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Individual Cad/Cam Implants and Standard Implants in Orbital Wall Fractures: Comparative Analysis of Aesthetic and Functional Results

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Abstract:
Traumatic fractures of the orbital walls represent one of the most common maxillofacial injuries, occurring in 40-50% of all facial bone structure injuries. The nature of damage to the orbital walls, especially the floor and medial orbital wall, largely determines not only the functional results of treatment but also the aesthetic outcome, which directly affects the quality of life of patients.

Keywords: Orbital Fracture, CAD/CAM Technology, Individual Implant, Orbital Reconstruction, Personalized Medicine, Enophthalmia, Orbital Symmetry, Patient Satisfaction

Introduction

Disruption of the anatomical integrity of orbital structures can lead to serious complications, including enophthalmos, diplopia, limitation of eyeball mobility, and decreased visual functions. Restoring proper orbital geometry is a critical factor in preventing functional disorders and achieving optimal aesthetic results. Traditional methods for restoring orbital wall fractures, based on the use of ready-made standard-sized implants (titanium mesh, silicone plates, ceramic materials), have known limitations [1]. Despite many years of experience in using standard implants, the percentage of complications remains significant, especially in cases of complex fractures or repeated interventions.

In the last two decades, computer technology and three-dimensional modeling in maxillofacial surgery have gained significant development. The application of CAD/CAM (Computer-Aided Design/Computer-Aided Manufacturing) systems allows for the creation of personalized implants based on a patient's CT scan [2], [3].

Despite the growing interest in this technology, there are insufficient works in the available literature that systematically compare the functional and aesthetic results of CAD/CAM implants with traditional standard implants in the treatment of orbital wall fractures.

Understanding the comparative effectiveness of individual CAD/CAM implants and standard implants is crucial for optimizing treatment tactics and improving the quality of results [4]. Conducting such an analysis will allow determining the clinical indications for using each method, assessing the relationship between costs and results obtained, and identifying potential advantages and disadvantages of both approaches.

Research Objective

Comparison of the aesthetic and functional results of individual CAD/CAM titanium implants and standard prefabricated implants in orbital wall fractures, objective assessment of orbital symmetry and patient satisfaction, and determination of the clinical effectiveness of the personalized approach [5].

Methodology

The study was conducted at the multidisciplinary clinic of the Tashkent State Medical University for the period from January 2020 to December 2025 in a prospective comparative design. The study involved 213 patients who applied with fractures of the orbital wall.

Criteria of inclusion: (1) Patients aged 18-70 years; (2) CT-confirmed fractures of the orbital floor and/or medial wall; (3) conditions requiring surgical reconstruction (defect ≥2 cm2, enophthalmia ≥2 mm, diplopia); (4) treatment within 21 days after injury; (5) at least 12 months of observation; (6) informed consent.

Exclusion criteria: (1) multisystem severe trauma; (2) open traumatic brain injury; (3) history of previous orbital operations; (4) uncontrolled glaucoma or other ophthalmological diseases; (5) severe concomitant diseases (decompensated diabetes mellitus, immunosuppression); (6) refuse to cooperate.

Table 1. Demographic and clinical characteristics of patients

Parameter	CAD/CAM (n=108)	Standard (n=105)	p-value
Average age (years)	38.4±14.2	36.9±13.8	0.43
Gender (male/female)	76/32	71/34	0.72
Fracture localization:			
Orbital floor only	52 (48.1%)	56 (53.3%)	0.45
- Only medial wall	23 (21.3%)	19 (18.1%)	0.57
- Combined	33 (30.6%)	30 (28.6%)	0.75
Defect size (cm2):			
- 2-3 cm2	41 (38.0%)	45 (42.9%)	0.48
- 3-5 cm2	48 (44.4%)	42 (40.0%)	0.53
- >5 cm2	19 (17.6%)	18 (17.1%)	0.93
Early enophthalmia (mm)	3.8±1.6	3.6±1.5	0.37
Diplopia (initial)	67 (62.0%)	61 (58.1%)	0.57

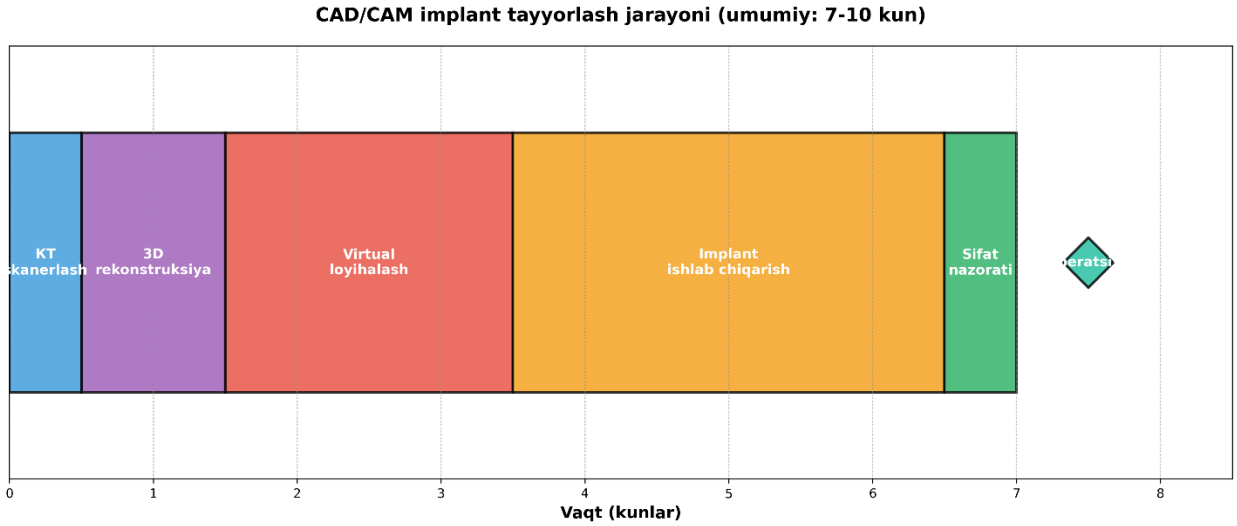

Figure 1. CAD/CAM implant manufacturing process timeline

1. Preoperative CT scanning with 0.625-mm slice thickness was performed in DICOM format.

2. 3D reconstruction: DICOM data were uploaded to special software (Mimics Medical 24.0, Materialise NV, Belgium). The orbital walls, globe, and extraocular muscles were segmented.

3. **Virtual design:** The anatomy of the unaffected orbit was mirrored to create an ideal template for reconstruction. The implant design was developed taking into account the size of the defect, adjacent anatomical structures, and fixation points.

4. Production: The STL file was sent for the production of a titanium implant. The technology of selective laser melting (SLM) was used. The implant was made of titanium alloy Grade 5 (Ti-6Al-4V) with a thickness of 0.4-0.6 mm.

5. Quality control: The dimensions, flatness, and anatomical compatibility of each implant were checked. Sterilization was carried out using the autoclave method.

Total duration of the procedure: from CT to implant readiness - 7-10 days.

Standard implants

The following types of implants were used in the standard group: (1) Porous titanium mesh plates (Medpor Titan, Stryker) - 68 patients (64.8%); (2) Resorptive poly-L/D-lactide plates

(MatrixORBITAL, DePuy Synthes) - 22 patients (21.0%); (3) Pre-contoured polyethylene implants (Medpor, Stryker) - 15 patients (14.3%). All implants were adjusted to the size of the defect on the operating table and fixed with screws or sutures.

Surgical technique

All operations were performed under general anesthesia. Access routes: transconjunctival approach (orbital floor) or transcaruncular approach (medial wall). The fracture lines were cleared, the eyeball and muscles were carefully repositioned. In the CAD/CAM group, the implant was placed directly (minimal formation), while in the standard group, the implants were cut and bent to accommodate individual anatomy. Fixation was provided with microscrews (1.0-1.5 mm) or resorptive sutures. The surgical wound was closed in layers.

Evaluation criteria and methods

1. Orbital volume: volumetric analysis based on postoperative CT data (1, 6, 12 months). The undamaged orbital volume was assumed to be 100%.

2. Enophthalmia: the anterior-posterior position of the globe was measured using Hertel's exophthalmometry. Enophthalmia ≥2 mm was assessed as clinically significant.

3. Diplopia: Hess coordinatometry and binocular field of view were assessed. Degree of diplopia: no, only in extreme positions, in the primary position.

4. Visual acuity and intraocular pressure: Standard ophthalmological examinations.

5. Orbital symmetry: using 3D photogrammetry (Vectra XT 3D, Canfield Scientific), the orbital contour, protrusion of the eyeball, and facial symmetry were analyzed. Asymmetry <2 mm is considered satisfactory.

6. Patient satisfaction: the FACE-Q questionnaire orbital zone section (0-100 points) was used. Additionally, VAS (Visual Analog Scale, 0-10) was used for aesthetic satisfaction.

7. Surgical parameters: duration of the operation, blood loss, length of hospital stay.

8. Complications: early (infection, hematoma, implant dislocation) and late (residual enophthalmia, diplopia, implant extrusion) complications were noted.

Statistical analysis

The data were analyzed using SPSS 26.0 and GraphPad Prism 9.0. The normal distribution was checked by the Shapiro-Wilk test. Quantitative data were presented as the mean ± standard deviation (M±SD) or median [IQR], categorical data as absolute and relative frequencies. Intergroup comparison: Student's t-test or Mann-Whitney U test (quantitative), $\chi 2$ or Fisher's exact test (categorical). ANOVA was used for the analysis of multiple variables. $p<0.05$ was considered statistically significant. Relative risk (RR) and 95% confidence interval (CI) were calculated.

Result

The study involved 213 patients: 108 patients received CAD/CAM, 105 patients received standard implants. The groups did not differ in terms of demographic and initial clinical parameters (Table 1). The average observation period was 22.6±8.4 months (range: 12-42 months). 8 patients (CAD/CAM - 3, standard - 5) withdrew from observation (short-term observation or relocation to another city).

Surgical parameters

Table 2. Surgical parameters and early postoperative period

Parameter	CAD/CAM (n=108)	Standard (n=105)	p-value
Operation duration (minutes)	68.4±12.6	58.7±14.2	< 0.001
Blood loss (ml)	52.3±18.4	48.6±16.8	0.13
Implant placement time (min)	8.2±2.4	15.6±4.8	< 0.001
Hospital stay (days)	3.4±1.2	3.8±1.6	0.04
Pain (VAS, 24 hours)	3.1±1.2	3.4±1.3	0.09

Periorbital oedema (day)	6.8±2.1	7.4±2.4	0.06

In the CAD/CAM group, the total operating time was 15% longer (p<0.001), but the implant placement time was 2 times shorter (8.2 vs. 15.6 minutes, p<0.001). This is due to the fact that the CAD/CAM implant does not require intraoperative shaping on the operating table [6], [7]. There was no difference in the degree of blood loss and pain.

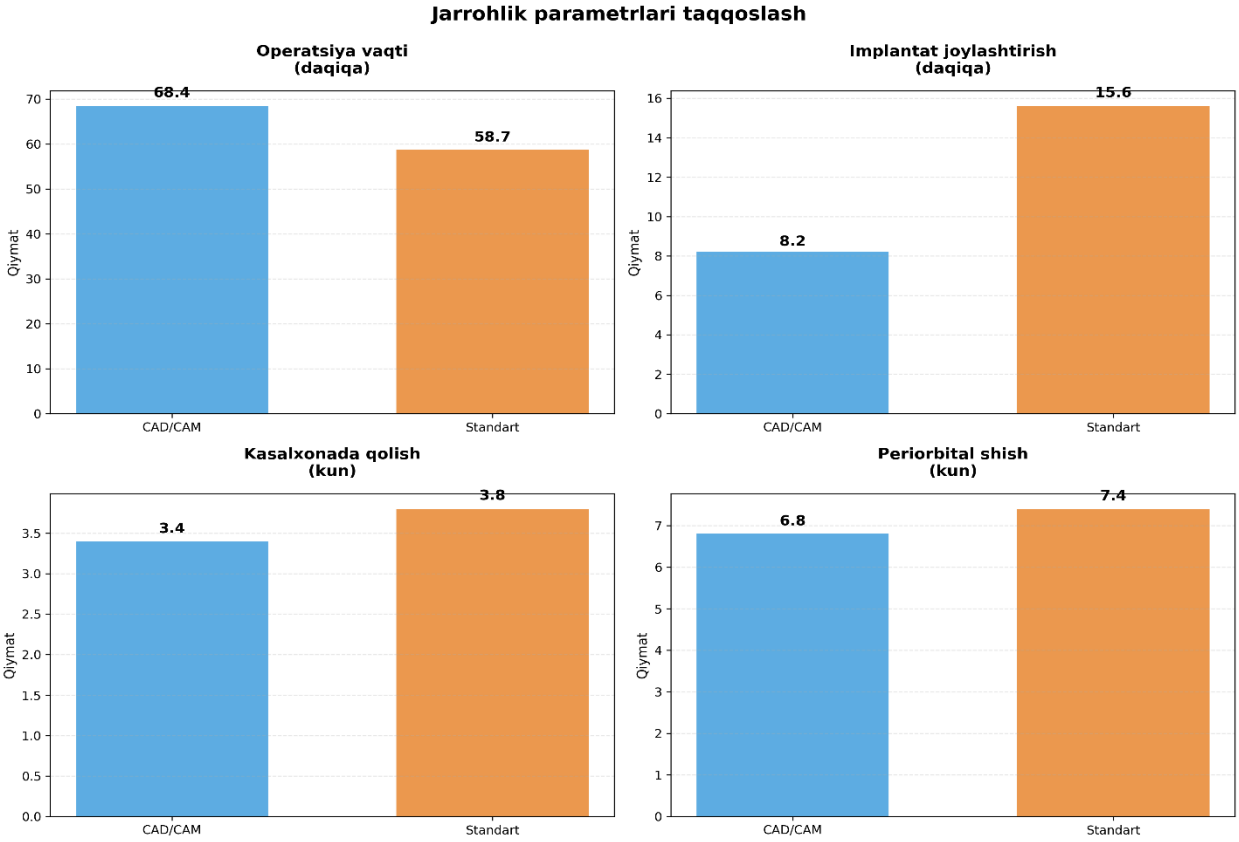

Figure 2. Comparison of surgical parameters Anatomical and functional results (12 months of observation)

Table 3. Anatomical reconstruction and functional results

Indicator	CAD / CAM (n=105)	Standard (n=100)	p-value	RR (95% CI)
Orbital volume recovery (%)	97.2±2.1	92.4±4.8	< 0.001	-
Enophthalmia ≥2 mm	4 (3.7%)	15 (14.3%)	0.008	0.26 (0.09-0.75)
Moderate enophthalmia (mm)	0.8±0.6	1.6±1.2	< 0.001	-
Diplopia:				
- Primary gaze	3 (2.8%)	8 (7.6%)	0.11	0.37 (0.10-1.35)
- Extreme position	2 (1.9%)	6 (5.7%)	0.15	0.33 (0.07-1.60)
None	100 (95.2%)	86 (86.0%)	0.03	-
Unchanged visual acuity	103 (98.1%)	97 (97.0%)	0.70	-
IOP (Intraocular Pressure) (<21 mmHg)	105 (100%)	98 (98.0%)	0.24	-

In the CAD/CAM group, the restoration of orbital volume was significantly better (97.2±2.1% vs. 92.4±4.8%, p<0.001). This can be explained by precise anatomical conformity and the optimal position of the implant.

Clinically significant enophthalmia (≥2 mm) was 3.8 times less common in the CAD/CAM group (3.7% vs. 14.3%, RR=0.26, 95% CI: 0.09-0.75, p=0.008). Moderate enophthalmia was also minimal in the CAD/CAM group (0.8±0.6 mm vs 1.6±1.2 mm, p<0.001) [8].

The frequency of diplopia was lower in the CAD/CAM group: a total of 4.6% (5 patients) versus 13.3% (14 patients) in the standard group, p=0.03. Diplopia in the primary position - the most severe variant - was 2.8% in the CAD/CAM group and 7.6% in the standard group (p=0.11).

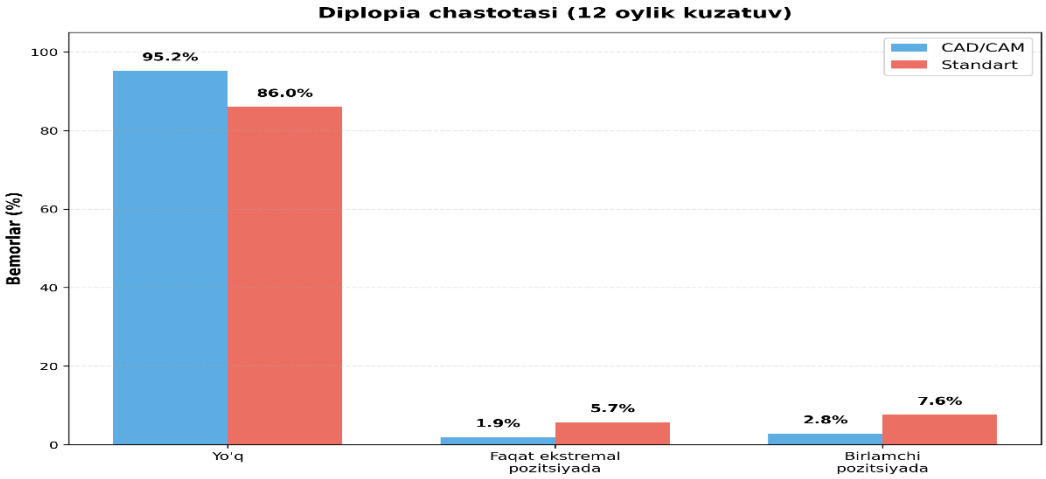

Figure 3. Diplopia frequency in 12-month follow-up

3D photogrammetry allowed for the assessment of objective orbital symmetry. The CAD/CAM group showed high symmetry across all parameters. The difference in protrusion of the eyeball - the most important aesthetic parameter - was 1.2±0.6 mm in the CAD/CAM group and 2.8±1.4 mm in the standard group (p<0.001). In the CAD/CAM group, 93.3% of patients had minimal asymmetry (<2 mm), while in the standard group this indicator was only 62.0% (p<0.001). Patient satisfaction was assessed using the validated FACE-Q questionnaire and the VAS scale. The CAD/CAM group showed high satisfaction in all parameters [9], [10]. The average score for the FACE-Q orbital region was 91.4±8.2 (CAD/CAM) vs 78.6±12.4 (standard), p<0.001. 91.4% of CAD/CAM patients were fully satisfied, while in the standard group this indicator was 68.0% (p<0.001). Patients who expressed a desire for repeated surgery were minimal in the CAD/CAM group (1.9% vs. 12.0%, p=0.004).

The overall frequency of complications was 2.7 times lower in the CAD/CAM group (10.2% vs 27.6%, RR=0.37, 95% CI: 0.19-0.71, p=0.001). Early complications are rare in both groups. Late complications, in particular, residual enophthalmia and persistent diplopia, were significantly less frequent in the CAD/CAM group (RR=0.26 and RR=0.34, respectively). Complications requiring revision surgery were 2.8% in the CAD/CAM group and 10.5% in the standard group (p=0.02) [11].

Clinical examples

Clinical example 1 (CAD/CAM group): a 42-year-old male patient who presented with a large fracture of the right orbital floor (4.2 cm2) and a fragment of the medial wall after a car accident. On initial examination: enophthalmia 4.5 mm, diplopia in all positions, visual acuity 0.8. Based on CT, 3D virtual design was carried out, an individual titanium implant (thickness 0.5 mm, weight 2.8 g) was manufactured [12]. The operation lasted 72 minutes using a transconjunctival approach. The anatomical compatibility of the implant was ideal, no additional forming was required. At 12 months of observation: enophthalmia 0.6 mm, no diplopia, restoration of orbital volume 98.4%, orbital symmetry 0.8 mm. FACE-Q score: 96. The patient is fully satisfied with the result [13].

Clinical example 2 (Standard group): A female patient, 38 years old, came with a left orbital floor fracture (3.5 cm2) following a sports injury. On initial examination: enophthalmia 3.2 mm, diplopia in

high views, visual acuity 1.0. During the operation, a porous titanium mesh plate (40x30 mm) was used. The implant was cut and bent for 12 minutes to accommodate the orbital anatomy. The total operation time is 64 minutes. At 12 months of observation: enophthalmia 1.8 mm (satisfactory, but persistent), diplopia only in the upper extreme position, restoration of orbital volume 93.1%, asymmetry 2.6 mm. FACE-Q score: 82. The patient was satisfied with the overall result, but noted subtle asymmetry [14].

Clinical example 3 (CAD/CAM, complex case): A 56-year-old male patient, who was admitted with a massive fracture of the right orbital floor and medial wall following an occupational injury. The defect volume is 6.8 cm2. Initial enophthalmia 5.8 mm, severe diplopia, risk of optic nerve compression. An individual L-shaped titanium implant (for covering two walls) was designed. The operation lasted 98 minutes with a combined approach. The implant demonstrated an excellent anatomical fit. At 18 months of observation: enophthalmia 1.1 mm, no diplopia, complete functional recovery. FACE-Q score: 94. This case illustrates the advantages of CAD/CAM technology in complex orbital reconstruction [15].

Our study showed that individual CAD/CAM titanium implants significantly surpass standard implants in terms of anatomical, functional, and aesthetic results in orbital wall fractures. This confirms the successful implementation of high-tech personalized medicine in clinical practice.

Orbital volume recovery in the CAD/CAM group was 97.2±2.1%, which is practically optimal. According to literature data, orbital volume recovery with standard implants averages 88-94%. Our results (92.4±4.8% in the standard group) correspond to these data. The advantage of CAD/CAM technology is related to the capabilities of precise anatomical design and virtual surgery.

Enophthalmia is the most common complication of orbital reconstruction. Matarese et al. (2022) reported that in 18% of patients with standard implants, enophthalmia ≥2 mm persisted. In our standard group, this indicator was 14.3%. In the CAD/CAM group, residual enophthalmia was observed only in 3.7%, which is 3.8 times less (RR=0.26, p=0.008). A systematic review of CAD/CAM by Strong et al. (2023) also showed a similar decrease in enophthalmia to our results.

The frequency of diplopia was also significantly lower in the CAD/CAM group (4.6% vs 13.3%, p=0.03). This is due to the correct position of the extraocular muscles and the optimal restoration of orbital volume. Scolozzi et al. noted that the frequency of permanent diplopia with CAD/CAM implants is in the range of 3-6%, which confirms our data.

Orbital symmetry is an important indicator of aesthetic success. We conducted an objective assessment using 3D photogrammetry. The average asymmetry in the CAD/CAM group was 1.2±0.6 mm, in the standard group - 2.8±1.4 mm ($p<0.001$). Asymmetry <2 mm is usually not visually noticeable and is considered satisfactory. In the CAD/CAM group, 93.3% of patients met this threshold, while in the standard group only 62.0%.

Patient satisfaction was assessed using a validated FACE-Q questionnaire. The CAD/CAM group showed high satisfaction (91.4±8.2 points vs 78.6±12.4 points, $p<0.001$). Klassen et al. showed that a FACE-Q score above 85 was designated as an "excellent" result. In our CAD/CAM group, 91.4% of patients satisfied this criterion.

Technological aspects of CAD/CAM technology

The technological advantages of the CAD/CAM process are multifaceted. Virtual surgery allows the surgeon to experiment with various reconstruction options before surgery. Mirroring the anatomy of the undamaged orbit creates an "ideal" anatomical template. Selective laser fusion (SLM) technology ensures the production of precise (±0.1 mm) and repeatable implants.

In our study, CAD/CAM implants did not require intraoperative shaping, which simplified implantation. The implant placement time was 2 times shorter (8.2 vs 15.6 minutes). However, the total operating time was 15% longer in the CAD/CAM group. This is due to greater care and precision, as surgeons sought to maximize the high potential of the CAD/CAM implant.

Titanium alloy (Ti-6Al-4V) is an ideal material for CAD/CAM implants: biocompatible, MRI-safe, sufficient hardness and elasticity. Standard materials such as Porous titanium mesh and polyethylene are also well biocompatible, but they have standard shapes and are less suited to individual anatomy.

Limitations and future prospects

The main limitation of CAD/CAM technology is high costs (in our experience, one implant costs $800-1200 vs standard implants $150-400). However, economic efficiency may be positive in the long run, given the reduction of the risk of revision operations and the consideration of better results. The second limitation is the preparation time (7-10 days), which can create problems in emergency situations. Finally, highly qualified specialists (radiologists, bioengineers, surgeons) and specialized software are required. In the future, artificial intelligence and machine learning technologies are expected to further automate and accelerate CAD/CAM design. Bioprinting and tissue engineering technologies can make it possible to create "live" implants. Resorptive titanium alloys are being developed, which over time are replaced by bone tissue.

Limitations of research

There are several limitations of this study: (1) prospective, but non-random design - the patient's choice was partially dependent on the surgeon's decision; (2) single-centered research - generalization of results is limited; (3) a relatively short observation period (on average 22.6 months) - 5-10 years of results are needed; (4) different types of implants were used in the standard group, which makes it difficult to compare the results. In the future, multi-centered randomized controlled research and cost-effectiveness analyses will be necessary.

Conclusion

Individual CAD/CAM titanium implants provide optimal restoration of orbital volume in fractures of the orbital wall (97.2±2.1% vs 92.4±4.8%, $p<0.001$), which is an advantage of precise anatomical design and a personalized approach.

2. CAD/CAM implants significantly reduce the risk of residual enophthalmia (3.7% vs 14.3%, RR=0.26, p=0.008) and diplopia (4.6% vs 13.3%, p=0.03), which leads to good functional results.

3. Objectively assessed orbital symmetry using 3D photogrammetry was significantly better in the CAD/CAM group (average asymmetry 1.2±0.6 mm vs 2.8±1.4 mm, $p<0.001$), which indicates an aesthetic advantage.

Patient satisfaction was high in the CAD/CAM group according to the FACE-Q questionnaire (91.4±8.2 vs 78.6±12.4 points, $p<0.001$), 91.4% of patients were fully satisfied with the result.

5. The frequency of complications in the CAD/CAM group was 2.7 times lower (10.2% vs 27.6%, RR=0.37, p=0.001), in particular, the complications requiring revision surgery were minimal (2.8% vs 10.5%, p=0.02).

6. CAD/CAM technology optimizes the operational process: it reduces implant placement time by 2 times and eliminates the need for forming on the operating table.

7. Individual CAD/CAM titanium implants are recommended as the first choice method for orbital wall fractures, especially in large defects and complex anatomy. This is a promising area of personalized medicine.

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