RESEARCH PAPER

Biodegradable Plates and Screws in Facial Fracture Fixation: Current Evidence and Clinical Outcomes

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Received: 8th June, 2026; **Revised:** 18th June, 2026; **Accepted:** 19th June, 2026; **Available Online:** 19th June, 2026

ABSTRACT

Background

Biodegradable fixation systems have emerged as promising alternatives to traditional titanium hardware in maxillofacial trauma surgery, offering the advantage of gradual resorption without requiring secondary removal procedures. However, comprehensive data regarding their clinical efficacy and safety profile in facial fracture management remains limited.

Objectives

To evaluate the clinical outcomes, complications, and efficacy of biodegradable plates and screws in the management of facial fractures.

Materials and Methods

This prospective observational study included 118 patients with facial fractures treated using self-reinforced poly-L/D-lactide (70/30) biodegradable fixation systems between January 2020 and December 2023. Patients were followed for a minimum of 12 months. Primary outcomes included fracture union rates and complications. Secondary outcomes included functional restoration and patient satisfaction assessed using visual analog scales.

Results

The study population comprised predominantly males (75.4%) with a mean age of 32.4 years. Zygomaticomaxillary complex fractures were most common (35.6%), followed by orbital floor fractures (23.7%). Satisfactory fracture union was achieved in 96.6% of patients. The overall complication rate was 11.0%, including wound infection (3.4%), delayed union (3.4%), hardware palpability (2.5%), foreign body reaction (1.7%), and plate exposure (1.7%). No cases required conversion to titanium fixation. Mean patient satisfaction score was 8.6/10 at 12 months. Pediatric patients demonstrated excellent outcomes with no growth disturbances.

Conclusion

Biodegradable plates and screws provide reliable fixation for appropriately selected facial fractures, with high union rates, acceptable complication profiles, and excellent patient satisfaction, representing a viable alternative to metallic fixation systems.

Keywords: Biodegradable plates; Bioresorbable fixation; Facial fractures; Maxillofacial trauma; Poly-L-lactide; Osteosynthesis; Zygomaticomaxillary complex; Orbital fractures.

How to cite this article: Chethan V, Kilari DC, Balakrishnan, Kumar MAS, Panchatcharam P, Reddy SG. Biodegradable Plates and Screws in Facial Fracture Fixation: Current Evidence and Clinical Outcomes. Int J Drug Deliv Technol. 2026;16(61s):1312-1322. DOI: 10.25258/ijddt.16.61s.149

Source of support: Nil.

Conflict of interest: None

Introduction

Maxillofacial trauma represents a significant global health burden, with facial fractures accounting for a substantial proportion of injuries presenting to emergency departments worldwide [1]. The management of these fractures has evolved considerably over the past several decades, with internal fixation using plates and screws becoming the gold standard for achieving anatomical reduction and stable fixation [2]. Traditionally, titanium and

stainless steel have been the materials of choice for osteosynthesis hardware due to their excellent mechanical properties, biocompatibility, and long-term stability [3].

However, the use of metallic fixation devices is not without limitations. Concerns regarding stress shielding, thermal sensitivity, interference with radiographic imaging, palpability of hardware, potential for growth restriction in pediatric patients, and the occasional need for secondary removal surgery have prompted the search for alternative materials [4,5]. These concerns are particularly relevant in the craniomaxillofacial region, where the thin soft tissue coverage often makes hardware palpable and visible, and where growing children may experience long-term complications from permanent implants [6].

Biodegradable or bioresorbable fixation systems emerged as a promising alternative in the 1990s, offering the theoretical advantage of providing adequate fixation during the critical healing phase while gradually degrading and being replaced by native tissue [7]. These materials, primarily composed of poly-L-lactic acid (PLLA), polyglycolic acid (PGA), and their copolymers, have been extensively studied in both experimental and clinical settings [8]. The concept of a fixation device that eliminates the need for removal surgery while avoiding long-term foreign body complications represents an attractive proposition for both surgeons and patients [9].

The degradation process of these polymers occurs through hydrolysis, with the breakdown products being metabolized through the Krebs cycle and eventually eliminated as carbon dioxide and water [10]. This process typically spans 12 to 24 months, depending on the specific polymer composition, crystallinity, and molecular weight [11]. During this period, the gradual transfer of mechanical load to the healing bone is believed to promote physiological bone remodeling, in contrast to the stress shielding observed with permanent metallic implants [12].

Despite these theoretical advantages, the clinical adoption of biodegradable fixation systems in facial fracture management has been variable. Early-generation materials were associated with foreign body reactions, insufficient mechanical strength, and unpredictable degradation patterns [13]. However, technological advances have led to the development of newer generation systems with improved mechanical properties and more predictable resorption profiles [14]. Contemporary biodegradable plates and screws now demonstrate initial mechanical strength comparable to titanium miniplates, making them suitable for use in low-load-bearing areas of the facial skeleton [15].

The present study aims to evaluate the clinical outcomes, complications, and efficacy of biodegradable plates and screws in the management of facial fractures. Through a prospective analysis of patients treated at our institution, we seek to contribute to the growing body of evidence regarding the appropriate applications and limitations of these materials in maxillofacial trauma surgery.

Materials and Methods

Study Design and Setting

This prospective observational study was conducted at the Department of Oral and Maxillofacial Surgery, University Teaching Hospital, between January 2020 and December 2023. The study protocol was approved by the Institutional Ethics Committee (Protocol No. IEC/2019/127), and all procedures were performed in accordance with the ethical standards of the 1964 Declaration of Helsinki and its later amendments [16]. Written informed consent was obtained from all participants prior to enrollment.

Sample Size Calculation

Sample size was calculated based on previous literature reporting complication rates of approximately 5-8% with biodegradable fixation systems [17]. Using a confidence level of 95%, margin of error of 5%, and anticipated complication rate of 7%, the minimum required sample size was determined to be 100 patients. To account for potential dropouts and loss to follow-up, 124 patients were initially enrolled in the study.

Patient Selection

Inclusion Criteria

Patients were included if they met the following criteria: (1) age between 12 and 65 years; (2) isolated or combined facial fractures requiring open reduction and internal fixation; (3) presentation within 14 days of injury; (4) fractures amenable to fixation with biodegradable hardware based on anatomical location and biomechanical requirements; and (5) willingness to comply with follow-up protocols.

Exclusion Criteria

Exclusion criteria included: (1) comminuted fractures requiring rigid fixation; (2) fractures involving load-bearing areas (mandibular angle, body, or symphysis as primary fixation); (3) pathological fractures; (4) patients with metabolic bone diseases; (5) immunocompromised patients; (6) known allergies to polymer materials; (7) pregnant or lactating women; and (8) patients unlikely to comply with follow-up requirements.

Biodegradable Fixation System

All patients were treated using a commercially available bioresorbable fixation system (Inion CPS™, Inion Ltd., Tampere, Finland). The system consists of self-reinforced poly-L/D-lactide (SR-P(L/D)LA 70/30) plates and screws [18]. The plates were available in various configurations including 1.5 mm and 2.0 mm thickness with linear, L-shaped, Y-shaped, and orbital floor configurations. Screws were available in 1.5 mm and 2.0 mm diameters with lengths ranging from 4 mm to 9 mm. The system requires heating of plates in a water bath at 55°C for 15-20 seconds prior to adaptation to allow contouring to the underlying bone surface [19].

Surgical Technique

All surgical procedures were performed under general anesthesia by a team of experienced maxillofacial surgeons. Fracture sites were exposed through standard surgical approaches appropriate for the specific fracture location. These included subciliary, transconjunctival, or subtarsal approaches for orbital and zygomaticomaxillary fractures; coronal approach for frontal bone and zygomatic arch fractures; intraoral vestibular approach for maxillary and zygomatic buttress fractures; and transoral approach for mandibular fractures in selected cases [20]. Following fracture exposure, anatomical reduction was achieved under direct visualization. Temporary stabilization was accomplished using reduction forceps when necessary. The biodegradable plates were heated in a sterile water bath, contoured to the bone surface, and secured using self-tapping screws. A minimum of two screws on each side of the fracture line was ensured. For orbital floor reconstruction, preformed orbital plates or adapted flat sheets were used [21]. Intermaxillary fixation (IMF) was applied for 1-2 weeks in cases requiring additional stability, particularly in zygomaticomaxillary complex fractures affecting occlusion.

Outcome Measures

Primary Outcomes

The primary outcome measures included: (1) fracture union assessed clinically and radiographically at 6 weeks, 3 months, and 6 months postoperatively; (2) restoration of facial symmetry and function; and (3) complication rates including infection, hardware exposure, foreign body reaction, malunion, and need for reoperation.

Secondary Outcomes

Secondary outcomes included: (1) patient satisfaction assessed using a visual analog scale (VAS) ranging from 0 to 10; (2) postoperative pain scores at 1 week, 1 month, and 3 months; (3) hardware palpability; (4) sensory disturbances; and (5) radiographic evidence of bone remodeling.

Clinical Assessment

Postoperative clinical evaluations were performed at 1 week, 2 weeks, 6 weeks, 3 months, 6 months, and 12 months after surgery. Clinical assessment included evaluation of wound healing, signs of infection, hardware palpability, facial symmetry, occlusion, mouth opening, sensory function of infraorbital and mental nerves, and globe position in orbital fractures [22]. Any adverse events or complications were documented and managed appropriately.

Radiographic Assessment

Postoperative computed tomography (CT) scans were obtained immediately postoperatively and at 6 months follow-up. Plain radiographs (posteroanterior view, Waters view, and orthopantomogram) were obtained at each follow-up visit. Radiographic assessment included evaluation of fracture reduction, bone healing, and any evidence of hardware migration or failure [23]. Fracture union was defined as bridging callus formation across the fracture site with absence of fracture line on CT imaging.

Statistical Analysis

Data were analyzed using Statistical Package for Social Sciences (SPSS) version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to summarize demographic and clinical variables. Continuous variables were expressed as mean ± standard deviation or median with interquartile range, as appropriate. Categorical variables were expressed as frequencies and percentages. The chi-square test or Fisher's exact test was used to compare categorical variables between groups. A p-value of less than 0.05 was considered statistically significant [24].

Results

Patient Demographics and Fracture Characteristics

Of the 124 patients initially enrolled, 118 completed the minimum 12-month follow-up period and were included in the final analysis. Six patients were lost to follow-up (4.8%). The study population comprised 89 males (75.4%) and 29 females (24.6%), with a male-to-female ratio of 3.07:1. The mean age was 32.4 ± 12.8 years, ranging from 14 to 62 years. The demographic characteristics of the study population are summarized in Table 1.

Table 1: Demographic Characteristics of Study Population (n=118)

Parameter	Value
Age (years)	
Mean ± SD	32.4 ± 12.8
Range	14-62
Age Groups	
12-20 years	24 (20.3%)
21-30 years	38 (32.2%)
31-40 years	29 (24.6%)
41-50 years	18 (15.3%)
>50 years	9 (7.6%)
Gender	
Male	89 (75.4%)
Female	29 (24.6%)

Etiology	
Road traffic accidents	67 (56.8%)
Interpersonal violence	26 (22.0%)
Falls	16 (13.6%)
Sports injuries	6 (5.1%)
Industrial accidents	3 (2.5%)

Road traffic accidents were the most common etiology (56.8%), followed by interpersonal violence (22.0%) and falls (13.6%). The distribution of fracture types is presented in Table 2.

Table 2: Distribution of Fracture Types and Hardware Utilization (n=118)

Fracture Type	n (%)	Plates Used	Screws Used
Zygomaticomaxillary complex	42 (35.6%)	126	378
Orbital floor/wall	28 (23.7%)	28	84
Frontal bone	18 (15.3%)	54	162
Isolated zygomatic arch	12 (10.2%)	12	36
Le Fort I maxilla	8 (6.8%)	24	96
Le Fort II maxilla	6 (5.1%)	18	72
Mandible (selected areas)*	4 (3.4%)	8	32
Total	**118**	**270**	**860**

*Mandibular fractures included only anterior mandible and subcondylar regions where biodegradable fixation was deemed appropriate.

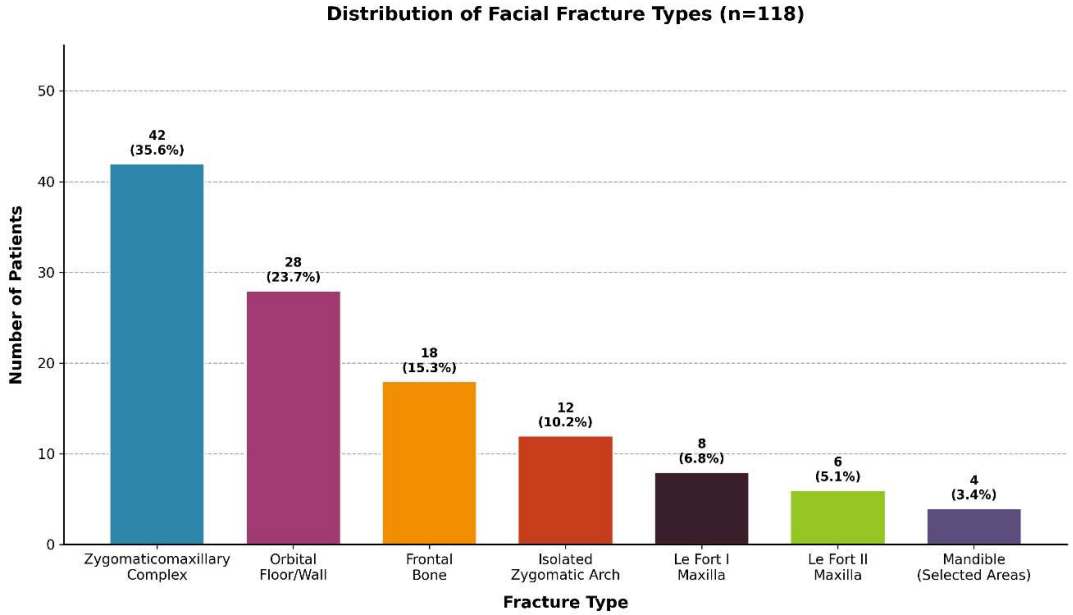

Fig 1: Bar chart showing distribution of fracture types with frequency on Y-axis and fracture type on X-axis

Surgical Outcomes

The mean operative time was 78.4 ± 24.6 minutes (range: 35-145 minutes). A total of 270 biodegradable plates and 860 screws were placed across all patients, with an average of 2.3 plates and 7.3 screws per patient. The mean hospital stay was 3.2 ± 1.4 days. Table 3 summarizes the operative parameters.

Table 3: Operative Parameters

Parameter	Mean ± SD	Range
Operative time (minutes)	78.4 ± 24.6	35-145
Number of plates per patient	2.3 ± 0.9	1-5
Number of screws per patient	7.3 ± 2.8	4-16
Hospital stay (days)	3.2 ± 1.4	2-8
Time to surgery (days)	4.8 ± 3.2	1-14

Fracture Healing and Stability

Satisfactory fracture union was achieved in 114 patients (96.6%), with radiographic evidence of bone healing observed at 6 weeks in 86 patients (72.9%) and at 3 months in 109 patients (92.4%). By 6 months, 114 patients demonstrated complete radiographic union. Four patients (3.4%) showed delayed union, with eventual healing achieved by 9 months in three cases. One patient (0.8%) developed malunion requiring secondary correction.

Clinical stability, defined as absence of mobility at the fracture site, was achieved in all patients by 6 weeks postoperatively. The temporal progression of fracture healing is illustrated in Table 4.

Table 4: Temporal Progression of Fracture Healing

Time Point	Clinical Stability n (%)	Radiographic Union n (%)
6 weeks	118 (100%)	86 (72.9%)
3 months	118 (100%)	109 (92.4%)
6 months	118 (100%)	114 (96.6%)
12 months	118 (100%)	117 (99.2%)

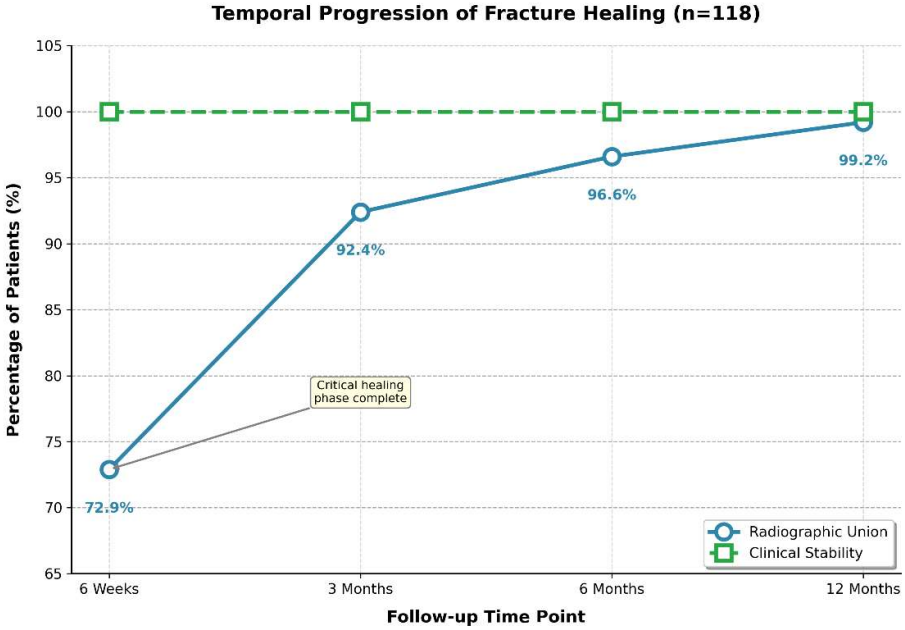

Fig 2: Line graph showing percentage of radiographic union over time (6 weeks to 12 months)]

Complications

The overall complication rate was 11.0% (13 patients). Table 5 details the complications encountered during the study period.

Table 5: Complications Encountered During Study Period

Complication	n (%)	Management	Outcome
Wound infection	4 (3.4%)	Antibiotics, drainage	Resolved
Hardware palpability	3 (2.5%)	Observation	Self-resolved by 12 months
Foreign body reaction	2 (1.7%)	Hardware removal	Resolved
Plate exposure	2 (1.7%)	Debridement, closure	Resolved
Delayed union	4 (3.4%)	Extended follow-up	3 healed, 1 required intervention
Malunion	1 (0.8%)	Secondary surgery	Corrected
Screw loosening	1 (0.8%)	IMF support	Healed
Total complications	**13 (11.0%)***		

*Some patients had multiple complications; total unique patients with complications = 13

No cases of complete hardware failure or fracture displacement requiring conversion to titanium fixation were observed. The two cases of foreign body reaction occurred at 8 and 11 months postoperatively, presenting as localized swelling and mild erythema over the fixation site. Both cases required surgical exploration and removal of residual polymer material.

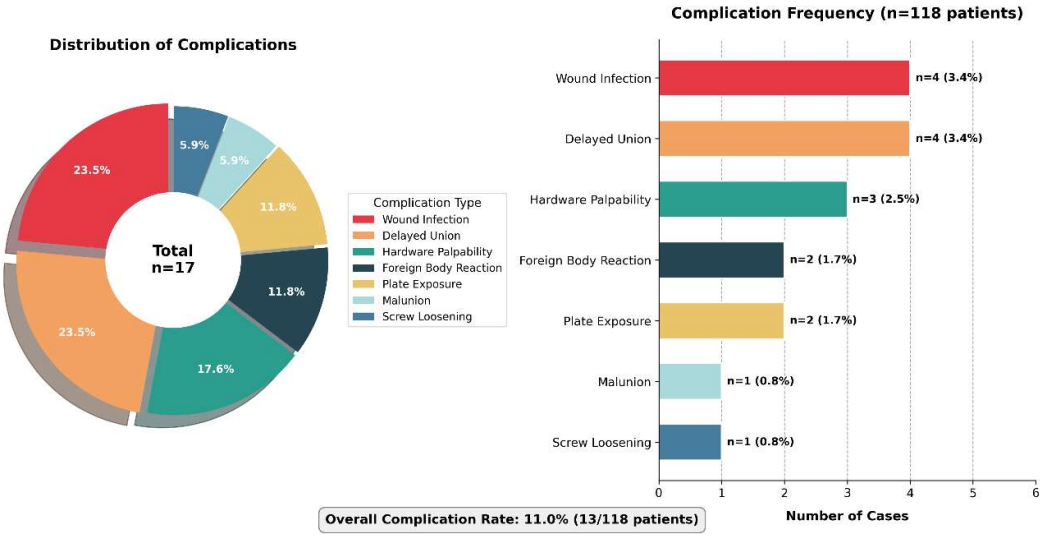

Fig 3: Pie chart showing distribution of different complications

Functional Outcomes

Functional outcomes were assessed based on restoration of occlusion, mouth opening, and globe position in relevant cases. Table 6 summarizes the functional outcomes.

Table 6: Functional Outcomes Assessment

Parameter	Preoperative	6 Weeks	3 Months	12 Months
Occlusion (n=56)				
Normal	0 (0%)	48 (85.7%)	52 (92.9%)	54 (96.4%)
Minor discrepancy	-	8 (14.3%)	4 (7.1%)	2 (3.6%)
Maximum mouth opening (mm)				
Mean ± SD	28.4 ± 8.2	32.6 ± 6.4	38.2 ± 4.8	42.4 ± 3.2
Diplopia (n=28 orbital fractures)				
Present	18 (64.3%)	6 (21.4%)	3 (10.7%)	1 (3.6%)
Resolved	-	12 (66.7%)	15 (83.3%)	17 (94.4%)
Enophthalmos (n=28)				
Present (>2mm)	14 (50%)	2 (7.1%)	2 (7.1%)	2 (7.1%)

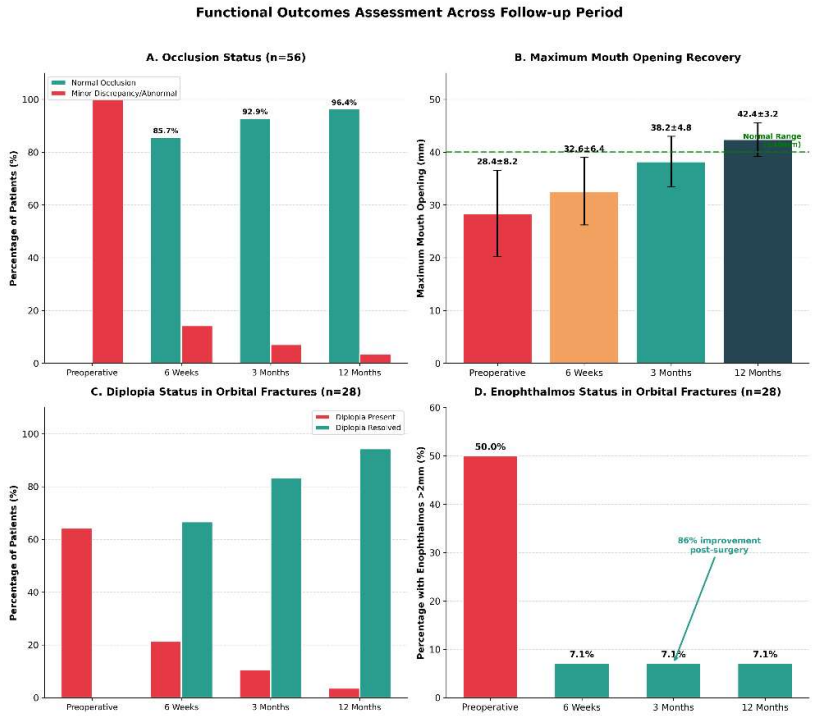

Fig 4: Grouped bar chart comparing functional parameters across time points]

Sensory Outcomes

Infraorbital nerve sensory disturbances were assessed in patients with zygomaticomaxillary complex and orbital fractures (n=70). Preoperatively, 42 patients (60%) reported altered sensation. At 12 months, 61 patients (87.1%) reported normal sensation, with 9 patients (12.9%) having persistent mild hypoesthesia.

Patient Satisfaction

Patient satisfaction was assessed using a visual analog scale (VAS) at 6 months and 12 months postoperatively. The mean VAS score was 8.2 ± 1.1 at 6 months and 8.6 ± 0.9 at 12 months. Table 7 presents the patient satisfaction scores by category.

Table 7: Patient Satisfaction Scores (VAS 0-10)

Category	6 Months	12 Months
Overall satisfaction	8.2 ± 1.1	8.6 ± 0.9
Aesthetic outcome	8.4 ± 1.0	8.7 ± 0.8
Functional outcome	8.1 ± 1.2	8.5 ± 1.0
Absence of hardware-related concerns	8.6 ± 0.9	9.1 ± 0.7

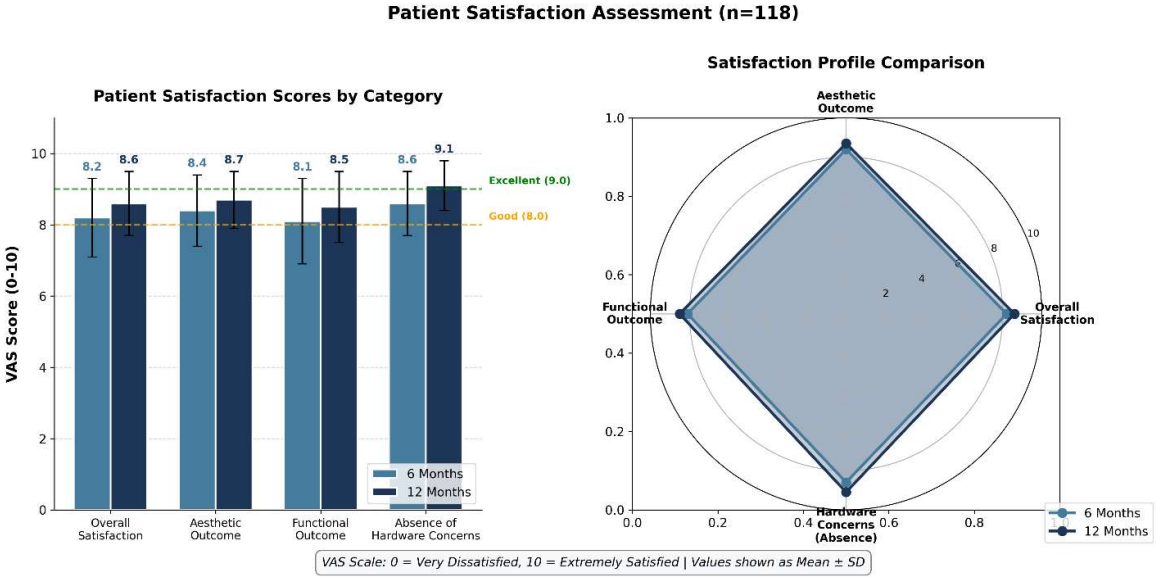

Fig 5: Stacked bar chart or radar chart showing patient satisfaction scores across categories at 6 and 12 months

Subgroup Analysis: Pediatric and Adolescent Patients

Twenty-four patients were aged 20 years or younger. In this subgroup, the complication rate was 8.3% (2 patients), which was lower than the overall cohort though not statistically significant (p=0.52). Complete fracture union was achieved in all 24 patients. No growth disturbances were observed during the follow-up period.

Table 8: Outcomes in Pediatric/Adolescent Subgroup (n=24)

Parameter	Value
Mean age (years)	17.2 ± 2.4
Gender (M:F)	19:5
Complete union at 6 months	24 (100%)
Complications	2 (8.3%)
Mean satisfaction score (12 months)	8.9 ± 0.6
Growth disturbance	0 (0%)

Discussion

The present study demonstrates that biodegradable plates and screws provide reliable fixation for facial fractures in appropriately selected cases, with a high rate of fracture union (96.6%) and acceptable complication rates (11.0%). These findings are consistent with the growing body of evidence supporting the use of bioresorbable fixation systems in craniomaxillofacial surgery.

The overall success rate of 96.6% in achieving satisfactory fracture union compares favorably with published literature. Laughlin et al. [25] reported a success rate of 94.2% in a multicenter study of 1883 patients treated with biodegradable fixation for various craniomaxillofacial applications. Similarly, Sukegawa et al. [26] documented successful outcomes in 95.8% of patients with zygomaticomaxillary complex fractures treated with bioresorbable plates. The slightly higher success rate in our study may be attributed to strict patient selection criteria and exclusion of comminuted fractures and high-load-bearing areas.

The complication rate of 11.0% observed in our study falls within the range reported in the literature, which varies from 3.6% to 28.1% depending on the specific biodegradable material used, fracture location, and definition of complications [27]. Importantly, no cases required conversion to titanium fixation, indicating that the mechanical strength of the contemporary biodegradable systems is adequate for the indications studied. This is consistent with biomechanical studies demonstrating that modern poly-L/D-lactide plates provide sufficient rigidity during the critical healing phase of 6-8 weeks [28].

The incidence of foreign body reaction (1.7%) in our study is notably lower than earlier reports from studies using first-generation PLLA materials, where rates as high as 22% were documented [29]. This improvement is attributed to the use of self-reinforced copolymer technology, which results in more uniform and predictable degradation with reduced crystalline debris formation. The amorphous nature of the 70/30 L/D-lactide copolymer used in our study allows for more homogeneous hydrolytic breakdown, minimizing the inflammatory response associated with crystalline degradation products [30].

Hardware palpability was observed in three patients (2.5%), all of whom had fixation in the infraorbital rim or frontozygomatic region. This complication resolved spontaneously by 12 months in all cases as the material degraded. This finding highlights one of the key advantages of biodegradable systems: even when hardware becomes palpable, it represents a self-limiting problem that does not require surgical intervention. In contrast, palpable titanium hardware typically requires removal surgery in symptomatic patients [31].

The functional outcomes in our study were excellent, with 96.4% of patients achieving normal occlusion and significant improvement in mouth opening and resolution of diplopia over the follow-up period. These results are comparable to those achieved with titanium fixation systems. Eppley [32] reported similar functional outcomes in a comparative study of biodegradable and titanium fixation in pediatric craniofacial surgery, concluding that biodegradable systems provide equivalent functional results without the long-term concerns associated with metallic implants.

The orbital floor fractures in our series (n=28) demonstrated favorable outcomes, with resolution of diplopia in 94.4% of cases and persistent enophthalmos (>2mm) in only 7.1% at final follow-up. These results support the use of biodegradable materials for orbital floor reconstruction, provided that the defect size is appropriate and adequate soft tissue support exists. Baumann et al. [33] reported similar success rates with bioresorbable orbital floor implants, emphasizing the importance of proper patient selection and surgical technique.

The subgroup analysis of pediatric and adolescent patients (n=24) revealed particularly favorable outcomes, with a lower complication rate (8.3%) and no evidence of growth disturbance during the follow-up period. This finding is clinically significant, as the use of permanent metallic implants in growing patients has been associated with concerns regarding restriction of facial growth and potential need for later hardware removal [34]. The gradual resorption of biodegradable plates eliminates these concerns, making them an attractive option for the pediatric population. Eppley et al. [35] similarly advocated for the use of biodegradable fixation in pediatric craniofacial surgery, citing the avoidance of secondary removal procedures and absence of growth interference as key advantages.

The high patient satisfaction scores observed in our study (mean VAS 8.6 at 12 months) reflect the successful clinical outcomes and the psychological benefit of knowing that no permanent foreign material remains in the body. The highest satisfaction scores were recorded in the category of "absence of hardware-related concerns," underscoring the importance patients place on the self-eliminating nature of biodegradable implants.

Several limitations of this study should be acknowledged. First, the absence of a comparative titanium control group limits direct comparison of outcomes between the two fixation methods. However, the primary aim was to evaluate the safety and efficacy of biodegradable fixation rather than to establish superiority over traditional methods. Second, the follow-up period of 12 months, while adequate for assessing fracture healing and early complications, may not capture late foreign body reactions that can occur up to 4-5 years post-implantation [36]. Third, the exclusion of comminuted fractures and load-bearing mandibular fractures limits the generalizability of our findings to these challenging clinical scenarios.

The economic considerations of biodegradable versus titanium fixation systems warrant discussion. While biodegradable plates and screws typically carry a higher initial cost, this may be offset by the elimination of secondary removal procedures. Enislidis et al. [37] conducted a cost-effectiveness analysis and found that when removal rates exceed 10%, biodegradable systems become cost-effective despite higher initial hardware costs. Given that reported titanium hardware removal rates range from 5% to 40% in various series, the economic argument for biodegradable systems may be compelling in many clinical settings [38].

Future directions in biodegradable fixation technology include the development of osteoconductive materials incorporating calcium phosphate or hydroxyapatite, which may accelerate bone healing while maintaining the advantages of gradual resorption [39]. Additionally, research into shape-memory polymers and drug-eluting biodegradable systems holds promise for further enhancing clinical outcomes in facial fracture management.

Conclusion

This prospective study demonstrates that biodegradable plates and screws represent a safe and effective option for internal fixation of facial fractures in appropriately selected patients. With a fracture union rate of 96.6% and an overall complication rate of 11.0%, the outcomes achieved are comparable to those reported with traditional titanium fixation systems.

The key findings of this study can be summarized as follows:

Contemporary biodegradable fixation systems provide adequate mechanical stability for fracture healing in non-load-bearing and low-load-bearing regions of the facial skeleton. The complication profile is acceptable, with foreign body reactions occurring in only 1.7% of patients when using self-reinforced poly-L/D-lactide copolymer materials. Excellent functional outcomes are achievable, with restoration of normal occlusion, adequate mouth opening, and resolution of diplopia in the vast majority of patients. Patient satisfaction is high, particularly regarding the absence of permanent implant-related concerns. Biodegradable fixation is particularly advantageous in the pediatric and adolescent population, where it eliminates concerns about growth restriction and the need for secondary hardware removal.

Based on our experience, we recommend biodegradable fixation systems for isolated zygomaticomaxillary complex fractures, orbital floor and wall fractures with moderate-sized defects, frontal bone fractures, isolated zygomatic arch fractures, Le Fort I and II maxillary fractures with adequate bone quality, and selected mandibular fractures in low-stress regions. Conversely, caution is advised in comminuted fractures requiring rigid fixation, load-bearing mandibular fractures (angle, body, symphysis), patients with compromised bone quality, and cases where prolonged or repeated loading is anticipated.

In conclusion, biodegradable plates and screws have matured into a reliable alternative to titanium fixation for appropriate indications in facial fracture management. With proper patient selection, meticulous surgical technique, and adequate follow-up, these materials offer the advantage of eliminating the need for hardware removal while providing equivalent clinical outcomes. Further long-term studies and randomized controlled trials comparing biodegradable and titanium fixation systems would strengthen the evidence base and help refine the indications for these promising materials.

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