Article

Clinical Efficacy Comparison of Bilaterally Threaded Elastic Locking Intramedullary Nailing Versus Minimally Invasive Percutaneous Locking Plate Fixation in Treating Midshaft Clavicle Fractures

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AIM: Midshaft clavicle fractures are a common form of upper extremity injury, with various treatment modalities available to stabilize displaced midshaft clavicular fractures. However, the optimal surgical method remains a matter of controversy. This study aimed to compare the clinical efficacy of bilaterally threaded elastic locking intramedullary nailing (BTELIN) versus minimally invasive percutaneous locking plate (MIPLP) fixation in treating midshaft clavicle fractures.

METHODS: A retrospective cohort analysis was conducted on 110 patients with midshaft clavicle fractures treated between May 2021 and April 2024. Fifty-two patients received BTELIN fixation (Group A), while 58 patients underwent MIPLP fixation (Group B). Perioperative indicators (operative time, intraoperative blood loss, and hospital stay), fracture healing time, visual analog scale (VAS) for pain, Constant-Murley Shoulder Score, Disabilities of the Arm, Shoulder and Hand (DASH) score, shoulder range of motion (ROM), and postoperative complications were compared between the two groups.

RESULTS: Compared with Group B, Group A exhibited significantly shorter operative time, less intraoperative blood loss, shorter hospital stay, and faster fracture healing time ($p < 0.001$). At 1 and 6 months postoperatively, VAS and DASH scores in Group A were significantly lower than those in Group B ($p < 0.001$), while Constant-Murley scores were significantly higher ($p < 0.001$). By 12 months postoperatively, there were no statistically significant differences in VAS or Constant-Murley scores between the two groups ($p > 0.05$); however, the DASH score in Group A remained significantly better than that in Group B ($p < 0.05$). Regarding shoulder ROM, Group A demonstrated superior movement in all directions at 3 months postoperatively ($p < 0.001$). At 12 months postoperatively, Group A maintained an advantage in external rotation and internal rotation ($p < 0.05$). There was no statistically significant difference in the incidence of various complications between the two groups ($p > 0.05$).

CONCLUSIONS: Both BTELIN and MIPLP are effective methods for treating midshaft clavicle fractures. BTELIN offers several advantages in terms of minimal invasiveness, promotion of fracture healing, accelerated early functional recovery, and, in particular, preservation of shoulder rotation function. Therefore, BTELIN may represent a promising surgical option.

Keywords: bone nails; bone plates; clavicle; fracture fixation, intramedullary

Introduction

Clavicle fractures are a common type of injury in clinical practice, accounting for 5%–10% of all adult fractures, with a particularly high incidence among young and active individuals. Approximately 80% of these cases occur in the midshaft region of the clavicle [1]. Historically, non-operative management—such as figure-of-eight bandaging or arm sling immobilization—has been the primary treatment approach for such fractures [2]. However, growing evidence from evidence-based medicine indicates that conservative treatment carries a higher risk of poor healing in significantly displaced midshaft clavicular fractures, and some patients may experience persistent shoulder dysfunction and malunion [3,4]. Consequently, surgical intervention has become an increasingly recommended strategy for unstable midshaft clavicle fractures, aiming to achieve anatomical reduction, provide stable fixation, reduce nonunion risks, and promote early functional recovery [5]. Multiple studies further confirm that surgical treatment offers more reliable healing conditions and faster functional recovery for completely displaced and comminuted midshaft clavicle fractures [6,7].

Currently, standard surgical approaches for midshaft clavicle fractures primarily include open reduction with plate fixation and intramedullary nailing [8]. While traditional open plating provides rigid initial stabilization, its excessive stiffness may eliminate physiological micromotion at the fracture site, leading to significant stress shielding effects that impair the biological environment for bone healing [9]. To overcome this limitation, the minimally invasive percutaneous locking plate (MIPLP) has been gradually introduced into clinical practice. This technique aims to pre-

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serve periosteal blood supply, minimize injury to the supraclavicular nerves, and optimize fixation through small incisions combined with biological fixation principles [10,11]. Intramedullary fixation represents a minimally invasive alternative with better cosmetic outcomes, although it is often considered less mechanically robust compared to plate systems [8]. In recent years, bilaterally threaded elastic locking intramedullary nailing (BTELIN)—developed based on traditional titanium elastic nails—has been designed to deliver continuous compression at the fracture site, thereby stimulating callus formation and accelerating fracture union [12]. Clinical reports suggest that patients treated with intramedullary nailing experience shorter fracture healing times and more rapid recovery of shoulder function compared with those undergoing conventional plate fixation [13].

Although existing research has compared traditional plating and intramedullary techniques and accumulated biomechanical data, systematic evaluations comparing two modern minimally invasive methods—namely, BTELIN versus MIPLP—across multiple key clinical dimensions remain limited [8,14,15]. There is still a lack of sufficient high-quality clinical studies comprehensively assessing their performance regarding surgical trauma, functional recovery, and complication profiles. Therefore, this study aims to conduct a retrospective clinical analysis to systematically compare the clinical efficacy of BTELIN versus MIPLP fixation in treating midshaft clavicle fractures. We will focus on evaluating differences between the two groups in terms of perioperative parameters, time to fracture union, shoulder function scores, and incidence of complications, with the aim of providing more reliable evidence-based guidance for clinical decision-making regarding the selection of surgical techniques.

Methods

Study Population

This retrospective cohort study included 110 patients with midshaft clavicle fractures who underwent surgical treatment at Hangzhou Normal University Affiliated Xiaoshan Hospital between May 2021 and April 2024. Among them, 52 patients received BTELIN fixation (Group A), and the remaining 58 patients underwent MIPLP fixation (Group B). This study was approved by the Ethics Committee of Hangzhou Normal University Affiliated Xiaoshan Hospital (approval number XSLS2025042) and strictly adhered to the Declaration of Helsinki. All participants provided written informed consent before inclusion in the study.

Inclusion and Exclusion Criteria

Inclusion criteria: (1) age ≥18 years; (2) acute, closed midshaft clavicle fracture confirmed by imaging (anteroposterior and 20°–45° cephalic tilt radiographs of the clavicle); fracture line located in the middle third of the clavicle; classified as Robinson type 2A2 or 2B2 [16], or AO/OTA type 15.2A–C [17]; (3) complete clinical data available.

Exclusion criteria: (1) open or pathological fracture; (2) concomitant fractures in other regions of the ipsilateral shoulder or upper extremity (including proximal humerus fracture, scapular fracture, and acromioclavicular joint/sternoclavicular joint dislocation); (3) associated neurovascular injuries around the shoulder joint, or prior surgical history involving the shoulder; (4) presence of severe medical comorbidities (e.g., uncontrolled coagulopathy, severe cardiovascular or pulmonary disease) that precluded surgical tolerance; (5) cognitive impairment or psychiatric disorders affecting postoperative rehabilitation compliance and follow-up evaluation.

Surgical Methods

All procedures were performed by the same senior orthopedic surgical team.

Group A: A 1.5–2 cm transverse incision was made over the anterior aspect of the clavicle. An entry point was created on the anterior cortex under fluoroscopic guidance. Closed or limited open reduction was performed via manual manipulation or using clamps. A pre-contoured, appropriately sized intramedullary nail was inserted from the proximal entry point into the medullary canal, spanning the fracture site to the distal fragment. Distal locking screws were inserted percutaneously. Subsequently, axial compression at the fracture site was achieved by tightening the dual-threaded end cap. Finally, proximal locking screws were inserted to complete the elastic fixation construct. The core principle of this technique lies in achieving biological fixation through an intramedullary device and utilizing its dual-threaded design to provide continuous elastic compression, thereby promoting callus formation.

Group B: Closed reduction of the fracture was first performed under fluoroscopic guidance. The intended plate trajectory along the anterosuperior border of the clavicle was planned. Two 2–3 cm longitudinal incisions were made, one at each end of the planned plate. A submuscular tunnel was created deep to the fascia through these incisions. The pre-contoured anatomical locking plate was then introduced through the tunnel and positioned against the bone surface. Percutaneous insertion of at least three bicortical locking screws was performed into the main proximal and distal fracture fragments through the plate ends. Additional fixation of intermediate fragments, if necessary, could be achieved percutaneously or through supplementary small incisions. This technique emphasizes minimal soft tissue dissection to preserve neurovascular structures and blood supply, achieving rigid stability via a submuscular plate position.

Observation Indicators

Baseline Characteristics

Gender, age, body mass index (BMI), affected side, mechanism of injury, Robinson classification of fracture, degree of clavicular shortening, time from injury to surgery, smoking history, presence of diabetes mellitus, and presence of osteoporosis.

Perioperative Parameters

Operative time, intraoperative blood loss, hospital stay, and fracture healing time. Fracture healing criteria [18]: Fracture healing time was determined based on both radiological and clinical evaluations. Radiological healing was defined as the presence of blurring of the fracture line and bridging callus crossing at least three of the four cortices on plain radiographs, or evidence of continuous bridging callus involving 25% of the cortex on computed tomography (CT) scans. Clinical healing was confirmed when the patient exhibited no local tenderness upon palpation and reported no pain during shoulder movement or weight-bearing activities involving the upper limb. The healing time (in weeks) was recorded when both sets of criteria were met postoperatively.

Visual Analog Scale (VAS)

VAS scores were collected preoperatively and at 1, 6, and 12 months postoperatively. The VAS is a validated scale used to assess joint pain intensity. It consists of a 10-cm horizontal line, with "0" indicating no pain and "10" representing the worst imaginable or unbearable pain. The distance from the "0" end to the marked position was measured in centimeters, yielding a score ranging from 0 to 10 [19].

Constant-Murley Score on the Affected Side

The Constant-Murley score was collected preoperatively and at 1, 6, and 12 months postoperatively. The Constant-Murley score is a composite assessment tool integrating both subjective and objective measures. It comprises four subscores: pain (subjective, up to 15 points), activities of daily living (ADL; subjective, up to 20 points), range of motion (ROM; objective, up to 40 points), and strength (objective, up to 25 points). The total score ranges from 0 to 100, with higher scores indicating better shoulder function [20].

Disabilities of the Arm, Shoulder and Hand (DASH) Score on the Affected Side

DASH scores were collected preoperatively and at 1, 6, and 12 months postoperatively. The DASH is a patient-reported outcome measure designed to evaluate upper extremity function and disability. It consists of two components totaling 30 items. The first section includes 23 items assessing difficulties with performing daily activities, and the second section contains 7 items evaluating symptoms such as pain, tingling, weakness, stiffness, as well as their impact on sleep and overall satisfaction. Each item is scored on a Likert scale ranging from 1 (no difficulty) to 5 (unable to do). The final DASH score was calculated using the formula:

$$\begin{aligned}&\text{DASH score}\\&=(\text{The sum of the scores of 30 indicators}-30)/1.20\end{aligned}$$

This transformation yields a scale ranging from 0 to 100, where 0 indicates no disability, and 100 represents severe functional impairment. Higher scores reflect greater upper limb disability [21].

Shoulder Range of Motion (ROM)

Active shoulder range of motion was assessed preoperatively and at 3 and 12 months postoperatively. In this study, a standard goniometer was used to quantify active ROM in both shoulders [22]. All measurements were performed by the same senior physical therapist who was blinded to patient grouping to ensure consistency and objectivity. Assessments were conducted with the patient in a seated position, following standardized protocols:

Shoulder anteflexion: The angle between the long axis of the arm and the trunk in the sagittal plane during upward elevation along the anterior aspect of the body. The goniometer's axis was placed over the lateral aspect of the acromion; the stationary arm aligned parallel to the mid-axillary line of the trunk, and the moving arm aligned with the lateral midline of the humerus.

Shoulder abduction: The angle formed as the arm was elevated in the coronal plane away from the side of the body. The fulcrum of the goniometer was centered on the lateral border of the acromion; the fixed arm remained parallel to the trunk, while the mobile arm followed the lateral midline of the humerus.

Shoulder external rotation: With the elbow flexed to 90° and the arm adducted against the side, the forearm was rotated outward in the horizontal plane. The goniometer's axis was placed over the olecranon process; the stationary arm extended vertically downward perpendicular to the floor, and the moving arm aligned with the ulna toward the styloid process.

Shoulder internal rotation: This was evaluated based on the highest spinal level reached by the tip of the thumb behind the back, starting from the lower lumbar region upward. The reach was recorded qualitatively and then converted into degrees using established anatomical landmarks and a predefined conversion method: reaching T12 corresponds approximately to 75°, L5 to 60°, and the buttocks/gluteal cleft to 45°. Values below the buttocks/gluteal cleft level were converted according to the same predefined conversion method.

Complications

Complications occurring within one year after surgery were documented based on electronic medical records and follow-up visits. These included implant-related irritation, nonunion of bone/delayed union, infection of the incisional wound, injury to the sensory branch of the supraclavicular nerve, and malunion.

Statistical Analysis

Statistical analysis was performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were first assessed for normality using the Kolmogorov-Smirnov test. Data conforming to a normal distribution are presented as mean ± standard deviation ($\bar{x}$ ± s). Between-group comparisons were conducted using independent samples *t*-tests, while within-group preoperative and postoperative comparisons utilized paired samples *t*-tests. For data not normally distributed, results are reported as median and interquartile range (Q1, Q3), with between-group and within-group comparisons analyzed using the Mann-Whitney U test and Wilcoxon signed-rank test, respectively. Longitudinal functional scores over time were evaluated using repeated measures analysis of variance (ANOVA) to assess the effect of time and group-by-time interaction, followed by pairwise post-hoc comparisons using the least significant difference (LSD)-*t* test. When the assumptions of normality or sphericity were violated, a generalized estimating equation (GEE) approach, which is more robust under such conditions, was employed. Categorical variables are expressed as frequencies (percentages). The χ^2 test or Fisher's exact test was used for between-group comparisons, as appropriate. All tests were two-tailed, and a *p*-value < 0.05 was considered statistically significant.

Results

Baseline Clinical Characteristics

As shown in Table 1, a total of 110 patients were included in this study: 52 in Group A (BTELIN group) and 58 in Group B (MIPLP group). There were no statistically significant differences between the two groups in baseline characteristics, including gender, age, BMI, characteristics related to fractures, cause of injury, Robinson fracture classification, degree of clavicular shortening, time from injury to surgery, smoking history, diabetes mellitus, or osteoporosis comorbidity ($p > 0.05$), indicating that the groups were comparable at baseline.

Perioperative Outcomes

As presented in Table 2, patients in Group A had significantly shorter operative times, less intraoperative blood loss, shorter hospital stays, and shorter fracture healing times compared to those in Group B ($p < 0.001$).

Pain Assessment

There was no significant difference in preoperative VAS scores between the two groups ($p > 0.05$). Intragroup comparisons showed that both groups exhibited significant reductions in VAS scores at 1 month postoperatively compared with preoperative values ($p < 0.001$); further significant decreases were observed at 6 months compared with 1 month ($p < 0.001$); and additional improvements occurred at 12 months compared with 6 months ($p < 0.001$). Intergroup comparisons revealed that VAS scores in Group A were significantly lower than those in Group B at both 1 and 6 months postoperatively ($p < 0.001$). However, by 12 months, there was no statistically significant difference between the two groups ($p > 0.05$). See details in Table 3.

GEE analysis (Table 4) demonstrated significant main effects for time and group, as well as a significant time × group interaction effect on VAS scores ($p < 0.001$), suggesting that pain improved significantly over time, the rate of improvement differed between groups, and surgical method was significantly associated with differences in the trajectory of recovery.

Shoulder Function Assessment

No significant difference in preoperative Constant-Murley scores was found between the two groups ($p > 0.05$). Within-group comparisons indicated significant increases in scores at 1 month postoperatively compared to baseline ($p < 0.001$); further significant improvements were observed at 6 months versus 1 month ($p < 0.001$). During 6 to 12 months, Group B continued to show significant improvement ($p < 0.001$), whereas no significant change was observed in Group A ($p > 0.05$). Between-group comparisons showed that Group A had significantly higher Constant-Murley scores than Group B at both 1 and 6 months postoperatively ($p < 0.001$). However, by 12 months, the difference became non-significant ($p > 0.05$). Details are provided in Table 5.

Repeated measures ANOVA (Table 6) confirmed significant main effects for time and group, as well as a significant time × group interaction ($p < 0.001$), indicating that shoulder function improved over time, recovery trajectories differed between the two groups, and the surgical approach was significantly associated with differences in functional recovery trajectories.

Upper Limb Function Assessment

Preoperative DASH scores did not differ significantly between the two groups ($p > 0.05$). Intragroup analyses revealed significant reductions in DASH scores at 1 month after surgery compared to baseline ($p < 0.001$); further substantial improvements were noted at 6 months compared with 1 month (both $p < 0.001$); and additional declines in DASH scores were observed at 12 months relative to 6 months ($p < 0.001$). At all three postoperative time points (1, 6, and 12 months), Group A consistently exhibited sig-

Table 1. Comparison of clinical characteristics between the two groups [$\bar{x}$ ± s, n (%)].

Characteristic/Groups	Group A (n = 52)	Group B (n = 58)	t/χ^2 value	p
Gender (male)	38 (73.08%)	45 (77.59%)	0.301	0.583
Age (years)	41.31 ± 12.50	39.83 ± 12.83	0.611	0.542
BMI (kg/m^2)	23.84 ± 3.07	24.16 ± 3.49	0.508	0.612
Characteristics related to fractures				
Injured on the dominant side (n, %)	29 (55.77%)	35 (60.34%)	0.236	0.627
Injured side (left side, n, %)	27 (51.92%)	31 (53.45%)	0.026	0.873
Cause of injury				
Fall injury	25 (48.08%)	30 (51.72%)	0.146	0.702
Traffic accident	18 (34.62%)	17 (29.31%)	0.356	0.551
Athletic injury	9 (17.31%)	11 (18.97%)	0.051	0.822
Robinson's classification of fractures			0.244	0.621
2A2 (Simple fracture)	32 (61.54%)	33 (56.90%)		
2B2 (Comminuted displaced fracture)	20 (38.46%)	25 (43.10%)		
Degree of bone fracture shortening (mm)	16.25 ± 3.72	15.87 ± 3.95	0.518	0.606
Time from injury to surgery (days)	4.51 ± 1.87	4.64 ±1.91	0.360	0.720
Smoking history	15 (28.85%)	19 (32.76%)	0.197	0.658
Diabetes mellitus	4 (7.69%)	5 (8.62%)	Fisher	1.000
Osteoporosis	8 (15.38)	11 (18.97)	0.246	0.620

BMI, body mass index.

Table 2. Comparison of perioperative indicators between the two groups [$\bar{x}$ ± s].

Group	Group A (n = 52)	Group B (n = 58)	t	p
Operative time (min)	44.23 ± 11.52	63.81 ± 12.73	8.422	<0.001
Intraoperative blood loss (mL)	28.25 ± 6.64	45.92 ± 9.33	11.324	<0.001
Length of stay (days)	5.58 ± 1.24	7.32 ± 1.61	6.296	<0.001
Fracture healing time (weeks)	9.81 ± 1.26	11.70 ± 2.15	5.542	<0.001

Table 3. Comparison of VAS scores between the two groups [Median (Q1, Q3)].

Time point/Group	Group A (n = 52)	Group B (n = 58)	Z	p
Before operation	7.00 (6.25, 8.00)	7.00 (6.00, 8.00)	0.676	0.499
1 month after the operation	3.00 (2.00, 3.00)^{a}	4.00 (3.00, 5.00)^{a}	5.105	<0.001
6 months after the operation	1.00 (1.00, 1.75)^{ab}	2.00 (1.00, 2.00)^{ab}	4.094	<0.001
12 months after the operation	0.00 (0.00, 1.00)^{abc}	1.00 (0.00, 1.00)^{abc}	1.869	0.062

VAS, visual analog scale; compared within the same group with the preoperative data, ^{a}p < 0.001; compared within the same group with the data at 1 month post-operation, ^{b}p < 0.001; compared within the same group with the data at 6 months post-operation, ^{c}p < 0.001.

Table 4. Results of generalized estimating equations analysis for VAS score before and after surgery.

Variable	Time effect		Intergroup effect		Interaction effect	
	Wald χ^2	p	Wald χ^2	p	Wald χ^2	p
VAS scores	3485.681	<0.001	26.098	<0.001	30.010	<0.001

nificantly lower DASH scores than Group B ($p < 0.05$). See Table 7 for specifics.

Repeated measures ANOVA (Table 8) revealed significant main effects for time and group, as well as a significant time × group interaction (time and group: $p < 0.001$; interaction: $p < 0.05$), demonstrating that upper limb function steadily improved over time, the extent and speed of recovery varied between groups, and surgical technique was associated with differences in long-term functional outcomes.

Shoulder Range of Motion

Preoperatively, no significant differences were observed between the two groups in any direction of shoulder motion—forward flexion, abduction, external rotation, or internal rotation (all $p > 0.05$). Within-group comparisons showed significant improvements in all directions of ROM at 3 months postoperatively compared to baseline ($p <$ 0.001), with further significant gains achieved at 12 months compared with 3 months ($p < 0.001$). Between-group anal-

Table 5. Comparison of Constant-Murley scores between the two groups [$\bar{x}$ ± s].

Time point/Group	Group A (n = 52)	Group B (n = 58)	t	p
Before operation	45.21± 8.43	44.76 ± 8.90	0.271	0.787
1 month after the operation	68.50 ± 7.35^{a}	62.24 ± 8.51^{a}	4.106	<0.001
6 months after the operation	95.35 ± 3.05^{ab}	92.74 ± 4.54^{ab}	3.497	<0.001
12 months after the operation	95.92 ± 3.26^{ab}	96.21 ± 3.11^{abc}	0.477	0.634

Compared within the same group with the preoperative data, $^{a}p < 0.001$; compared within the same group with the data at 1 month post-operation, $^{b}p < 0.001$; compared within the same group with the data at 6 months post-operation, $^{c}p < 0.001$.

Table 6. Results of repeated measures ANOVA for Constant-Murley scores before and after surgery.

Variable	Time effect		Intergroup effect		Interaction effect	
	F	p	F	p	F	p
Constant-Murley scores	1300.773	<0.001	13.682	<0.001	7.862	<0.001

ANOVA, analysis of variance.

Table 7. Comparison of DASH scores between the two groups [$\bar{x}$ ± s].

Time point/Group	Group A (n = 52)	Group B (n = 58)	t	p
Before operation	65.31 ± 9.17	66.10 ± 8.79	0.461	0.646
1 month after the operation	38.46 ± 7.81^{a}	45.62 ± 8.96^{a}	4.444	<0.001
6 months after the operation	7.85 ± 3.54^{ab}	11.29 ± 4.83^{ab}	4.219	<0.001
12 months after the operation	4.27 ± 2.28^{abc}	5.71 ± 2.72^{abc}	2.990	0.003

DASH, Disabilities of the Arm, Shoulder and Hand. Compared within the same group with the preoperative data, $^{a}p < 0.001$; compared within the same group with the data at 1 month post-operation, $^{b}p < 0.001$; compared within the same group with the data at 6 months post-operation, $^{c}p < 0.001$.

Table 8. Results of repeated measures ANOVA for DASH scores before and after surgery.

Variable	Time effect		Intergroup effect		Interaction effect	
	F	p	F	p	F	p
DASH scores	1998.232	<0.001	28.193	<0.001	5.184	0.002

yses indicated that at 3 months, Group A demonstrated significantly greater ROM in all directions than Group B ($p < 0.001$). By 12 months, no significant differences were observed in forward flexion or abduction ($p > 0.05$); however, Group A still demonstrated significantly better external and internal rotation compared with Group B ($p < 0.05$). Refer to Table 9 for detailed data.

Repeated measures ANOVA (Table 10) confirmed significant main effects of time and group, as well as a significant time × group interaction ($p < 0.05$), indicating that ROM improved progressively over time, recovery trajectories differed between groups, and the surgical technique significantly impacted preservation of rotational mobility.

Postoperative Complications

Within one year after surgery, there was no statistically significant difference in the incidence of various complications between the two groups of patients ($p > 0.05$). The recorded complications included implant-related irritation, delayed union/nonunion, wound infection, supraclavicular nerve sensory disturbance, and malunion. See details in Table 11.

Discussion

This study systematically evaluated the clinical efficacy of BTELIN versus MIPLP fixation in treating midshaft clavicle fractures, revealing distinct recovery patterns between the two methods across different postoperative stages. The results demonstrated that the BTELIN exhibited significant advantages in perioperative parameters, early functional recovery, and specific ranges of motion—findings that can be reasonably attributed to its unique design features and technical characteristics.

Our findings indicated that patients in Group A had significantly shorter operative times, less intraoperative blood loss, and reduced hospital stays compared to those in Group B. These outcomes align closely with the minimally invasive nature of the nailing technique. The BTELIN fixation achieves stable fixation within the medullary canal with limited soft tissue dissection, which may help preserve the

Table 9. Comparison of shoulder ROM between the two groups [$\bar{x}$ ± s].

Active direction	Group	Before operation	3 months postoperatively	12 months postoperatively
Anteflexion (°)	Group A (n = 52)	68.58 ± 15.25	148.79 ± 10.78^{a}	176.12 ± 3.27^{ab}
	Group B (n = 58)	67.86 ± 16.50	139.55 ± 12.51^{a}	174.71 ± 4.31^{ab}
	t	0.237	4.127	1.916
	p	0.813	<0.001	0.058
Abduction (°)	Group A (n = 52)	62.44 ± 14.73	142.92 ± 11.35^{a}	172.65 ± 4.97^{ab}
	Group B (n = 58)	61.78 ± 15.72	134.19 ± 13.48^{a}	170.84 ± 6.35^{ab}
	t	0.226	3.651	1.651
	p	0.821	<0.001	0.102
External rotation (°)	Group A (n = 52)	25.83 ± 8.49	68.38 ± 7.20^{a}	82.17 ± 5.47^{ab}
	Group B (n = 58)	26.16 ± 9.11	60.84 ± 9.74^{a}	79.40 ± 6.66^{ab}
	t	0.196	4.573	2.367
	p	0.845	<0.001	0.020
Internal rotation (°)	Group A (n = 52)	28.63 ± 6.93	52.81± 5.95^{a}	68.29 ± 4.49^{ab}
	Group B (n = 58)	29.09 ± 7.27	47.29 ± 7.36^{a}	65.98 ± 5.78^{ab}
	t	0.339	4.294	2.321
	p	0.735	<0.001	0.022

ROM, range of motion; compared within the same group with the preoperative data, $^{a}p < 0.001$; compared within the same group with the data at 3 months postoperatively, $^{b}p < 0.001$.

Table 10. Results of repeated measures ANOVA for shoulder range of motion before and after surgery.

Variable	Time effect		Intergroup effect		Interaction effect	
	F	p	F	p	F	p
Anteflexion (°)	2345.513	<0.001	7.982	0.006	6.118	0.003
Abduction (°)	2332.133	<0.001	7.713	0.006	4.235	0.017
External rotation (°)	1400.798	<0.001	12.195	<0.001	6.472	0.002
Internal rotation (°)	1082.847	<0.001	11.143	0.001	5.126	0.007

Table 11. Comparisons of postoperative complications between the two groups [n (%)].

Group	Group A (n = 52)	Group B (n = 58)	χ^2	p
Implant-related irritation	9.6% (5/52)	12.1% (7/58)	0.170	0.680
Nonunion of bone/delayed union	3.8% (2/52)	3.4% (2/58)	Fisher	1.000
Infection of the incisional wound	1.9% (1/52)	3.4% (2/58)	Fisher	1.000
Injury to the sensory branch of the supraclavicular nerve	0% (0/52)	5.2% (3/58)	Fisher	0.245
Malunion	5.8% (3/52)	1.7% (1/58)	Fisher	0.342
Total	21.2% (11/52)	25.9% (15/58)	0.337	0.562

biological environment at the fracture site [23]. This approach may reduce surgical trauma and potentially help preserve periosteal blood supply, which may partly explain the lower levels of early postoperative pain and facilitate earlier initiation of active rehabilitation exercises observed in this study. In contrast, although MIPLP fixation reduces soft tissue damage through small incisions and submuscular plate placement, it still necessitates some degree of subperiosteal dissection, potentially compromising local vascular integrity and thus delaying early functional recovery [24].

Notably, this study observed a significantly shorter time to fracture union in the intramedullary nailing group compared to the plating group—a result consistent with the biological advantages of intramedullary fixation. Elastic intramedullary nails provide flexible stabilization that permits beneficial micromotion at the fracture interface, an optimal mechanical environment for callus formation and secondary bone healing [25]. Conversely, while locking plates offer rigid fixation and superior initial stability, their pronounced stress-shielding effect may impair natural bone remodeling processes [26,27]. A prospective randomized study similarly reported that intramedullary nailing led to significantly faster radiographic union than locking compression plate fixation in clavicular shaft fractures [28].

It is noteworthy that there were temporal differences in functional recovery. Group A demonstrated significantly better functional outcomes, as measured by the Constant-Murley and DASH scores at early and mid-term follow-ups (up to 6 months postoperatively). However, by 12 months after surgery, no significant difference in Constant-Murley scores was observed between the two groups. This finding aligns with previous research indicating that BTELIN provides comparable long-term shoulder function outcomes to MIPLP fixation in adolescent clavicle fractures [29]. Another study also reported no significant difference in clavicular functional scores between intramedullary nailing and plating techniques [30]. These results suggest that although BTELIN fixation accelerates early recovery, the long-term shoulder functional outcomes of both fixation methods may converge over time. However, in our study, DASH scores remained significantly lower in Group A even at 12 months postoperatively, indicating better upper limb function. This observation is consistent with a randomized controlled trial reporting superior DASH scores in patients treated with flexible locked intramedullary nail fixation than those receiving precontoured locked plate fixation at 12 months postoperatively [31]. This discrepancy may stem from the fact that the DASH questionnaire places greater emphasis on task-specific performance of the upper extremity, thereby reflecting potentially better real-world functional capabilities among patients treated with intramedullary nailing during daily activities. In this study, the combined use of Constant-Murley and DASH scores provided complementary insights. While the Constant-Murley score—based primarily on physician-administered physical examination—captured the significant improvements in shoulder range of motion and strength in the intramedullary nail group at early follow-up, the patient-reported DASH score further highlighted superior overall upper limb function of these patients in activities of daily living. Notably, the DASH score remained significantly better in the intramedullary nail group even at 12 months postoperatively, when the Constant-Murley scores showed no difference between groups. This suggests that even after shoulder-specific physiological function has normalized, subtle differences in patients' self-perceived upper limb function during daily tasks may persist, which can be more sensitively detected by the DASH measure.

Our study further revealed dimension-specific differences in shoulder ROM recovery between the two groups. At 3 months postoperatively, Group A exhibited significantly greater ROM in all directions, underscoring its advantage in facilitating early rehabilitation. By 12 months, however, no intergroup differences in forward flexion and abduction were found, suggesting that both constructs provide sufficient stability to accommodate mechanical demands along major movement planes [32]. Nevertheless, Group A maintained significantly better external and internal rotation ROM at final follow-up—a clinically relevant finding. Preservation of rotational mobility is critical for overall shoulder function, particularly for tasks such as grooming or fastening clothing behind the back [33]. The elastic fixation provided by the BTELIN allows for moderate physiological micromotion at the fracture site, which may facilitate adaptive remodeling and coordination of the joint capsule and rotator cuff musculature [23]. In contrast, while MIPLP ensures rigid stabilization, it may alter normal biomechanical transmission across the clavicle and potentially disrupt coordinated movement patterns within the shoulder complex, particularly in rotational dimensions [34].

The overall complication rates were comparable between the two groups, falling within the range previously reported in the literature [29,30]. Notably, three cases of supraclavicular nerve sensory branch injury occurred in patients with MIPLP fixation, whereas none were observed in the BTELIN fixation patients. It should be emphasized that the severity of initial fracture displacement may represent a risk factor for iatrogenic nerve injury following MIPLP procedures, highlighting the importance of considering individual anatomical variations and fracture characteristics when selecting a surgical approach [35].

This study has several limitations. Firstly, as a retrospective cohort study, treatment allocation to BTELIN or MIPLP groups was primarily based on comprehensive clinical decision-making by the surgical team according to specific fracture morphology, soft tissue conditions, individual patient preferences, and expectations for recovery speed at the time of treatment, rather than random assignment. Although baseline characteristics were comparable between the two groups, residual confounding factors that were not measured or adjusted for may still exist. This non-random allocation method represents a potential source of selection bias in the present study. Although we attempted to minimize its influence through rigorous inclusion/exclusion criteria and baseline comparisons between groups, the presence of unmeasured confounding factors cannot be fully excluded. Furthermore, shoulder internal rotation was assessed using the vertebral-level method, which measures a composite movement rather than pure glenohumeral internal rotation. The conversion from vertebral levels to absolute degrees in this study was based on an empirical approximation without formal validation. Therefore, the absolute degree values for internal rotation should be interpreted with caution, and future studies are encouraged to adopt more precise measurement techniques, such as goniometry with the shoulder abducted to 90°. Secondly, the relatively small sample size may limit the statistical power to identify rare complications. Furthermore, detailed records regarding patient adherence to postoperative rehabilitation protocols were not available, which could act as a potential confounder influencing functional recovery outcomes. Future multicenter, large-scale, prospective randomized controlled trials with extended follow-up periods are necessary to further validate these findings.

Conclusions

This comparative study demonstrates that both BTELIN and MIPLP are effective methods for treating midshaft clavicle fractures. However, BTELIN exhibits several advantages. Intraoperatively, it reduces operative time and blood loss, facilitating earlier postoperative discharge. Regarding bone healing, its elastic fixation provides a more favorable biomechanical environment for callus formation, resulting in shorter fracture union times. Concerning functional recovery, BTELIN provides more effective early pain relief, enabling faster and more comprehensive restoration of shoulder joint function and range of motion, with particularly prominent outcomes in rotational function (internal and external rotation). In terms of safety, although the overall complication rates were comparable between the two groups, the occurrence of supraclavicular nerve injury in the MIPLP group may indicate a potential difference in neural protection between the two techniques, although this finding should be interpreted cautiously due to the limited number of events. Consequently, BTELIN achieves a favorable balance among safety, minimally invasive characteristics, promotion of fracture healing, and quality of functional recovery. It is especially suitable for patients seeking rapid rehabilitation and prioritizing optimized preservation of shoulder rotational function, and can be considered a preferred treatment option.

Availability of Data and Materials

The data analyzed are available from the corresponding author upon reasonable request.

Author Contributions

ZYP contributed the original conception of the work. ZYP, FCQ, JWG and YSC collected the clinical data, performed the research, and drafted the manuscript. All authors have been involved in revising the manuscript critically for important intellectual content. All authors gave final approval of the version to be published. All authors have participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to its accuracy or integrity.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of Hangzhou Normal University Affiliated Xiaoshan Hospital (approval number XSLS2025042) and strictly adhered to the Declaration of Helsinki. All participants provided written informed consent before inclusion in the study.

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Conflict of Interest

The authors declare no conflict of interest.

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