Implementation and validation of a digital registration system for midface and orbital reconstruction in Iran

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Abstract

***Aim*: To design, validate, and implement a digital registry system for midface and orbital reconstructions.**
***Materials and Methods*: This descriptive-analytic study was conducted at Shariati Hospital, Tehran, between 2021 and 2024. In the first phase, we reviewed existing literature and guidelines on craniofacial registries to identify elements for designing a digital registry. In the second phase, we developed a structured questionnaire with demographic, clinical, procedural, and postoperative outcomes. The questionnaire underwent pilot testing for reliability and content validity.**
***Results*: An expert survey led to the inclusion of 28 items on patient demographics, medical history, disease characteristics, surgical details, postoperative outcomes, and patient satisfaction. In a study with 19 patients, the average age was 34.05 years, with most patients being male (63.2%) and non-smokers (73.7%). Trauma was the leading cause of injury (73.7%), and most patients underwent one to two surgeries. Postoperative outcomes were generally favorable, with complications like infection (10.5%) and fistula formation (21.1%) observed. Patients reported good functional recovery, with high satisfaction in speech and eating abilities. Quality of life assessments showed diverse responses, with 47.4% of patients rating their health-related quality of life as better than before their illness. Self-assessments of facial aesthetics indicated a higher perception of sunken features, unattractiveness, and facial damage.**
***Conclusion*: Our study showed the feasibility and clinical application of a digital data recording system for midface and orbital reconstruction, integrating comprehensive patient data, surgical outcomes, and quality of life metrics. This provides a platform for ongoing research to improve reconstructive techniques and support evidence-based clinical decision-making.**

Keywords: Facial Reconstruction; Three-Dimensional Printing; Reconstructive Surgical Procedures; Digital Imaging; Patient Registries; Outcome Assessment.

How to Cite

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Introduction

Midface and orbital reconstruction is a field of reconstructive surgery aimed at the restoration of function and aesthetics following trauma, tumor ablation, or congenital deformities (1). The midface anatomical region is supported by six paired bones—nasal, maxilla, palatine, lacrimal, zygoma, and inferior nasal concha—of which the maxilla and zygoma contribute to the basic bony framework (2). Because of its intricate three-dimensional (3D) anatomy, midface reconstruction presents unique challenges requiring a cautious approach to restoring both bony architecture and soft tissue. Previously, reconstruction was possible only in prosthetic forms, such as obturators, but microvascular free flaps were developed to improve functional and aesthetic outcomes (3). Despite these improvements, achieving the optimal results is challenging due to the midface's complex anatomy and the need to integrate many reconstructive techniques to restore skeletal support, soft tissue volume, and orbital position (1).

Digital technology has become a tool in the reconstruction of midfacial and orbital defects, improving the precision and predictability of surgical interventions, particularly in complex cases requiring bony recontouring 4. Application of 3D imaging has transformed preoperative planning by providing complete visualization of both acquired and congenital deformities and facilitating the application of computer-assisted surgical techniques 5. In addition, patient-specific biomodels—original or pre-corrected representations—have improved preoperative simulations and surgical outcomes. The contribution of biomedical engineering advancements has also led to the development of 3D-printed implants with superior functionalization and predictive design features. These advancements have transformed reconstructive surgery, introducing new protocols and approaches that optimize outcomes in orbital and midfacial reconstruction (5, 6).

Systematic recording and documentation of midface and orbital reconstructions are necessary to improve patient outcomes, long-term follow-up, and establish research in reconstructive surgery. With the complexity of such procedures and their related high functional and aesthetic impact, having a specialized registry facilitates the data collection and postoperative outcomes, which can reduce redundant diagnostic studies and unwarranted interventions [7]. Registries have been widely applied in various medical specialties, demonstrating their utility in disease course monitoring, treatment efficacy assessment, and facilitating multi-center research collaboration (8). The registries enable evidence-based decision-making, improve healthcare provider performance monitoring, and reduce the implementation of standardized treatment protocols (9). Moreover, standardized and uniform data entry minimizes inconsistency across institutions, increasing the validity of research findings and optimizing patient care (9). Implementing a strong registry for orbital and midface reconstructions can correct existing data-gathering flaws, improve clinical follow-up care, and improve reconstructive surgery overall.

A recent study in Iran focused on detecting and validating a registry system for children's developmental motor disorders (10). Despite the benefits of registries in medicine and dentistry, Iran lacks a registry system for midface and orbital reconstructions. Given the increasing application of digital technology in facial reconstruction and the need for a structured database to assess patient outcomes and optimize follow-up care, we aimed to design a patient registry system specifically for individuals undergoing midface and orbital defect reconstruction using digital technology in Iran.

Materials and Methods

Study Design and Setting

The present descriptive-analytic study was conducted to design and validate a digital registry system for midface and orbital defect reconstructions using 3D-printed prostheses at Shariati Hospital, Tehran, Iran, between 2021 and 2024. The study was structured into two primary phases. In the first phase, a comprehensive review of existing guidelines and literature on craniofacial registries was performed. Databases including PubMed, Web of Science, Scopus, and Science Direct were systematically searched using keywords such as "midface reconstruction", "orbital defects", "patient-specific implants", "3D printing", "digital registries", and "outcome tracking". Full-text English articles published between 2010 and 2023 were evaluated to identify data elements and best practices for registry design. Furthermore, national protocols from the Iranian Ministry of Health and institutional guidelines from Tehran University of Medical Sciences were reviewed to align the registry with local ethical and operational standards.

In the second phase, a structured questionnaire was developed based on findings from the literature review. The questionnaire had four sections: 1) demographic and administrative data (e.g., patient age, surgical dates), 2) clinical and defect characteristics (e.g., etiology, classification), 3) procedural details (e.g., implant material, use of 3D guides), and 4) postoperative outcomes (e.g., complications, patient satisfaction). A five-point Likert scale ("strongly disagree" to "strongly agree") was used to assess the relevance of each data element. The questionnaire was pilot-tested by a panel of six maxillofacial surgeons and data management specialists at Tehran University of Medical Sciences to assess reliability. Participants were asked to retake the survey after one week, and internal consistency was evaluated. Eight experts, including surgeons, radiologists, and health informaticians, confirmed content validity.

Data Collection

The preliminary survey list included 29 variables rated by specialists to determine their relevance for inclusion in the registry. These variables were demographic factors, clinical history, surgical details, and postoperative outcomes, incldluing age, sex, patient satisfaction, patient health and quality of life, patient facial aesthetics, lesion location (i.e., cheek, near nasolabial fold, and on nasolabial fold), malignancy type (e.g., squamous cell carcinoma, basal cell carcinoma, and others), history of radiotherapy, history of hyperbaric oxygen

therapy, number of surgeries, secondary surgery for aesthetic improvement, etiology of defect (e.g., malignancy, trauma, and infection), extent of bone and soft tissue defect based on Brown et al. classification (11), involvement of midface structures (i.e., lip, nose, and eyelid), nasal floor and lateral wall reconstruction, wound dehiscence or postoperative infection, presence of hematoma or meningitis, preservation of nasal bone, absence of fistula and nasal secretion leakage into the oral cavity, acceptable facial contour, acceptable cheek projection symmetry, lack of oral content entering the nasal cavity (assessed by the ability to eat and drink without leakage), overall ability to speak postoperatively (evaluated by having the patient talk about a topic, counting the total words spoken, and determining the percentage of words understood by the examiner), annual follow-ups, orbital floor reconstruction using titanium mesh, clavicle bone, iliac or rib bone, use of 3D-printed surgical guides, and use of 3D CT scans for improved anatomical understanding before surgery. Each element was scored on a 5-point Likert scale (1 = least impactful, 5 = most impactful). Elements with a mean score ≥2.5 were retained.

A validated patient satisfaction questionnaire assessed four domains: facial symmetry, scar appearance, speech function, and mastication ability. Responses were recorded on a 4-point scale (1 = poor, 4 = excellent). Also, scar visibility was categorized as "significantly noticeable," "mildly noticeable," or "barely detectable." Speech clarity was evaluated by asking patients to describe a standard passage, with intelligibility scored as a percentage of correctly understood words.

The quality of life questionnaire included 12 items evaluating physical, emotional, and social well-being. Domains included pain intensity (rated from "no pain" to "uncontrollable pain"), functional limitations (e.g., difficulty chewing or speaking), and psychological impact (e.g., anxiety related to appearance). Each item used a 5-point Likert scale, with higher scores indicating better quality of life.

A 10-item aesthetic questionnaire assessed subjective perceptions of facial symmetry, contour, and attractiveness. Patients rated statements on a 4-point agreement scale (1 = strongly agree, 2= = somewhat agree, 3 = somewhat disagree, and 4 = strongly disagree). The 10 items in the aesthetic questionnaire include statements such as "Parts of my face appear very large," "Parts of my face appear sunken," "My face looks deformed," "The shape of my face is abnormal," "My face looks unattractive," "My face seems disproportionate," "My face appears damaged," "My face looks unnatural," "My face appears uneven and rough," and "The two sides of my face are different."

Study population and statistical analysis

The study population included healthcare professionals and patients from Shariati Hospital. All eligible specialists (n = 18) were invited to participate in the validation phase, with 15 completing the questionnaire. For patient data collection, consecutive sampling was applied to include all individuals undergoing midface/orbital reconstruction with 3D-printed prostheses during the study period. Inclusion criteria required patients to be ≥18 years old with defects attributable to trauma, malignancy, or congenital causes. No exclusion criteria were applied to minimize selection bias. Data were collected prospectively using REDCap electronic forms linked to hospital records, with automated validation checks to reduce missing entries. A calibrated and blind examiner conducted evaluations and clinical examinations. However, due to the inability to use a separate examiner and due to the examiner's access to the patient's file, it was not possible to blind the examiner.

Statistical analysis was performed using SPSS version 26.0. Continuous variables were reported as mean ± standard deviation (SD), while categorical variables were summarized as frequencies and percentages.

Ethical Considerations

Written informed consent was obtained from the subjects, allowing anonymized data use for research, audits, and follow-up. We followed national and international guidelines and regulations. It was conducted in accordance with the Declaration of Helsinki. The study protocol was approved by the institutional ethics committee (code: IR.TUMS.DENTISTRY.REC.1401.146).

Results

An expert survey was conducted to determine the relevance of various information items for inclusion in the registry. Finally, 28 items were included with mean values above 2.5 (Table S1). The final registry design had a set of variables organized into different domains to capture detailed patient and procedural data. Demographic information, including visit date, treating physician, personal identifiers, gender, birth details, contact information, occupation, education level, and marital status, was included (Table S2). Personal history variables included lifestyle factors such as smoking habits, waterpipe use, alcohol and substance abuse, as well as drug allergies, pregnancy status, and past medical/surgical history (Table S3). Disease history included details on lesion location, injury cause (malignancy, trauma, or infection), type of malignancy, extent of bone and soft tissue defects, involvement of vital midface structures, and history of radiotherapy (Table S4). Surgical information was recorded with variables such as type and number of surgeries, secondary procedures for aesthetic improvement, specific reconstruction details (e.g., alveolar arch, lateral nasal wall, preservation of nasal bone, orbital floor reconstruction), and the use of advanced digital tools like 3D-printed surgical guides and 3D CT scanning for enhanced preoperative assessment (Table S5). Postoperative follow-up records included the number of follow-up sessions and detailed outcomes such as wound dehiscence/infection, hematoma, meningitis, fistula formation, functional abilities (e.g., eating, drinking, and speaking), and overall aesthetic outcomes (Table S6). Furthermore, patient satisfaction was measured using a questionnaire (Table S7), quality of life was evaluated (Table S8 and Table S9), and patients self-assessed their facial aesthetics using a 10-item scale (Table S10).

Table S1. Mean Scores of Various Factors Influencing Surgical Outcomes Rated by the Experts.

Item	Mean	Item	Mean
Age	4.44	Wound dehiscence or postoperative wound infection	4.5
Gender	3.8	Hematoma formation	4.1
Patient satisfaction	4.3	Postoperative meningitis	4.0
Patient health and quality of life	4.3	Preservation of nasal bone	4.0
Patient facial aesthetics	4.2	Absence of fistula and infiltration of oral secretions into the nasal cavity	4.4
Lesion location	4.3	Acceptable facial contour	3.8
Type of malignancy	4.6	Presence/absence of enophthalmos	4.5
History of radiotherapy	5.0	Acceptable projection	4.2
History of hyperbaric oxygen therapy	3.7	Ability to eat and drink without leakage	4.5
Number of surgeries	4.4	Overall ability to speak after surgery	4.2
Secondary surgery for aesthetic improvement	4.4	Annual follow-up	3.8
Cause of injury	4.5	Orbital floor reconstruction	4.5
Extent of bone and soft tissue defect	4.4	Use of 3D-printed surgical guides	4.2
Involvement of vital midface structures	4.8	Use of 3D CT scanning for preoperative anatomical assessment	4.3

Table S2. Demographic Information.

Variable	Description/Options
Visit Date	Date of the patient's visit
Treating Physician's Name	Name of the physician in charge
National ID	Patient's national identification number
First Name and Last Name	Patient's full name
Gender	Options: Female, Male
Date of Birth	Patient's birth date
Place of Birth	City/Town of birth
Province	Province of birth
City	City of residence
Address	Full address
Contact Number	Telephone or mobile number
Occupation	Patient's occupation
Education Level	Options: Illiterate, Primary, Middle School, High School Diploma, Bachelor's, Master's, PhD or higher
Marital Status	Options: Single, Married

Table S3. Patient Personal History.

Variable	Description/Options
Smoking Habits	Current use or past use; if applicable, number of cigarettes per day and date of cessation
Family History of Smoking	Options: Yes, No
Waterpipe Use	Options: Yes, No
Alcohol Consumption	Options: Yes, No
Substance Abuse	Options: Yes, No. Specify type.
Drug Allergy	Specify type of allergy and drug name
Current Pregnancy Status	Options: Pregnant, Not Pregnant
Past Medical History	Relevant previous illnesses
Past Surgical History	Previous surgeries undertaken
Medications (Past and Current)	List of medications used in the past and currently

Table S4. Disease History.

Variable	Description/Options
Lesion Location	Specify location (e.g., Cheek; near the nasolabial fold; on the nasolabial fold)
Cause of Injury	Options: Malignancy, Trauma, Infection
Type of Malignancy	Options: squamous cell carcinoma, basal cell carcinoma, other
Extent of Bone and Soft Tissue Defect	Based on Brown et al. (2002) classification: • Class 1: Maxillectomy without fistula • Class 2: Moderate defect without involvement of orbital floor/eye • Class 3: Extensive defect with involvement of orbital floor and/or eye • Class 4: Very extensive defect with significant orbital involvement
Involvement of Vital Midface Structures	Options: Lip, Nose, Eyelid
History of Radiotherapy	Options: Present, Absent
History of Hyperbaric Oxygen Therapy	Options: Present, Absent

Table S5. Surgery Details.

Variable	Description/Options
Type of Surgery	Specify the surgical procedure performed
Number of Surgeries Performed	Total number of surgeries
Secondary Surgery for Aesthetic Improvement	Options: Yes, No
Reconstruction of the Alveolar Arch and Lateral Nasal Wall	Options: Yes, No
Preservation of the Nasal Bone	Options: Yes, No
Orbital Floor Reconstruction	Materials used: Titanium mesh, Clavicle bone, Iliac bone or Rib, Porex, or other
Use of 3D Printed Surgical Guides	Options: Yes, No
Use of 3D CT Scanning for Preoperative Anatomical Assessment	Options: Yes, No

Table S6. Postoperative Follow-up.

Variable	Description/Options
Number of Follow-up Sessions	Total number of follow-up visits
Wound Dehiscence or Postoperative Wound Infection	Options: Present, Absent
Hematoma Formation	Options: Present, Absent
Postoperative Meningitis	Options: Present, Absent
Absence of Fistula and Infiltration of Oral Secretions into the Nasal Cavity	Options: Present, Absent
Ability to Eat and Drink Without Leakage	Options: Yes (no oral contents entering the nasal cavity), No
Acceptable Facial Contour	Options: Acceptable, Unacceptable
Absence of Enophthalmos	Options: Present, Absent
Acceptable Cheek Projection	Options: Acceptable, Unacceptable
Overall Ability to Speak After Surgery	Assessment based on functional evaluation

Table S7. Patient Satisfaction Questionnaire (Facial Appearance).

Parameter	Response Scale (1 = Poor, 2 = Acceptable, 3 = Good, 4 = Excellent)
Facial Symmetry	Rate the overall appearance and proportion of the face
Cheek Prominence	Rate the prominence and balance of the cheeks
Scar Appearance	Rate the visibility and severity of surgical scars (1 = Very noticeable, 2 = Quantitatively noticeable, 3 = Hardly noticeable)
Speech	Rate clarity and effectiveness of speech post-surgery
Eating/Drinking Ability	Rate the functional ability to eat and drink without complications

Table S8. Quality of Life Questionnaire.

Domain	Response Options
Pain	• I have no pain • I have slight pain (no medication required) • I have moderate pain (requires regular medication, e.g., paracetamol/NSAIDs) • I have severe pain (controlled only with prescription medication) • I have severe pain (uncontrolled)
Appearance	• No change in my appearance • Slight change • My appearance bothers me but I remain active • I feel significantly depressed and limit my activities because of my appearance • I cannot interact with others due to my appearance
Activity	• My activity level remains the same as before • Occasionally, I cannot perform activities at my previous pace • I often feel tired and my activities have decreased (though I still go out) • I do not go out due to lack of energy • I mostly stay in bed or on the sofa
Recreation/Entertainment	• No restrictions on recreational activities • Some restrictions exist, but I still enjoy life • I often wish I could go out but cannot • Significant restrictions exist, and I mostly stay at home watching TV • I cannot engage in any enjoyable activities
Swallowing	• I can swallow as usual • I can swallow some solid foods • I can only swallow liquid foods • I cannot swallow anything due to aspiration
Chewing	• I can chew as usual • I can chew soft solids but not certain foods • I cannot chew even soft solids
Speaking	• My speech is as usual • I have difficulty with some words (but telephone speech is understandable) • Only my family and friends understand my speech • My speech is not understandable

To be continurìed

Taste	• I can usually taste food flavors • I can taste most foods normally • I cannot taste some foods • I cannot taste any food
Saliva	• My saliva is normal with typical consistency • My saliva is slightly reduced but sufficient • I have excessive saliva • I have no saliva
Mood	• My mood is excellent and unrelated to my illness • My mood is generally good with occasional effects from my illness • I am in good spirits and not depressed • I am somewhat depressed • I am very depressed
Anxiety	• I am not worried about my illness • I am somewhat anxious • I am worried about my illness • I am very anxious about my illness

Table S9. General Quality of Life Questions.

Question	Response Options
Compared to before you became ill, how do you rate your current health-related quality of life?	• Much better• Somewhat better• The same• Somewhat worse• Much worse
Overall, how would you rate the quality of your health-related quality of life over the past 7 days?	• Excellent• Very good• Good• Fair• Poor• Very poor
Overall, considering not only your physical and mental health but also other factors such as family, friends, and leisure activities that contribute to your well-being, how would you rate your overall quality of life over the past 7 days?	• Excellent• Very good• Good• Fair• Poor• Very poor

Table S10. Patient Self-Assessment of Facial Aesthetics.

Item	Response Scale (4-Point: 1: Completely Agree, 2: Somewhat Agree, 3: Somewhat Disagree, 4: Completely Disagree)
Some parts of my face appear very large.	
Some parts of my face appear sunken.	
My face looks deformed.	
The shape of my face is not normal.	
My face appears unattractive.	
My face appears disproportionate.	
My face looks damaged.	
My face looks unnatural.	
My face appears uneven and rough.	
The two sides of my face are different.	

In the next step, a total of 19 patients were enrolled in the study, with a mean ± SD age of 34.05 ± 15.76 years. The gender distribution was seven females (36.8%) and 12 males (63.2%). The mean ± SD follow-up duration was 2.79 ± 1.81 years. In terms of education, 5.3% (n=1) were illiterate, 26.3% (n=5) had primary education, 21.1% (n=4) completed middle school, 21.1% (n=4) held a high school diploma, 21.1% (n=4) had a bachelor's degree, and 5.3% (n=1) had a master's degree. Lifestyle assessments indicated that 73.7% (n=14) were non-smokers, 10.5% (n=2) smoked fewer than five cigarettes per day, and 15.8% (n=3) smoked more than five cigarettes per day. A family history of smoking was absent in 84.2% (n=16) of patients, and 78.9% (n=15) reported no waterpipe use. Furthermore, 94.7% (n=18) denied substance abuse and 78.9% (n=15) reported no alcohol consumption.

Regarding disease characteristics, trauma was the predominant cause of injury (73.7%; n=14), followed by malignancy (15.8%; n=3) and infection (10.5%; n=2). The extent of the defect was distributed as Class 1 (5.3%; n=1), Class 3 (10.5%; n=2), and Class 4 (15.8%; n=3). Involvement of midface structures was noted in 5.3% (lip only), 21.1% (eyelid only), 36.8% (nose and eyelid), and 21.1% (lip, nose, and eyelid), with a history of radiotherapy present in 21.1% of cases. Surgical data showed that 36.8% (n=7) patients underwent one surgery, 31.6% (n=6) had two, 15.8% (n=3) had three, and 5.3% (n=1) each underwent five, six, or even ten surgeries. Secondary surgery for aesthetic improvement was performed in 63.2% (n=12) patients, while reconstruction of the alveolar arch and lateral nasal wall, as well as preservation of the nasal bone, were achieved in 36.8% (n=7) cases each (Table 1).

Table 1. Baseline Characteristics of Study Participants.

Variable	Category	Number (n=19)	Percentage (%)
Education Level	Illiterate	1	5.3
	Primary	5	26.3
	Middle School	4	21.1
	High School Diploma	4	21.1
	Bachelor's	4	21.1
	Master's	1	5.3
Cigarette Use	Non-smoker	14	73.7
	<5 cigarettes/day	2	10.5
	>5 cigarettes/day	3	15.8
Family History of Smoking	Absent	16	84.2
	Present	3	15.8
Waterpipe Use	Not used	15	78.9
	Used	4	21.1
Substance Abuse	Not used	18	94.7
	Used	1	5.3
Alcohol Consumption	Not consumed	15	78.9
	Consumed	4	21.1
Cause of Injury	Malignancy	3	15.8
	Trauma	14	73.7
	Infection	2	10.5
Extent of Bone and Soft Tissue Defect	Class 1	1	5.3
	Class 3	2	10.5
	Class 4	3	15.8

To be continuried

Involvement of Vital Midface Structures	Lip	1	5.3
	Eyelid	4	21.1
	Lip and nose	1	5.3
	Nose and Eyelid	7	36.8
	Lip, Nose, and Eyelid	4	21.1
History of Radiotherapy	Present	4	21.1
	Absent	15	78.9
Number of Surgeries	1 time	7	36.8
	2 times	6	31.6
	3 times	3	15.8
	5 times	1	5.3
	6 times	1	5.3
	10 times	1	5.3
Secondary Surgery for Aesthetic Improvement	Yes	12	63.2
	No	7	36.8
Reconstruction of Alveolar Arch and Lateral Nasal Wall	Yes	7	36.8
	No	12	63.2
Preservation of Nasal Bone	Yes	7	36.8
	No	12	63.2

Postoperative outcomes were generally favorable. Infection was observed in 10.5% of patients, with hematoma formation and meningitis absent in all cases. Fistula formation occurred in 21.1% and oral secretion leakage into the nasal cavity in 15.8% of patients. Acceptable facial contour was achieved in 68.4% of cases, and acceptable cheek projection was noted in 52.6% of patients, while enophthalmos was present in 26.3% of cases. Furthermore, the overall ability to speak after surgery was rated as excellent by the majority of patients (Table 2).

Table 2. Frequency and Percent of Postoperative Outcomes.

Variable	Category	Frequency (n)	Percentage (%)
Infection	Present	2	10.5
	Absent	17	89.5
Hematoma and Meningitis	Present	0	0
	Absent	19	100
Fistula	Present	4	21.1
	Absent	15	78.9
Leakage	Present	3	15.8
	Absent	16	84.2
Facial Contour	Acceptable	13	68.4
	Unacceptable	6	31.6
Enophthalmos	Present	5	26.3
	Absent	14	73.7
Cheek Projection	Acceptable	10	52.6
	Unacceptable	9	47.4
Overall Speaking Ability	30% Ability	1	5.3
	50% Ability	2	10.5
	80% Ability	1	5.3
	100% Ability	15	78.9

Regarding patient satisfaction, facial contour was rated as poor by 21.1% of patients, acceptable by 26.3%, good by 31.6%, and excellent by 21.1%. Cheek prominence received similar ratings, with 10.5% rating it as poor, 10.5% as acceptable, 42.1% as good, and 26.3% as excellent. Scar appearance was predominantly rated as good (68.4%), while speech and the ability to eat and drink were rated as excellent by 78.9% and 73.7% of patients, respectively (Table 3).

Table 3. Frequency and Percent of Patient Satisfaction Outcome.

Variable	Category	Frequency (n)	Percentage (%)
Facial Contour Symmetry	Poor	4	21.1
	Acceptable	5	26.3
	Good	6	31.6
	Excellent	4	21.1
Cheek Projection	Poor	4	10.5
	Acceptable	2	10.5
	Good	8	42.1
	Excellent	5	26.3
Scar Visibility	Highly noticeable	2	10.5
	Slightly noticeable	4	21.1
	Barely noticeable	13	68.4
Speaking Ability	Poor	4	21.1
	Acceptable	0	0
	Good	0	0
	Excellent	15	78.9
Eating and Drinking Ability	Poor	0	0
	Acceptable	2	10.5
	Good	3	15.8
	Excellent	14	73.7

Quality of life was also evaluated. Regarding pain, mostly (52.6%) reported no pain. Other domains such as appearance, activity, recreation, swallowing, chewing, speaking, taste, saliva, mood, and anxiety were also assessed (Table 4). Regarding questions evaluating the general status, compared to the month before becoming ill, 15.8% of patients rated their current health-related quality of life as much better, 31.6% as somewhat better, 31.6% as the same, 10.5% as somewhat worse, and 10.5% as much worse. When asked about their overall health-related quality of life over the past seven days, 5.3% reported it as excellent, 26.3% as very good, 31.6% as good, 10.5% as fair, 21.1% as poor, and 5.3% as very poor. Similarly, when considering their overall quality of life—which includes not only physical and mental health but also factors such as family, friends, and leisure activities—over the past seven days, patients had identical ratings: 5.3% excellent, 26.3% very good, 31.6% good, 10.5% fair, 21.1% poor, and 5.3% very poor.

Patients self-assessed their facial aesthetics using a 10-item questionnaire. Overall, self-assessments revealed that most did not perceive any part of their face as excessively large, with 73.6% strongly or somewhat disagreeing that some parts appear very large. In contrast, 63.2% strongly or somewhat agreed that some parts of their face appear sunken. A similar 63.2% strongly or somewhat agreed that the overall shape of their face is not normal. In terms of attractiveness, around 31.6% strongly agreed that their face appears unattractive. Regarding the perception of facial damage, 42.1% of respondents strongly agreed that their face appears damaged. Furthermore, 31.6% and 36.8% strongly agreed that their face appeared unnatural and uneven, respectively (Table 5).

Table 4. Frequency and Percent of Quality of Life.

Category	Response	Frequency (%)
Pain	I have no pain.	10 (52.6%)
	I have mild pain that does not require medication.	5 (26.3%)
	I have moderate pain that requires regular medication (e.g., Paracetamol or Novafen).	3 (15.8%)
	I have severe pain controlled only by prescription medication (e.g., Morphine).	1 (5.3%)
	I have severe pain that is not controlled even with medication.	0 (0%)
Appearance	No changes in my appearance.	0 (0%)
	There is a slight change in my appearance.	7 (36.8%)
	My appearance bothers me, but I remain active.	5 (26.3%)
	I feel significantly disfigured and have limited activities due to my appearance.	6 (31.6%)
	I cannot interact with others because of my appearance.	1 (5.3%)
Activity	My activity level has remained the same.	18 (94.7%)
	Sometimes, I cannot perform my activities at the same pace, but this is not constant.	1 (5.3%)
	I often feel tired, and my activities have decreased, though I still go out.	0 (0%)
	I do not go out because I lack the strength.	0 (0%)
	I usually stay in bed or on a chair and do not leave the house.	0 (0%)
Recreation and Entertainment	I have no limitations in leisure and entertainment at home or outside.	7 (36.8%)
	There are some activities I cannot do, but I still enjoy life.	5 (26.3%)
	I often wish I could go out, but I cannot.	2 (10.5%)
	I have severe limitations in what I can do; I mostly stay home and watch TV.	3 (15.8%)
	I cannot engage in any enjoyable activities.	2 (10.5%)
Swallowing	I can swallow as usual.	17 (89.5%)
	I can swallow some specific solid foods.	1 (5.3%)
	I can only swallow liquid foods.	1 (5.3%)
	I cannot swallow anything because it enters my lungs incorrectly.	0 (0%)
Chewing	I can chew as usual.	16 (84.2%)
	I can chew soft solid foods but cannot chew some other foods.	3 (15.8%)
	I cannot even chew soft solid foods.	0 (0%)
Speaking	My speech is normal.	15 (78.9%)
	I have difficulty pronouncing some words, but my speech is understandable on the phone.	0 (0%)
	Only my family and friends can understand my speech.	1 (5.3%)
	My speech is not understandable.	3 (15.8%)
Taste	I can normally taste food.	16 (84.2%)
	I can taste most foods normally.	1 (5.3%)
	I cannot taste some foods.	2 (10.5%)
	I cannot taste any food at all.	0 (0%)

To be continurìed

Saliva	My saliva is normal in quantity and consistency.	15 (78.9%)
	My saliva is slightly reduced but still sufficient.	2 (10.5%)
	My saliva is significantly reduced.	2 (10.5%)
	I have no saliva at all.	0 (0%)
Mood	My mood is great and unrelated to my illness.	3 (15.8%)
	My mood is generally good, and my illness only occasionally affects it.	2 (10.5%)
	I have a good mood and am not depressed about my illness.	2 (10.5%)
	I am somewhat depressed about my illness.	5 (36.8%)
	I am very depressed about my illness.	7 (36.8%)
Anxiety	I am not worried about my illness.	6 (31.6%)
	I am slightly anxious about my illness.	5 (26.3%)
	I am worried about my illness.	2 (10.5%)
	I am extremely anxious about my illness.	6 (31.6%)

Table 5. Frequency and Percent of Perception of Participants of Their Facial Aesthetics.

Question	Strongly Disagree	Somewhat Disagree	Somewhat Agree	Strongly Agree
1. Some parts of my face appear very large.	7 (36.8%)	7 (36.8%)	2 (10.5%)	3 (15.8%)
2. Some parts of my face appear sunken.	3 (15.8%)	4 (21.1%)	6 (31.6%)	6 (31.6%)
3. My face appears deformed.	4 (21.1%)	4 (21.1%)	6 (31.6%)	5 (26.3%)
4. The shape of my face is not normal.	1 (5.3%)	6 (31.6%)	6 (31.6%)	6 (31.6%)
5. My face appears unattractive.	2 (10.5%)	6 (31.6%)	5 (26.3%)	6 (31.6%)
6. My face appears disproportionate.	2 (10.5%)	4 (21.1%)	7 (36.8%)	6 (31.6%)
7. My face appears damaged.	1 (5.3%)	3 (15.8%)	7 (36.8%)	8 (42.1%)
8. My face appears unnatural.	2 (10.5%)	4 (21.1%)	7 (36.8%)	6 (31.6%)
9. My face appears uneven and rough.	2 (10.5%)	3 (15.8%)	7 (36.8%)	7 (36.8%)
10. The two sides of my face are different.	1 (5.3%)	5 (26.3%)	5 (26.3%)	8 (42.1%)

Discussion

The study used an expert survey to develop a detailed registry capturing patient and procedural data across 28 domains. Validation of the items in a pilot sample showed that postoperative complications were generally low, with minimal infections, and most patients achieved a favorable facial contour and cheek projection. Patient satisfaction was typically high, particularly regarding facial contour, cheek prominence, and scar appearance. In addition, patients reported excellent speaking ability and quality of life outcomes. Self-assessments of facial aesthetics showed that many patients perceived their faces as sunken or abnormal, although few reported parts of their face being extensive. These findings highlight the effectiveness of the registry in supporting clinical practice and research on facial reconstruction.

In this study, 28 data elements were identified and validated by expert consensus for the design of a patient registry system specific to craniofacial defect reconstruction. These data elements included a range of factors relevant to treatment outcomes. In

accordance with the findings of Chang et al., our expert panel rated patient satisfaction, lesion location, age, sex, and malignancy type as critical determinants of prosthetic reconstruction success for midfacial defects using local flaps (12). Moreover, prior radiotherapy was an influencing factor, a finding corroborated by our experts, who included it in the final tool (13). In addition, hyperbaric oxygen therapy accelerates wound healing and reduces infection risk, a significant factor in reconstructive surgery, which was also included in our questionnaire (14).

The extent of bone and soft tissue involvement in craniofacial defects affects the surgical outcomes. In this regard, Smolka et al. determined that the type of surgical intervention, prosthetic selection, and flap design should be considered based on the nature of the defect (15), a finding which our study supports. Given the potential involvement of various midfacial structures, surgical outcomes and prognoses can vary (16). The expert panel in our study highlighted different postoperative functional and aesthetic outcomes, including preservation of the nasal bone, acceptable cheek projection, absence of enophthalmos, prevention of nasal secretions entering the oral cavity, satisfactory facial contour, and the ability to eat and drink without leakage. These findings underscore the importance of using patient-specific and defect-specific factors in reconstructive planning to achieve optimal results. Moreover, our data support previous evidence that applying advanced digital tools—such as 3D-printed surgical guides and 3D CT imaging—improved preoperative planning and intraoperative accuracy (17). Therefore, a digital registry system can facilitate evidence-based decision-making, optimize patient outcomes, and serve as a platform for future research in midface and orbital reconstruction.

In line with advancements in 3D technology, Biswas's article demonstrated that using 3D-printed surgical guides and preoperative 3D CT imaging significantly improved surgical accuracy and treatment outcomes (18). Our findings support this result, particularly concerning orbital floor reconstruction, where materials such as porous polyethylene and titanium mesh have been shown to influence success rates. Moreover, postoperative complications such as wound infection, hematoma, and meningitis remain concerns in craniofacial reconstructive surgery, as highlighted in the study by Bender-Heine et al. (19). These findings further underscore the need for comprehensive patient registries that collect postoperative outcomes to facilitate ongoing evaluation of surgical techniques and materials, as the relevant items were also included in the questionnaire for our registry and assessed in the pilot validation study.

Despite the importance of patient registries, establishing standardized data collection systems in developing countries remains challenging. In resource-limited settings such as Iran, the large volume of patient data and the lack of integrated information systems hinder health data's effective recording and management (10). Our findings addressed the need to develop infrastructure to support registry implementation in craniofacial reconstruction. Nevertheless, future studies should explore the feasibility of integrating such systems within existing healthcare frameworks to ensure accurate and standardized data collection. Another aspect is the increasing role of patient-specific implants in craniofacial reconstruction. Custom-designed 3D-printed implants provide superior anatomical fit and functional outcomes compared to conventional approaches. Integrating such advanced technologies into registry data collection could further enhance patient outcomes by allowing for real-time assessment of prosthetic efficacy and long-term complications (20).

The strength of our study is the development of standardized evaluation forms for initial assessments and follow-ups, which can improve clinical decision-making and patient care and support future research in digital facial reconstruction. However, the study has several limitations. Our sample size was relatively small and drawn from a single institution, which may limit the generalizability of our findings. Moreover, the follow-up period was relatively short, which can restrict the evaluation of long-term outcomes and complications. Data collection also relied partly on retrospective information, possibly introducing recall or documentation bias. In addition, the high costs and technical requirements associated with advanced digital tools, such as 3D-printed surgical guides and 3D CT scanning, may challenge our registry system's immediate scalability and widespread adoption. Future studies should address these limitations by using larger, multicenter cohorts with extended follow-up durations and by assessing the cost-effectiveness of the proposed digital evaluation framework.

Conclusions

Our study showed the feasibility and clinical application of a digital data recording system for midface and orbital reconstruction. The registry successfully integrated demographic, personal history, disease, surgical, and postoperative follow-up information, as well as patient satisfaction and quality of life metrics. This structured approach enables a complete evaluation of surgical outcomes and patient-reported experiences and supports clinical decision-making by highlighting important areas for improvement in reconstructive techniques. Furthermore, implementing advanced digital tools—such as 3D-printed surgical guides and 3D CT scanning—has improved preoperative planning and intraoperative accuracy. The registry provides a platform for ongoing research, facilitating longitudinal follow-up and the collection of high-quality data for improvements in midface and orbital reconstruction. Future studies with larger patient cohorts and longer follow-up durations are warranted to validate these findings and refine the system for widespread clinical adoption.

Ethics approval and consent to participate

Written informed consent was obtained from the subjects, allowing anonymized data use for research, audits, and follow-up. We followed national and international guidelines and regulations. It was

conducted in accordance with the Declaration of Helsinki. The study protocol was approved by the institutional ethics committee (code: IR.TUMS.DENTISTRY.REC.1401.146).

Consent for publication

Not applicable.

Availability of data and materials

The data supporting this study's findings are available on request from the corresponding author. However, due to privacy or ethical restrictions, the data are not publicly available.

Competing interests

The authors declare that they have no conflicts of interest.

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