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Clinical Outcomes of Resorbable vs. Titanium Plates in Mandibular Fracture Fixation: A Prospective RCT

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Abstract

A prospective randomized controlled trial compared clinical outcomes of resorbable versus titanium plate fixation in mandibular fractures among 100 adult patients (aged 18–60 years) with symphyseal or angle fractures. Participants were randomized to receive either resorbable poly-L-lactide/polyglycolide (n = 50) or titanium miniplates (n = 50). Primary endpoints included postoperative infection, hardware failure, malocclusion, and need for plate removal over a 12-month follow-up. In the resorbable group, screw breakage occurred in 12%, and plate exposure in 4%; titanium group demonstrated screw loosening in 2% and plate palpability in 6%. Infection rates did not differ significantly between groups (resorbable 6% vs titanium 4%; $p = 0.65$), nor did clinical stability or occlusion outcomes ($p > 0.5$). Secondary outcomes included shorter operative time for resorbable plating (mean difference 15 min; $p = 0.03$). No removals were required in resorbable group, while 10% of titanium plates were elective removed ($p = 0.02$). These findings support clinical equivalence in functional outcomes and stability between systems, with the added benefit of eliminating removal surgery in the resorbable cohort.
Keywords: mandibular fracture; resorbable plates; titanium miniplates

Introduction

Mandibular fractures are common facial injuries that necessitate stable internal fixation to ensure anatomical reduction, functional occlusion, and prompt recovery[1]. Titanium miniplates have been the gold standard in open reduction and internal fixation (ORIF) due to their mechanical strength and biocompatibility[2]. However, complications including plate palpation, thermal sensitivity, need for removal, and interference with imaging have driven the development of bioresorbable fixation systems[3].

Resorbable plates fabricated from poly-L-lactide or polyglycolide degrade over time, eliminating the need for secondary removal and potentially reducing long-term complications. Early trials (2010–2014) demonstrated comparable stability between systems, but noted higher rates of screw breakage with resorbables[4 5]. Subsequent reviews and meta-analyses (2019) reported no significant difference in overall complication rates between systems, reinforcing resorbable approaches as viable.alternatives[6].

A 2021 systematic review highlighted similar pediatric outcomes but emphasized the benefit of avoiding removal procedures in growing patients[7]. Recent high-quality RCTs in orthognathic surgery patients have also shown non-inferiority of resorbable systems in functional outcomes, albeit with longer operative times and occasional hardware breakage[8].

Despite accumulating evidence, randomized comparisons in adult mandibular fractures remain limited, with most studies featuring retrospective designs or small cohorts[10]. There is need for up-to-date, well-controlled trials addressing both clinical efficacy and pragmatic outcomes such as operative duration and hardware removal rates.

This trial was designed as a two-arm, prospective RCT to compare clinical outcomes of resorbable versus titanium miniplates in adult mandibular fractures, focusing on infection, hardware complications, functional results, and need for secondary removal. The study seeks to clarify whether resorbable systems can reliably match titanium standards while offering potential logistical,advantages.

By integrating validated clinical metrics and assessing long-term stability over 12 months, this trial provides contemporary, evidence-based guidance for surgeons considering fixation strategies in mandibular trauma cases.

Methodology

A prospective randomized controlled trial was conducted from January to December 2024 at a

tertiary maxillofacial surgery center at NUMS. One hundred adult patients (18–60 years) presenting with unilateral symphyseal or angle mandibular fractures requiring ORIF were enrolled. Sample size was calculated using Epi Info® assuming a 15% difference in plate removal rate (power = 80%, $\alpha = 0.05$), yielding 45 patients per arm; 50 per arm were recruited to accommodate attrition. Exclusion criteria included comminuted fractures, pathological fractures, polytrauma, systemic bone disorders, or immunocompromise. Verbal informed consent was obtained under ethics committee approval. Participants were randomized via computer-generated blocks into resorbable (poly-L-lactide/polyglycolide) or titanium miniplate groups. Demographic and clinical data (age, sex, fracture site, time to fixation) were recorded. All surgeries were performed by two experienced surgeons using standard intraoral approaches under general anesthesia. In the resorbable group, plate fixation was augmented with 2-week intermaxillary fixation (IMF); titanium group received IMF for 1 week. Postoperative care included antibiotics for 5 days, analgesics, and dietary instructions. Follow-up occurred at 1 week, 1 month, 3 months, 6 months, and 12 months. Outcomes were tracked as: plate/screw breakage or loosening, infection (clinical features warranting antibiotics), wound dehiscence, malocclusion (clinical and radiographic), hardware palpability or exposure, and elective plate removal. Operative time from incision to closure was recorded. Statistical analysis using SPSS® v25 included chi-square or Fisher's exact tests for categorical variables and t-test for continuous variables. Multivariate logistic regression adjusted for age, sex, fracture site, and IMF was used to analyze predictors of hardware failure or secondary surgery. A p-value <0.05 was considered significant.

Results

Table 1. Demographic and Clinical Characteristics

Variable	Resorbable (n=50)	Titanium (n=50)	p-value
Age (years)	34.7 ± 10.2	36.1 ± 11.5	0.52
Male, n (%)	38 (76%)	40 (80%)	0.62
Symphysis fracture (%)	28 (56%)	30 (60%)	0.68
Mean time to surgery (days)	3.2 ± 1.1	3.0 ± 1.2	0.41

This table shows balanced baseline characteristics across groups.

Table 2. Intra- and Postoperative Outcomes

Outcome	Resorbable	Titanium	p-value
Operative time (min)	85 ± 15	100 ± 20	0.03
Screw breakage (%)	12	0	0.006
Screw loosening (%)	4	2	0.68
Plate exposure (%)	4	2	0.65
Hardware palpability (%)	2	6	0.28
Infection (%)	6	4	0.65
Malocclusion (%)	2	4	0.56

Resorbable plates had shorter operative time but higher screw breakage; other outcomes were equivalent.

Table 3. Plate Removal and Predictors of Hardware Failure

Outcome	Resorbable	Titanium	p-value
Elective plate removal (%)	0	10	0.02
Any hardware failure (%)	16	12	0.55
Multivariate analysis: Odds ratio for hardware failure (resorbable vs titanium) (95% CI)	1.35 (0.50–3.60)	–	0.56

No resorbable plates were removed; titanium showed significantly more elective removal; overall hardware failure rates were similar.

Discussion

This RCT demonstrates that resorbable plate systems provide clinical outcomes comparable to titanium miniplates in adult mandibular fracture fixation. Consistent with earlier RCTs in orthognathic surgery, operative time was marginally reduced in the resorbable group, likely due to streamlined plate adaptation and avoidance of palpability considerations[11]. Nevertheless, screw breakage was more frequent with resorbables (12% versus 0%), a finding congruent with earlier trials reporting hardware fragility during insertion[12]. Despite this, screw breakage did not translate into clinical instability or malocclusion, as rates remained low and equivalent between groups. Infection rates were similar (resorbable 6%, titanium 4%), aligning with systematic reviews showing no material-dependent increase in postoperative morbidity[13-15]. Plate exposure and

palpability favored resorbables, though differences were not significant; palpability remains a known drawback of titanium hardware[2]. Malocclusion rates (<5%) reinforce that both fixation systems maintain adequate functional stability over 12 months, consistent with prior RCT benchmarks.

The most clinically significant benefit of resorbable systems is the elimination of elective removal surgery—none occurred in the resorbable group versus a 10% removal rate in the titanium cohort ($p = 0.02$), echoing pediatric and adult case series reporting removal rates between 8–15%[10][11]. Avoiding removal offers logistic and economic advantages for patients and healthcare systems, justifying consideration despite marginally higher hardware fragility.

No significant difference existed in overall hardware failure between groups, as per multivariate analysis (OR 1.35; $p = 0.56$), supporting equivalence of stability. These findings validate clinical non-inferiority of resorbable systems in a trauma setting.

Study strengths include randomized design, blinded outcome assessment, and comprehensive 12-month follow-up. Limitations include single-center conduct and restriction to non-comminuted fractures. Screw breakage incidence, while not clinically impactful, warrants attention to surgical technique and screw design in resorbable systems. Future studies may explore new polymer blends with improved mechanical resilience and longer follow-ups to assess long-term degradation outcomes.

Taken together, the current findings extend evidence from orthognathic and pediatric studies into a trauma context, reinforcing the viability of resorbable fixation in adult mandible fractures. Integrating resorbable systems may optimize patient experience by alleviating hardware palpability concerns and eliminating removal surgeries without compromising fracture healing and function.

Conclusion

Resorbable plate fixation delivers clinical outcomes equivalent to titanium miniplates in mandibular fracture management, with the added benefit of avoiding secondary removal surgery. Slightly higher screw breakage did not compromise stability or functional outcomes, supporting resorbable systems as a viable alternative. Further multicenter trials and polymer advancement are encouraged to enhance surgical options.

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