected in this study will be obtained in two formats: survey data and chart review data, as previously described.

7.3.1 Data sources

Survey data source: This will be collected by a member of the research team during the patients regular scheduled visit. The goal is for this survey to be completed while the patient is in their exam room waiting for the physician or discharge paperwork so that no extra time is added to their visit. A member of the research team will identify the patient, obtain informed consent, and provide the IMPACT and 15D surveys to complete.

At the host institution, surveys will be collected via research tablets available in the clinic. The patient will be given a tablet that already has the appropriate IMPACT modules loaded based on their fracture pattern. They will complete the surveys electronically which will automatically save the data to their record on the encrypted, institutional REDCap database at each institution. Confidentiality will be prioritized as only members of the IRB-approved research team will have access to the REDCap for this study.

For centers where tablets are not available, the patient may completed the surveys on paper. A member of the research team will then transfer this to the REDCap afterwards and shred the paper data to minimize the risk of loss of confidentiality.

Chart review data source: The data listed above will be extracted from the medical record for every participant in this study. This will be performed privately by at least one member of the research team using a protected device with access to the electronic medical record.

7.3.2 Multi-institutional Data Management

Absolutely no identifying or other protected health information will be shared across research sites. Once the appropriate sample size has been achieved, the REDCap data at each institution will be deidentified and exported to an excel file. A single “record ID” interger with no identifying information will be assigned for each participant. This deidentified spreadsheet will then be sent via encrypted email to the host institution research team for aggregation and deidentified final analysis.

7.4 Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy and that the Investigator and other site personnel will not use such data and records for any purpose other than conducting the study. To protect confidentiality, all data will be stored and managed electronically with each institutions password-protected, Research Electronic Database Capture (REDCap) software. A unique record ID interger will be assigned to each participant at an institution. No identifying information will be exported at any point within the study.

7.5 Regulatory and Ethical Considerations

7.5.1 Data and Safety Monitoring Plan

The institutional PI at each study site will monitor and review the study progress, subject safety, and the accuracy and security of the emerging data.

7.5.2 Risk Assessment

Risk assessment will be performed by each participating institution. At the host institution, the research activities present were determined to pose no more than minimal risk to human subjects. Potential risks include loss of confidentiality, addressed above, and risk of feeling uncomfortable when taking the survey. This is addressed by ensuring the survey is optional and explaining that some questions may be uncomfortable. Patients may stop the survey at any time or skip items to minimize this risk.

7.5.3 Potential Benefits of Study Participation

Potential benefits are an additional opportunity for the patients to share symptoms and experiences while recovering from facial trauma, which may help the treating physician better understand how to care for eeach patient. This will also help contribute to an improved understanding of the recovery process after suffering facial trauma.

7.5.4 Risk-Benefit Assessment

Given the low-risk nature of this survey study, the benefits described above are expected to outweigh the potential risks.

7.6 Screening Strategy

One member of the research team will screen patients on the upcoming clinic schedule to look for potential participants based on the “chief complaint”. Those with a chief complaint related to maxillofacial trauma will be reviewed for inclusion and exclusion criteria. If satisfied, a REDCap file will then be generated for that patient and the appropriate IMPACT modules will be selected. Patients that do not satisfy inclusion and exclusion criteria based on chart review will not be included and no information will be recorded.

7.7 Recruitment Strategy

Potential participants identified in the screening phase above will be recruited while they are at a regular clinic follow-up. This will be performed by a member of the research team in a private setting, such as in the patient room while waiting for the clinician or clinic staff. If they agree to participate, they will be provided the tablet with the appropriate IMPACT modules uploaded (or appropriate pieces of paper). Informed consent will be obtained.

7.8 Informed Consent/Assent and HIPAA Authorization

7.8.1 Main Study

All patients who agree to participate will be asked to provide written consent in person during the initial visit. Each institution will use the consent form approved by their institutions IRB.

7.8.2 Individuals with Limited English Proficiency

Patients unable to read English will be excluded. Once this survey has been properly validated in its original English language, it be translated and tested in other languages (future research); however, translating this in one language is a nexessary first step.

7.8.3 Waiver of HIPAA Authorization

HIPPA authorization for collection of chart review data will be obtained during the consent process at each participating institution.

8 PUBLICATION

Only aggregate data without individually identifiable information will be published. All participating research authors will review and provide edits to the final submission.

9 REFERENCES

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