RESEARCH / ARAŞTIRMA
DOI: 10.26650/IUITFD.1438826
İst Tıp Fak Derg 2024 / J Ist Faculty Med 2024

MID-TERM OUTCOMES OF MID-SHAFT CLAVICULAR NON-UNIONS TREATED BY PLATE FIXATION WITH AUTOLOGOUS BONE GRAFTING: DOES THE TYPE OF INITIAL TREATMENT HAVE AN INFLUENCE ON THE SURGICAL RESULTS?

OTOLOG KEMİK GREFTİ İLE PLAK FİKSASYONU İLE TEDAVİ EDİLEN MİD-ŞAFT KLAVİKULA KAYNAMAMALARININ ORTA DÖNEM SONUÇLARI: BAŞLANGIÇ TEDAVİSİNİN TİPİNİN CERRAHİ SONUÇLARA ETKİSİ VAR MIDIR?

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Cite this article as: Demirel M, Kocazeybek E, Bayram S, Koyuncu D, Erşen A. Mid-term outcomes of mid-shaft clavicular non-unions treated by plate fixation with autologous bone grafting: Does the type of initial treatment have an influence on the surgical results? J Ist Faculty Med 2024;87(3):220-226. doi: 10.26650/IUITFD.1438826

ABSTRACT

Objective: The recent literature is scarce regarding the outcomes of mid-shaft clavicular non-union treated by open reduction and internal fixation (ORIF) with autologous bone grafting, and the influence of the type of initial treatment has not yet been investigated. The study aims: (1) to present the mid-term surgical results of mid-shaft clavicular non-unions treated by plate fixation with autologous bone grafting and (2) to determine the effect the type of initial treatment has on the surgical results.

Material and Method: The study reviews 14 patients (eight females) who'd undergone ORIF with autologous bone grafting due to atrophic mid-shaft clavicular nonunion where clinical and radiographical outcomes were recorded. The study divides the patients into two groups based on their initial treatment: Group A (eight with non-surgical treatment) and Group B (six with surgical treatment).

Result: The mean QuickDASH score at final follow-up was 22. The Constant Score significantly improved from 40 to 87 postoperatively. The mean Preoperative Visual Analogous Scale (VAS) score went down from 7 to 2 ($p<0.001$). A solid union was achieved in all patients. In the preoperative between-group comparison, no significant differences were observed for any of the clinical outcome. At final follow-up, Group A exhibited significantly higher Constant Scores.

Conclusion: Regardless of the type of initial treatment, plate fixation with autologous bone grafting is effective in obtaining

ÖZET

Amaç: Otolog kemik grefti ile açık redüksiyon ve internal fiksasyon (ORIF) ile tedavi edilen mid-şaft klavikula kaynamamasının sonuçlarıyla ilgili güncel literatür azdır. Bu çalışmanın amaçları şunlardı: (1) otolog kemik grefti ile plak fiksasyonu ile tedavi edilen mid-şaft klaviküler kaynamamaların orta dönem cerrahi sonuçlarını ardışık bir vaka serisinde sunmak ve (2) başlangıç tedavi yönteminin klinik sonuçlara olan etkisini araştırmaktır.

Gereç ve Yöntem: Atrofik mid-şaft klavikula kaynamaması nedeniyle otolog kemik grefti ile ORIF uygulanan 14 hasta (sekiz kadın) retrospektif olarak incelendi. Genel çalışma popülasyonunda çeşitli klinik ve radyografik sonuçlar kaydedildi. Hastalar daha sonra başlangıç tedavisinin türüne göre iki gruba ayrıldı: Grup A (sekizi cerrahi olmayan tedavi) ve Grup B (altısı cerrahi tedavi).

Bulgular: Son değerlendirmede ortalama QuickDASH skoru 22 idi. Constant skoru ameliyat sonrası 40'tan 87'ye anlamlı olarak arttı. Ameliyat öncesi ortalama görsel analog skala (VAS) skoru son değerlendirmede 7'den 2'ye ($p<0,001$) geriledi. Tüm hastalarda kaynama görüldü. Ameliyat öncesi dönemde gruplar arası karşılaştırmada, klinik sonuçları arasında anlamlı bir fark gözlenmedi. Son değerlendirmede gruplar arası karşılaştırmada grup A anlamlı derecede daha yüksek Constant puanları sergiledi.

Sonuç: Başlangıç tedavisinin türü ne olursa olsun, otolog kemik grefti ile plak tespiti, mid-şaft klaviküler kaynamaması olan hastalarda füzyon elde etmede ve klinik durumu iyileştirmede etkilidir.

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Submitted/Başvuru: 17.02.2024 • **Revision Requested/Revizyon Talebi:** 23.02.2024 •
Last Revision Received/Son Revizyon: 17.04.2024 • **Accepted/Kabul:** 22.04.2024 • **Published Online/Online Yayın:** 28.05.2024

solid fusion and improving the clinical status of patients with mid-shaft clavicular non-union. Additionally, this technique can provide shorter time to union and greater improvements in specific shoulder function in patients who've undergone non-surgical treatment.

Keywords: Mid-shaft clavicular non-union, initial treatment, plate fixation, autologous bone grafting

Ek olarak, bu teknik, başlangıçta konservatif tedavi gören hastalarda kaynamanın daha kısa sürede gerçekleşmesini ve spesifik omuz fonksiyonlarında daha büyük iyileşmeler sağlayabilir.

Anahtar Kelimeler: Mid-şaft klavikula kaynamama, başlangıç tedavisi, plak ile osteosentez, otolog kemik greftleme

INTRODUCTION

Clavicular fractures are common injuries accounting for up to 10% of all fractures in adults and most often occur at the middle-third segment (1, 2). Mid-shaft clavicular non-union is a rare but potentially serious complication that may require surgical intervention due to pain and functional impairment in the upper extremity (3-6).

Although different surgical techniques, involving intramedullary, external and internal fixation have been introduced in the management of mid-shaft clavicular nonunions, little consensus is found on which technique is the ideal method of fixation (5-8). Open reduction and internal fixation (ORIF) with autogenous bone graft have been reported as an acceptable method for treating this rare disorder in older case series, with favorable results (5, 6, 9-11). However, according to a literature review, more recent published studies investigating the outcomes of ORIF with plate and screws in such patients are lacking.

Mid-shaft clavicular non-union can occur following initial surgical or non-surgical treatment (5). Although clinical and radiological outcomes after treatment by ORIF in such patients have been evaluated, the influence of the type of initial treatment on the surgical results has not yet been investigated in the literature as far as is known. This study assumes the choice of initial treatment to be a possible critical factor in the success of treatment by ORIF in mid-shaft clavicular non-union.

The primary aim of this study is to present the mid-term surgical results of mid-shaft clavicular non-unions treated by plate fixation with autologous bone grafting in a consecutive case series. The secondary aim is to determine the influence of the type of initial treatment on the surgical results.

MATERIALS and METHODS

The study has retrospectively identified 17 patients with atrophic mid-shaft clavicular nonunion who were diagnosed and treated at an institution using ORIF with autologous bone grafting between 2009-2015. The study has evaluated all patients based on the eligibility criteria (Table 1). After excluding three patients (one missed the follow-up, and two had inadequate medical records), the study enrolled the remaining 14 patients (six males, eight females; 14 clavicles) who met the inclusion criteria and invited them to a final follow-up appointment. All patients had been initially treated surgically or non-surgically at an outside hospital and admitted to the institute's department with a painful clavicular nonunion and limitations in daily activities. All participants gave informed consent, and the study was approved by the İstanbul Faculty of Medicine Clinical Research Ethics Committee (Date: 26.01.2024, No: 02).

Table 1: Eligibility criteria for inclusion and exclusion of the study participants

Inclusion criteria	Exclusion criteria
A diagnosis of mid-shaft clavicular non-union	Missed follow-up
Complete medical records and radiographic images	Inadequate medical records
Willingness to participate in the study	Pathological fracture
	Concomitant fracture in the same extremity
	Unwillingness to participate in the study

Study protocol

Part I: Clinical and radiographic assessment of the entire study population

Demographic and clinical data were obtained from the hospital's database, as well as the patients' medical records including gender, age, mechanism of injury, initial treatment, the period from injury to the non-union surgery, follow-up period, occupational history and presence of pre- and post-operative neurological symptoms (brachialgia). Complications were also recorded.

Clinical outcome measures

The shortened Disabilities of the Arm Shoulder and Hand Questionnaire (QuickDASH) scores were measured at the patients' final follow-ups (12). The Constant Score and Visual Analogous Scale (VAS) were both measured immediately before the non-union surgery and again at the final follow-up (13).

The Constant Score is a validated shoulder-specific outcome measure consisting of two objective and two subjective individual parameters that add up to an overall

maximum of 100 points: range of motion (40 points), strength (25 points), pain (15 points), and activities of daily living (20 points). The QuickDASH score is a functional outcome measure for evaluating overall upper-extremity disability and involves an 11-item scale with possible scores ranging from 0 (no disability) to 100 (severe disability). VAS is used to assess changes in pain intensity. The VAS score used in the current study is a simplified measure where pain intensity during daily activity is rated on a scale of 0–10, with 0 showing no pain and 10 showing the highest pain (14).

Radiographical outcome measures

Non-union is defined as persistent pain and no radiographic sign of a bridging callus at the fracture site six months after the initial treatment (8). Clavicular length is measured from the anterolateral angle of the acromion to the sternal notch on standard anterior-posterior clavicle radiographs immediately before the non-union surgery and at the final follow-up. A clavicular reconstruction ratio was utilized to evaluate the restoration of clavicular length, with a reconstruction ratio of 1 implying the reconstructed length of the non-united clavicle to be equal to that of the contralateral uninjured clavicle. Union is defined as evidence of continuity of cortex or bridging callus on standard radiographs of the clavicle (anterior-posterior 30° cephalad and anterior-posterior perpendicular to cassette).

Part II: Assessing the initial treatment method's effect on the surgical results

All the patients included in the study were first divided into two groups based on the type of initial treatment: Group A (8 patients with non-surgical treatment; 4 AO type 15.2 A1, 2 AO type 15.2A2, and 2 AO type 15.2 B1) and Group B (6 patients with surgical treatment; 2 AO type 15.1 A1, 3 AO type 15.2 A2, and 1 AO type 15.2 B2). The parameters described above were then compared between the two groups.

In Group A, the initial treatment was sling immobilization in three patients and figure-of-eight bracing in five patients (Figure 1). In Group B, all patients initially underwent ORIF with plate and screws for their clavicle fractures, with non-union having developed as a result of loosening of the osteosynthesis (Figure 2).

Surgical technique

The main indication for non-union surgery was pain and functional impairment in all the patients. All operations were performed by 1 of 2 experienced orthopedic surgeons. A standardized protocol for the surgical technique was used in all patients. Patients were placed on a radiolucent table in a beach-chair position with a folded towel under the involved shoulder. The involved upper extremity and iliac crest were draped free to respectively enable manipulation and harvesting of the autologous bone graft. The standard anterior approach to the middle-third of the

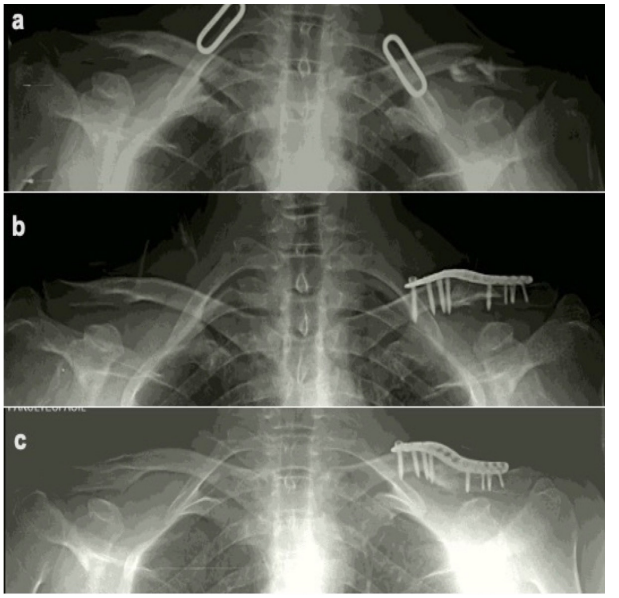

Figure 1: The preoperative radiograph shows a nonunion case of mid-shaft clavicle following the initial non-surgical treatment (a). The postoperative standard radiographs demonstrate continuity of cortex as evidence of union at the nonunion site (b and c).

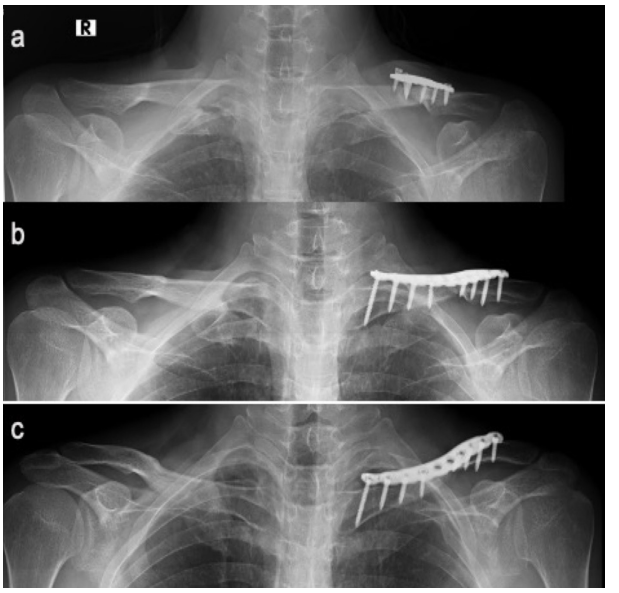

Figure 2: The preoperative radiograph displays a case of nonunion of the mid-shaft clavicle following initial surgical treatment. Note that loosening of the osteosynthesis with the pull-out of the screws (a). The postoperative standard radiographs show continuity of cortex as evidence of union at the nonunion site (b and c).

clavicle was used. In Group B, all previously inserted implants and screws were first removed, and then the nonunion site was exposed. In both groups, pseudoarthrotic tissue was removed, and the sclerotic bony ends of the atrophic non-union area were refreshed using curettes,

rongeurs, and osteotomes until cortical bone bleeding was observed (the paprika sign). The medullar canal was then opened on both sides of the nonunion area using a high-speed drill. In the later stage, a cancellous autogenous bone graft was routinely taken from the iliac crest and inserted onto the non-union area in all cases. One patient from Group A and two patients from Group B developed a gap at the non-union site after resection of the sclerotic bony ends, which was then reconstructed with an intercalary iliac-crest graft. In the final stage, ORIF was performed using a 3.5 mm superior anterior limited-contact dynamic-compression plate (Synthes, LCP clavicle plate®, Bettlach, Switzerland) under an image intensifier. Reconstruction and stability were evaluated via direct observation and fluoroscopic imaging intraoperatively. After confirming stability, wound closure was performed.

Postoperative rehabilitation protocol

All patients had undergone the same rehabilitation protocol. The shoulder joint was immobilized for comfort with an arm-sling for 4-6 weeks postoperatively. During this period, the patients were allowed to execute active elbow flexion and extension. After six weeks, the arm-sling was removed, and active-assisted physical therapy was initiated until union was demonstrated radiographically. After bony union was achieved, progressive strengthening exercises were performed. Return to recreational and occupational activities were allowed three months post-operation.

Statistical analysis

Statistical analyses were performed using SPSS ver. 25.0 software (IBM Corp, Armonk, NY, USA). A $p<0.05$ was considered significant. The Shapiro–Wilk test and histogram graphics were used for normality tests. Data were presented as maxima, minima, and arithmetic means. Student's t-test and the Mann–Whitney U test were used for the between-group analysis. Fisher's exact test was used for categorical variables. For intra-group differences from before to final follow-up, the paired samples t-test was used, with the Mann-Whitney U test used for between-group differences at baseline and the final follow-up assessment, both measuring significance at $p<0.05$.

RESULTS

Part I: Baseline characteristics and results for the entire study population

Baseline characteristics

The study examined five females and nine males with a mean age of 45 years (range=31-65 years). The right side was involved in six patients and the left side in eight patients. The dominant side was involved in seven patients. The mean period from injury to non-union surgery was 10 months (range=6-24 months), and the mean follow-up was 44 months (range=24-72 months). Preoperative brachialgia was present in one patient, which resolved fully after the non-union surgery (Table 2).

Table 2: Demographic characteristics of the study participants.

Number of patients	14
Gender (Female/Male)	5/9
Age (years), mean (min–max)	45 (31-65)
Left/Right side	8/6
Involvement of the dominant side	7 cases
Follow-up (month), mean (min-max)	44 (24-72)
Period from injury to non-union surgery (month), mean (min-max)	10 (6-24)
Mechanism of injury, n (%)	
Simple fall	9 (64**%**)
Car accident	3 (21**%**)
Motorcycle accident	2 (15**%**)
Occupations, n (%)	
Office worker	6 (42**%**)
Housewife	4 (30**%**)
Teacher	2 (14**%**)
Hairdresser	1 (7**%**)
Police officer	1 (7**%**)

Clinical results

With favorable functional outcomes, all patients returned to their daily activities without difficulties or much effort. The mean QuickDASH score was measured as 22 (range=12-33) at the final follow-up. The Constant Score significantly improved from 40 (range=28-52) preoperatively to 87 (range=78-99) postoperatively. The mean preoperative VAS score significantly reduced from 7 (range=5-9) to 2 (range=0-4; $p<0.001$) at the final follow-up (Table 3). Four patients experienced complete relief from pain, with the remaining patients reporting substantial relief from pain.

Radiographic results

The reconstruction ratio significantly improved from 0.79 (range=0.74-0.84) preoperatively to 0.94 (range=0.87-0.99) postoperatively ($p<0.001$). Solid union was achieved in all patients, with the mean time to union being eight months (range=4-13 months; Figures 1 and 2; Table 3).

Part II: Comparing the results between the two groups

Group A is comprised of three females and five males with a mean age of 47 (range=34-65) years, and Group B consists of two females and four males with a mean age of 40 (range=31-59) years. The comparison of the baseline characteristics between the two groups is demonstrated in Table 4.

Table 5 details the comparison of the clinical and radiographical outcomes at pre-op and final follow-up assessments between the two groups. In the intra-group comparisons, all the clinical outcome measures were sig-

Table 3: Preoperative and final follow-up clinical and radiographical outcomes of the study participants

Variables	Preoperative	Postoperative	p values
Clinical outcomes			
QuickDASH score, (mean) (min-max)		22 (12-33)	0.002*
Constant score, (mean) (min-max)	40 (28-52)	87 (78-99)	0.003*
VAS score, (mean) (min-max)	7 (5-9)	2 (0-4)	<0.001*
Radiographical Outcomes			
Reconstruction ratio, (%) mean (min-max)	0.79 (0.74-0.84)	0.94 (0.99-0.87)	<0.001*
Time to union (months) mean (min-max)		8 (4-13)	

*p<0.05

nificantly improved preoperatively after non-union surgery compared to preoperatively. In the preoperative between-group comparison, no significant differences were observed among any of the clinical outcome measures.

Table 4: Comparison of the demographic characteristics between the two groups

Variables	Group A (n=8)	Group B (n=6)	p values
Mean age (years), mean (min–max)	47 (34–65)	40 (31–59)	0.131[a]
Gender (female/male)	3/5	2/4	0.516[b]
Period from injury to non-union surgery (months), mean (min-max)	9 (6–12)	12 (6–24)	0.231[a]
Follow-up (months), mean (min-max)	42 (24–70)	46 (24–72)	0.623[a]

[a] Mann-Whitney U test, p<0.05; [b] Fisher's exact test, p<0.05

Table 5: Comparison of clinical and radiographical outcomes at preoperative and final follow-up assessments

Variables	Group A			Group B			Follow-up comparisons between groups	
	Pre-operative	Final follow-up	p values[a]	Preopera-tive	Final follow-up	p values[a]	Preoperative p values[b]	Final fol-low-up p values[b]
Clinical outcomes								
QuickDASH score, mean (min-max)	-	19 (12-30)		-	25 (18-35)	0.004	-	0.07
Constant score, mean (min-max)	42 (36-52)	90 (82-99)	0.001*	39 (28-47)	83 (81-93)	0.001	0.49	0.01*
VAS score, mean (min-max)	8 (5-9)	2 (0-3)	0.001*	7 (4-9)	3 (1-4)	0.001	0.81	0.51
	Radiographical outcomes							
Reconstruction ratio, (%) mean (min-max)	0.79 (0.75-0.86)	0.95 (0.92-0.99)	0.001*	0.77 (0.74-0.80)	0.93 (0.87-0.97)	0.001*	0.07	0.06
		Preoperative			Final follow-up			
Time to union, (months) mean (min-max)		7 (4-12)			10 (6-13)		0.01*	

VAS: Visual Analogous Scale; [a] For within-group differences from pre- to final follow-up, the paired samples T test was used, p<0.05; [b] For between-group differences at baseline and the final follow-up assessment, Mann–Whitney U test was used, p<0.05; * p<0.05

At the final follow-up between-group comparison, no significant differences were observed in the QuickDASH or VAS scores, while Group A exhibited significantly higher Constant Scores.

With respect to radiographical outcomes, the reconstruction ratio significantly increased in the respective Groups A and B from 0.79 (range=0.75-0.86) and 0.77 (range=0.74-0.80) preoperatively to 0.95 (range=0.92-0.99) and 0.93 (range=0.87-0.97) at the final follow-up. Otherwise, no significant difference was observed in the between-group comparisons either at baseline or at the final follow-up. Time to union was significantly shorter in Group A (mean=7 months, range=4-12) than in group B (mean=10 months, range=6-13).

DISCUSSION

Earlier case series have shown plate fixation with autologous bone grafting to be an acceptable method for treating patients with mid-shaft clavicular nonunion by providing favorable clinical results and higher rates of bony union (5, 6, 9-11). However, the more recent literature as best is known contains little information apart from a few retrospective case series supporting the use of this technique (8,15,16). Accordingly, the study has primarily aimed to investigate the mid-term outcomes of plate fixation with autologous bone grafting in a consecutive case series of mid-shaft clavicular non-union. Current data from the study have confirmed the feasibility and effectiveness of this technique.

In one of several recent clinical studies on the topic, Huang et al. achieved radiographic consolidation in all patients (n=21) using AO reconstruction plate at a mean time of 13.6 (range=11-27) weeks (8). All patients were subjectively satisfied with the outcome of their operation. They used an autologous iliac bone graft for only atrophic non-unions. Baker and Mullet later reported a case series of 15 patients treated by a pre-contoured locking plate without the use of distant bone graft from the iliac crest at a mean follow-up of 12.4 months (15). All patients in their case series achieved radiographical union along with favorable clinical outcomes. The authors concluded the distant bone graft to perhaps be unnecessary for clavicular non-union and even atrophic types. More recently, Beirer et al. reported the results of 14 patients with clavicular non-union (n=11) and/or malunion (n=3) treated by an LCP with autologous iliac bone graft at a short-term follow-up (mean=27 months, range=12-44 months) (16). All but one patient in their series had mid-shaft non- or mal-union. The authors achieved union in all patients and observed significant improvement in the relative Constant Scores.

This study examined ORIF consecutively performed with an LCP and autologous bone grafting for the treatment of atrophic non-union of the mid-shaft clavicle in 14 patients. The primary goal with this treatment approach was to obtain solid fusion, relieve symptoms, and improve clinical status. In this study's case series and consistent with the recent literature above, all patients achieved radiographical union at a mean time of eight months (range=4-13) without implant failure. An autologous bone graft originating from the iliac crest was routinely used. While an intercalary bone graft was required in three cases with a large defect, a cancellous bone graft was adequate to fill the defect area in the remainders. In contrast to Baker and Mullet, who determined distant bone graft from the iliac crest as unnecessary, this study considers this procedure to represent a safer option that generates high rates of bony union for the treatment of clavicular non-union, especially for those with a large defect (15).

Discussing the quality of life and functional status of the patients involved in this study is also necessary. In the present case series, four patients reported complete relief from pain, with the remaining patients experiencing a substantial relief from pain. The present study population consists of young and middle-aged patients with a mean age of 45 (range=31-65) years. Thus, symptomatic clavicular nonunion had imposed a significant socioeconomic burden and affected the quality of life of the study's patients who had physically demanding occupations prior to non-union surgery due to pain and inability to use their affected extremities. In contrast, this study considers the substantial improvement in Constant Scores and satisfactory QuickDASH scores at the final follow-up after non-union surgery to correspond to higher rates of returning to work with an enhanced quality of life in the study population. Comparable to the recent literature mentioned above, the current study's results have demonstrated ORIF using an LCP with autologous bone grafting to be effective in providing pain relief and improving clinical status.

As reviewed above, the existing literature has mainly focused on the treatment outcomes of ORIF with plate and screws for mid-shaft clavicular non-unions. Different from previous studies, this article has also explored as a secondary outcome whether the type of initial treatment received has an influence on the surgical results, with a significantly shorter time to union being found in patients who'd initially received non-surgical treatment. Performing non-union surgery as a revision surgery appears to have longer consolidation times as an expectation. With respect to clinical status, while both groups exhibited poor results in terms of Constant Score and VAS score before the non-union surgery, post-operative outcomes demonstrated each group's clinical status to be satisfactory. Nonetheless, despite no differences in QuickDASH and VAS scores at the final follow-up, patients who'd initially undergone surgical treatment exhibited better postoperative Constant Scores. Constant Score spe-

cifically measures the shoulder joint function, whereas QuickDASH is a general tool for assessing overall upper extremity function. Therefore, these findings may be interpreted to mean that plate fixation with autologous bone grafting is able to provide favorable overall clinical status regardless of the type of initial treatment. However, patients who initially received non-surgical treatment can experience significantly greater improvements in specific shoulder function.

Finally, several limitations need to be considered. The major limitations of the study are its retrospective nature and limited sample size. Nevertheless, compared to most of the studies cited herein, the present study has included a larger patient cohort with longer follow-up (8, 15, 16). Lastly, the existing literature on the topic has mostly been limited to retrospective case series. Thus, further prospective controlled studies are needed to confirm which technique is the ideal method of fixation in the management of mid-shaft clavicular nonunion.

CONCLUSION

In conclusion, evidence from this study has shown that, regardless of the type of initial treatment, plate fixation with autologous bone grafting is effective in obtaining solid fusion, relieving pain, and improving clinical status in patients with mid-shaft clavicular non-union at mid-term follow-up. Nonetheless, this technique can confer a shorter time to union and greater improvements in specific shoulder function in patients who'd initially undergone non-surgical treatment for a mid-shaft clavicle fracture.

Ethics Committee Approval: The study has ethical approval from the İstanbul Faculty of Medicine Clinical Research Ethics Committee (Date: 26.01.2024, No: 02).

Informed Consent: Written informed consent was obtained from participants who participated in this study.

Peer Review: Externally peer-reviewed.

Author Contributions: Conception/Design of Study- M.D., A.E.; Data Acquisition- E.K., S.B., D.K.; Data Analysis/Interpretation- M.D., S.B.; Drafting Manuscript- M.D., S.B., E.K., D.K.; Critical Revision of Manuscript- A.E.; Final Approval and Accountability- A.E., M.D., S.B., E.K., D.K.

Conflict of Interest: The authors have no conflict of interest to declare.

Financial Disclosure: The authors declared that this study received no financial support.

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