



Original article

A multicentric study on the newly developed reconstruction locking plate for midshaft clavicular fracture

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Abstract

Objectives: To examine the efficacy and clinical and radiological outcomes of the use of a streamlined clavicle plate® (MEIRA, Aichi, Japan) for midshaft clavicular fractures.

Methods: This was a retrospective cohort study of 155 patients with displaced midshaft clavicular fractures treated using a streamlined clavicle plate between 2015 and 2019 in 18 hospitals across Japan. A questionnaire regarding bone union and postoperative complications was used, and 136 cases were followed up for one year or until bone union. Plate fitting was evaluated retrospectively using surgical records, radiographic findings, and surgeon's opinion.

Results: During surgery, plate bending was needed in 19 cases (12.3%), poor fitting was observed in 8 cases (5.2%), and bone union was achieved in 133 cases (97.8%). Total implantation failure, including plate breakage and screw loosening, occurred in 10 cases (6.5%) from the intraoperative to postoperative period. Subjective complications were observed in 26 cases (16.8%): incongruity around the surgical scar or in the anterior chest in 23, and contracture of the shoulder in three. Plate removal was performed in 66 cases (48.5%) per patient's request.

Conclusion: The use of a streamlined clavicle plate is effective for midshaft fractures of the clavicle, and the success rates of bone union and implantation using this approach are comparable to those of other existing plates.

Key words: clavicle midshaft fracture, multicentric study, superior plate of the clavicle

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Introduction

Clavicle fractures are common injuries in adults, accounting for 5% of all fractures. Eighty percent of clavicular fractures in adults occur in the middle one-third of the bone¹⁻². There are various methods for treating midshaft clavicle fractures, such as the use of intramedullary Kirschner wires,

Steinmann pin fixation, and plate fixation³⁻⁷. Currently, open reduction and internal fixation of severely displaced fractures of the middle third of the clavicle are recommended for adult patients⁸. In particular, plate fixation can help in obtaining a stable anatomical reduction in severely displaced or comminuted fractures. Plates such as reconstruction and reconstruction locking compression plates (LCPs), which can be bent to accommodate the S-shaped curvature of the clavicle, are preferred⁹⁻¹¹. Plate fixation can be technically difficult because of the complex anatomy of the clavicle, with its S-shaped curvature and cephalad-to-caudad bow². To address this problem, pre-contoured anatomic plates have been developed. Some anatomical clavicle plates include the LCP Superior Anterior Clavicle plate® (Depuy Synthes, Massachusetts, USA), VariAx Clavicle Locking Plate System® (Stryker Corporation, Michigan, USA), and Locking Clavicle Plating System® (Acumed, Oregon, USA), each with features that are low-profile and designed to fit

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the superior surface of the clavicle with minimal soft-tissue irritation. A streamlined clavicle plate® (MEIRA, Aichi, Japan; SC plate) was developed based on the computed tomography (CT) data of Japanese patients; its thickness was 2.9 mm—the thinnest among the locking plates—with a strength of no less than the existing plates. There are several reports and single-center studies on patients treated through plate fixation; however, there are few studies that involve multiple centers and a large sample size¹⁾. In this multicenter study, we aimed to assess the safety, adaptability, efficacy, and clinical and radiological outcomes of using the SC plate®, a reconstruction locking plate, for midshaft clavicular fractures.

Materials and Methods

This was a retrospective cohort study of patients with displaced midshaft clavicular fractures treated using an SC plate between 2015 and 2019 in 18 hospitals across Japan. The ethics committee of the University of Tsukuba Hospital approved the study (reference number: R01-044), and informed consent was obtained from all participants. The inclusion criteria included surgical cases with midshaft fractures that were evaluated to require surgery by orthopedic surgeons in each hospital. The exclusion criterion was the distal or proximal end of the clavicle fracture. We collected relevant information on 155 cases using a questionnaire at each facility. In addition to the patient's basic information (age, sex, mechanism of injury, radiographic findings, waiting period from the injury, and so on), the questionnaire asked about the size of the plate used for fixation (eight, nine, ten holes), whether plate bending was needed, the quality of fit between the plate and the clavicle, the time of surgery, and occurrence of any complications during the surgery. The SC plate length ranged between 85 mm (eight holes) and 105 mm (ten holes), and the width between 24.8 mm (eight holes) and 31.1 mm (nine and ten holes), all of which passed the mechanical load tests under the approval number 22800BZX00003000. The injury patterns were classified according to the guidelines of the Orthopaedic Trauma Association/Arbeitsgemeinschaft für Osteosynthesefragen (OTA/AO) and Robinson's classification²⁾. The quality of the plate fitting was retrospectively evaluated from the surgical records, radiographs, and surgeon's opinion. We also investigated the achievement of bone union, the occurrence of implantation failure, and the need for reoperation due to implantation failure. In 136 cases, follow-up was performed for more than one year or until bone union to observe any postoperative complications. Unfortunately, we could not follow-up 19 cases because the patients dropped out or were transferred to another hospital. The indication and the technique of the surgery, as well as the rehabilitation plans, were decided by each hospital.

One orthopedic surgeon in each facility retrospectively evaluated bone healing using radiographs. The level of bone healing was judged by three or more cortical bone continuity in two directions of the radiographic images. In case of any difficulty in assessing the bone union using the radiographic images, a consensus was reached between the surgeon and the first author.

Furthermore, we investigated the quality of the fitting in 22 patients who had undergone CT postoperatively at the first author's facility. The quality of the fitting was defined as good (no overhang), fair (mild anterior or posterior overhang of the plate over the clavicle), or poor (both anterior and posterior plate overhang or screw-hole overhang). The decision regarding the quality was made via a three-dimensional CT (3DCT) using the modified Huang's evaluation²⁾.

Results

A total of 155 patients (123 men and 32 women; mean age, 41.7 ± 19.7 years) underwent SC plate fixation for midshaft clavicular fractures between April 2015 and December 2019 at the institutes included in this study. Eighty-seven patients had fractures on the right side, whereas 68 had fractures on the left side. Thirty-two patients were smokers, and 94 patients were non-smokers. Smoking status remained unknown in 28 patients. Regarding the mechanism of injury, high-energy incidents, including traffic accidents, falls from great heights or during sports, occurred in 79 patients; low-energy incidents, such as falling down, occurred in 72 patients, and the mechanism was unknown in four patients. According to the OTA/AO classification, 27, 76, and 52 patients were categorized as 15.2A, B, and C, respectively. According to Robinson's classification, four, five, 98, and 48 patients were categorized as Types 2A1, A2, B1, and B2, respectively (Table 1). Eight-hole, nine-hole, and ten-hole plates were used for 67, 62, and 26 patients, re-

Table 1 Patient characteristics and the number of each patient

Patient characteristics	Number of patients
Gender	Male 123, Female 32
Age, average (range)	41.2 (13–87) years
Smoking, current	Yes 32, No 94, Unknown 28
Mechanism of injury	High 79, Low 72, Unknown 4
Fracture type (AO classification)	
A	27
B	76
C	52
Fracture type (Robinson classification)	
A1	4
A2	5
B1	98
B2	48

spectively. During the surgery, plate bending was needed in 19 patients (12.3%), and poor fitting was confirmed in eight patients (5.2%). The average time of surgery was 91 minutes (range: 51–156 minutes). Intraoperative complications occurred in three cases (breakage of the plate during plate bending occurred in one case and difficulty in insertion of the most proximal screw occurred in two cases). Bone union was achieved in 133 (97.8%) of the 136 patients who could be followed up for over one year or until bone union had been achieved. The average time to bone union was 153.1 days (range: 44–482 days). Postoperative complications, including screw loosening, were observed in seven patients (5.1%), and plate breakage did not occur. Total implantation failure occurred in ten patients (6.5%) from the intraoperative to postoperative period. Subjective complications were seen in 26 patients (16.8%): a sense of incongruity around the surgical scar or anterior chest in 23 patients and contracture of the shoulder in three patients. Plate removal was implemented per patient's request in 66 (48.5%) of the 136 patients who will be followed up for over one year or until bone union (Table 2).

Upon evaluation of the quality of the plate fitting in 22 cases using 3DCT, the fitting was found to be good in ten patients, fair in four patients, and poor in eight patients. The summary of the representative cases is as follows:

In case 1, a 35-year-old man sustained a Robinson 2B1 clavicular fracture. The fracture was fixed with a ten-hole SC plate, and bone union was achieved after three months.

The fitting of the plate was good in the 3DCT scan using the modified Huang's evaluation²⁾ (Figure 1). He exhibited excellent function but retained a sense of incongruity around the surgical scar; thus, the plate was removed one year after the surgery.

In case 2, a 17-year-old boy sustained a Robinson 2A2

Table 2 Outcomes. The total number of patients is 155; however, bone union was evaluated in only 136 patients

Outcomes	The number of patients
Plate size	Total 155
8 hole	67
9 hole	62
10 hole	26
Plate bending	
Yes	19
No	136
Plate fitting	
Good	147
Not good	8
Implant failure	10
Bone union	Total 136
Yes	133
No	3

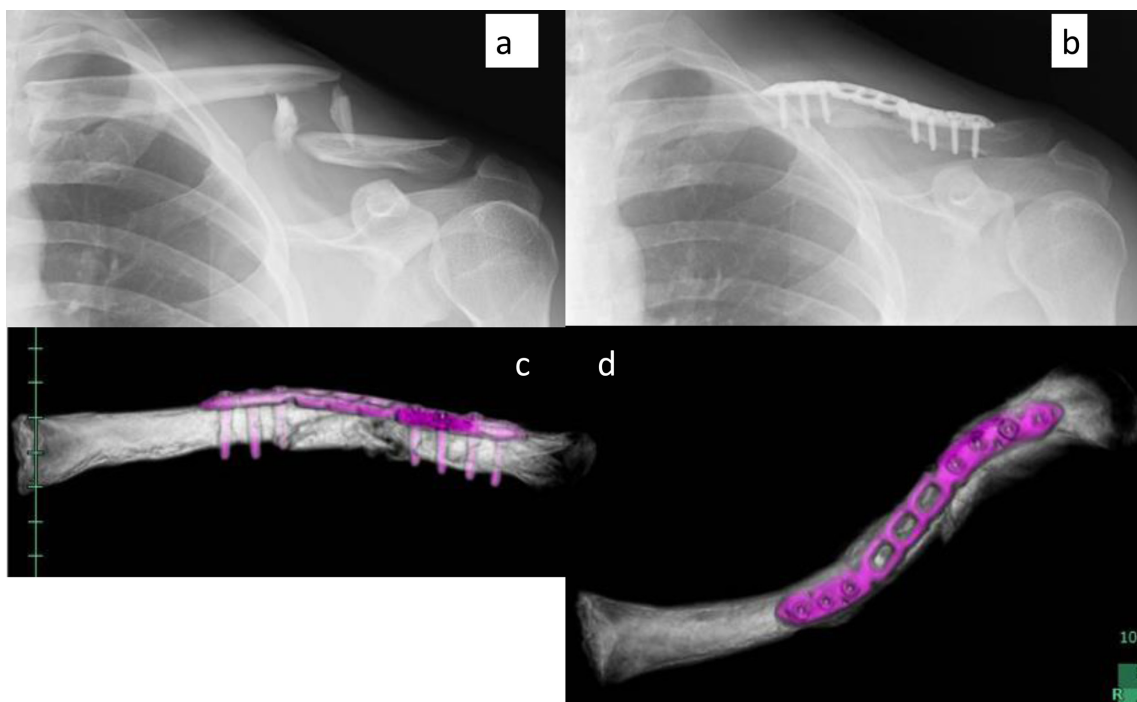


Figure 1 a: Robinson 2B1 clavicular fracture (39-year-old man). b: Fracture fixated using a ten-hole SC plate. c: Bone union achieved after three months. d: 3DCT shows a good quality plate fitting.

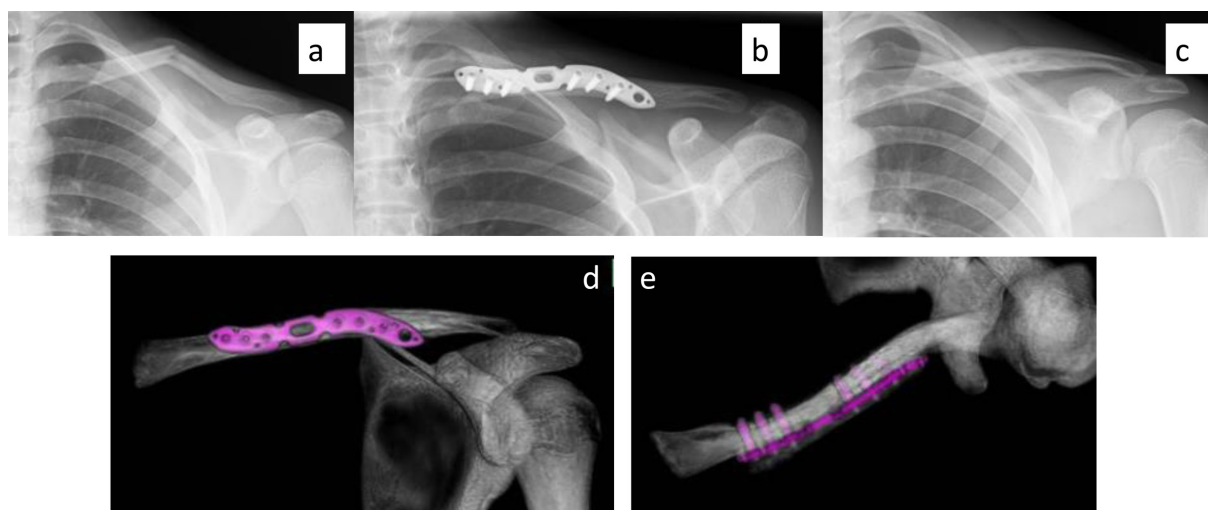


Figure 2 a: Robinson 2A2 clavicular fracture (17-year-old boy). b: Fracture fixated using an eight-hole SC plate. c: The plate removed one year after surgery. d: 3DCT performed three months after surgery indicates poor fitting; the plate was anteriorly set. e: Bone union achieved three months after surgery.

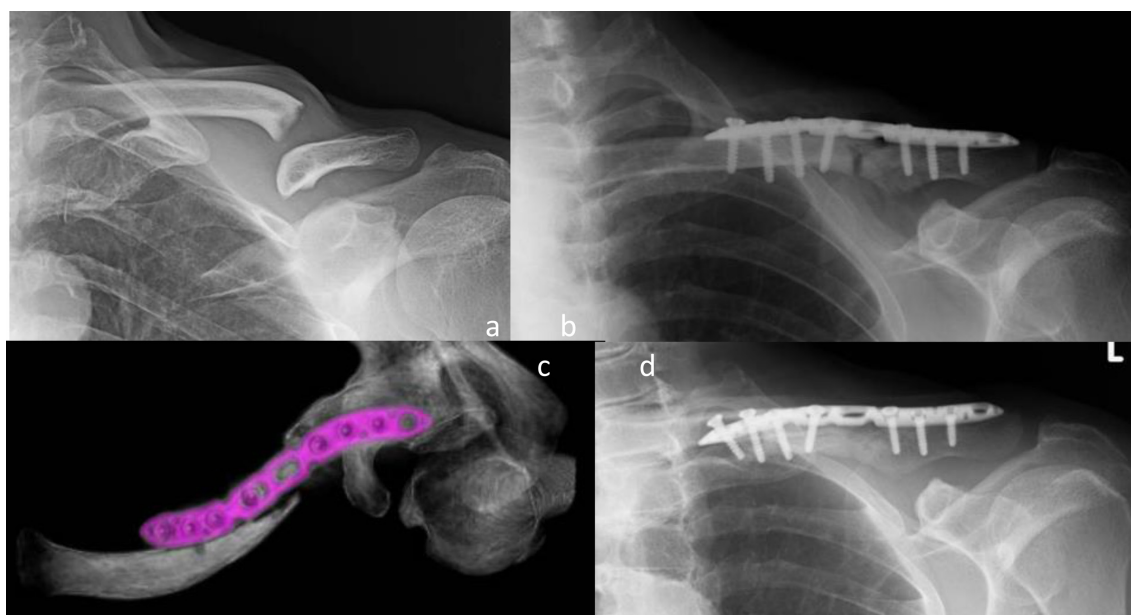


Figure 3 a: Robinson 2B1 clavicular fracture (69-year-old man). b: Fracture fixated using a nine-hole SC plate. c: 3DCT performed one month after surgery indicates poor fitting. d: Loosening of the two proximal screws; however, bone union was achieved three months after surgery.

clavicular fracture, which was fixed with an eight-hole SC plate. From the 3DCT results performed three months after surgery, we realized that the distal part of the plate was placed anterior to the bone. The plate fitting quality was evaluated as poor; however, bone union was achieved three months after surgery. Plate removal was performed one year after the surgery (Figure 2).

In case 3, a 69-year-old man sustained a Robinson 2B1 clavicular fracture, which was fixed with a nine-hole

SC plate. One month after surgery, 3DCT showed that the quality of the plate fitting was poor. At three months after surgery, loosening of the two proximal screws was observed; nevertheless, bone union was achieved by limiting the shoulder's range of motion for two months after surgery (Figure 3).

Discussion

This was a multicenter study that included a larger number of cases of midshaft fracture treated with plate fixation for the clavicle than in previous studies^{1,9,13}. The bone union rate was 97.8%, while the implantation failure rate was 6.5% (10/155 cases). Woltz *et al.* described the rate of implantation failure to be 12.6% in their retrospective cohort study¹. Gilde *et al.* reported significantly more implant-related complications when using a reconstruction plate than when using a dynamic compression plate (8.5% vs. 1.2%, $p=0.03$). Although their plate was an anteroinferior type plate, unlike our superior reconstruction locking plate, it is expected to be a more durable and effective implant⁹. Robinson *et al.* described a reoperation rate of 2.3% in 86 cases due to implantation failure of the locking clavicle plating system[®] (Acumed, Oregon, USA)¹³. Their plate system had two direction types (anterior and superior), and all surgeries were performed by shoulder specialists (Table 3).

In our study, orthopedic specialists or residents performed several surgeries. Plate breakage or deviations may thus have been caused by both the lack of strength of the plate, as well as by technical problems by the surgeons. However, in superior types of clavicle plates, insertion of proximal screws is difficult because it is obstructed by the patient's head. Hence, in several cases, a cortical screw was selected for the proximal hole to lean in the direction of the insertion. A locking screw was not used because of the poor angle of insertion in some cases. These problems may lead to loosening of the screw; however, the strength and durability of our plates are not inferior to those of other existing plates. The SC plates in our study feature slight elasticity, allowing them to pull up the bone in the proper reduction position. The three locking holes on both sides create slightly smaller hole distances, unlike in other existing plates, helping to reduce the mechanical load on both sides. There are also some notches on the plate to be used for wiring in the case of comminuted fractures; therefore, the bending of the plate is easier in the SC plate compared to that in the other existing plates.

This SC plate was designed to set the upper part of the clavicle, and the quality of the fitting was good in 132 cases

(94.8%). Although plate bending was needed in 19 cases (12.3%), all these cases had good quality plate fitting according to the surgeon's opinion. In contrast, another study reported poor fitting in eight of 22 cases, suggested by 3DCT findings with the modified Huang's method². Although bone union was achieved in all these cases, technical errors, including poor reduction or poor setting position of the plate, were revealed. Ordinarily, CT is not used to investigate the achievement of bone union, except when patients exhibit any complications; however, it is true that plate setting is difficult if the fracture site is too distal or too proximal. In such cases, fair fitting may not be inevitable using this SC plate, as it only has three size options and a superior type of setting. Further development of this plate is needed to address several types of midshaft clavicle fractures. Kim *et al.* described a real-size 3D-printed model as a preoperative and intraoperative tool for minimally invasive plating of comminuted midshaft clavicle fractures¹⁴. Such trials are useful for providing more precise treatment, as well as for developing new types of plates.

There are some limitations to this multicenter study. First, we conducted a retrospective study using questionnaires; thus, the evaluations were sourced from several investigators. In order to assess the quality of plate fitting, we depended on the surgical records and the surgeon's opinion. We evaluated only 22 cases using 3DCT; however, due to the harmful effects of radiation, it is inappropriate to use CT for patients who follow a favorable recovery process. Second, it could not be directly compared with other plates or treatment methods, such as conservative or intramedullary nails. Further research is warranted to address these limitations.

Conclusion

In conclusion, this multicenter study demonstrated the effectiveness of our SC plate for treating midshaft clavicle fractures. The rates of bone union and implant failure were 97.8% and 6.5%, respectively, indicating that this plate may have sufficient strength for bone union and would not lead to serious complications. Therefore, this SC plate is not considered inferior to the existing plates.

Table 3 Summary of literature: nonunion, implant failure, and plate removal rates

Study	Number of patients	Plate type	Nonunion (%)	Implant failure (%)	Plate removal (%)
Shin <i>et al.</i> , 2012 ¹¹	125	Recon.		12	
Robinson <i>et al.</i> , 2013 ¹²	86	Precontoured locking	1.7	2.3	11.6
Waltz <i>et al.</i> , 2016 ¹	111	3.5 mm Recon.	2.7	8.1	37.8
Gilde <i>et al.</i> , 2014 ⁹	85	2.7 mm DCP	1.2	1.2	11.8
	71	2.7 mm Recon.	7	8.5	7
Ours	155	2.8 mm Recon. Locking	2.2	6.5	48.5

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