

Treatment of displaced fractures of the clavicle middle-third with pre-contoured locking plate

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Abstract

Introduction: The aim of this study is to analyze results in a group of patients with displaced mid-diaphyseal fractures of clavicle treated with pre-contoured locking plates. We analyzed bone healing rates, functional results and complications.

Materials and Methods: Forty-six displaced clavicle fractures type 2B in the Edinburgh Classification were treated with pre-contoured locking plates. The patients were 36 males (one with bilateral fracture) and nine women aged 33 years old on average (ranging from 17 to 56). Patients were evaluated with X-rays and the Constant score, the QuickDASH test and the visual analogue scale for pain.

Results: Average follow-up was 30 months (ranging from 12 to 46). Forty-five fractures healed, and one did not. The average Constant score was of 96 (ranging from 56 to 100) and the average QuickDASH score was of 2 (ranging from 0 to 32). Pain throughout follow-up was 0.3 marks. We verified 10 complications in nine patients (21%), although only three complications (6.5%) were considered to be major complications. In seven patients (15%) we removed the plate due to intolerance (one of them was the case of the patient with mal-union, and this was considered to be a second complication in the same patient).

Conclusions: Reduction and stabilization of displaced fractures of the clavicle middle-third with pre-contoured locking plates is an effective treatment with low rates of major complications that, sometimes, have to do with technical errors.

Key words: mid-diaphyseal fracture; clavicle; functional results; treatment with pre-contoured locking plate.

Level of evidence: III

TRATAMIENTO CON PLACA PRECONTORNEADA BLOQUEADA DE FRACTURAS DESPLAZADAS DEL TERCIO MEDIO DE LA CLAVÍCULA

Resumen

Introducción: El objetivo de este trabajo es analizar los resultados de un grupo de pacientes con fracturas mediodiafisarias desplazadas de clavícula tratadas con placa precontorneada bloqueada. Se analizaron la tasa de consolidación ósea, los resultados funcionales y las complicaciones.

Materiales y Métodos: Cuarenta y seis fracturas de clavícula desplazadas de tipo 2B de Edimburgo fueron tratadas con placa bloqueada precontorneada. Los pacientes eran 36 hombres (uno con fractura bilateral) y nueve mujeres, con una edad promedio de 33 años (rango 17-56). Los pacientes fueron evaluados con radiología y el puntaje de Constant, el test QuickDASH y la escala analógica visual para dolor.

Conflict of interests: The authors have reported none.

Resultados: El seguimiento promedio fue de 30 meses (rango 12-46). Cuarenta y cinco fracturas consolidaron y una no. El puntaje de Constant promedio fue de 96 (rango 56-100) y el de QuickDASH promedio, 2 (rango 0-32). El dolor en el seguimiento fue de 0,3 puntos (rango 0-6). Se registraron 10 complicaciones en nueve pacientes (21%), aunque solo tres (6,5%) fueron consideradas mayores. En siete pacientes (15%), se retiró la placa por intolerancia (uno de ellos fue el paciente con mala consolidación, se registró como segunda complicación en el mismo paciente).

Conclusiones: La reducción y estabilización de las fracturas desplazadas del tercio medio de la clavícula con placas precontorneadas y bloqueadas son un tratamiento eficaz con un bajo índice de complicaciones mayores relacionadas, a veces, con errores técnicos.

Palabras clave: Fractura mediodiafisaria; clavícula; resultados funcionales; tratamiento con placa bloqueada precontorneada.
Nivel de Evidencia: III

Introduction

Clavicle fractures are the commonest ones in adulthood—they represent 2.6 to 5% of all fractures in the body, and around 40% of fractures in the shoulder. Mid-diaphyseal fractures embody 69-82% of clavicle fractures and, far from remaining a stable percentage, displaced or comminute fractures of the clavicle middle-third are on the increase in young and middle-aged adults, almost always associated with car crashes or sport injuries.^{1,2}

Traditionally, clavicle fractures have been treated non-operatively. There have been reports of satisfactory results with or without closed fracture reduction and different immobilization methods.^{3,4} Over the past years, however, the analysis of the sub-groups of displaced mid-diaphyseal fractures and multifragmentary fractures treated conservatively shows high non-union and mal-union rates with negative effects on functional scores.⁵⁻⁷

Publications on open reduction and osteosynthesis report high complication rates, with infection, bone reduction loss, material migration, loosening or rupture of plates, and protrusion of osteosynthesis material and discomfort.⁸

The development of specific pre-contoured plates for clavicle fracture and the introduction of angular locking open new perspectives in the surgical treatment of these fractures. Although biomechanic studies support the use of these plates, we did not find clinical trials showing results.⁹⁻¹²

The aim of this study is to analyze bone healing rates, functional results and complications in patients with displaced mid-diaphyseal fractures of clavicle treated with pre-contoured locking plates.

Materials and Methods

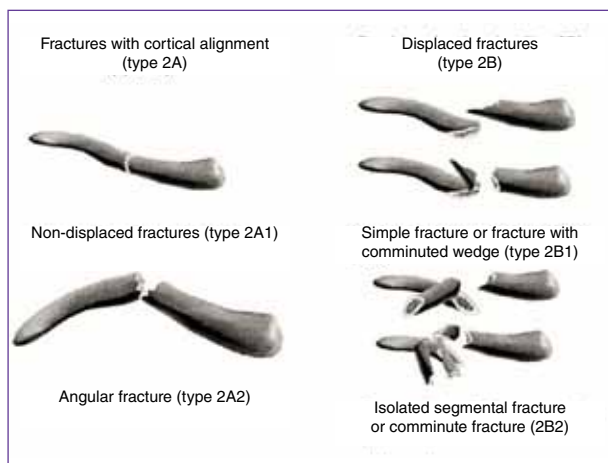
Since December 2008 until December 2011 we operated on 50 diaphyseal clavicle fractures in 49 patients. All of them received open reduction and fixation with pre-contoured locking plate (Acumed®, Beaverton, Oregon, USA.)

Inclusion criteria were: Edinburgh Classification type 2B fractures (Figure 1), occurring within the previous month, closed fractures, <60 years old, and minimal follow-up of one year.

Four patients were lost to final follow-up; therefore, the series was finally made up of 46 fractures in 45 patients: 36 males (including the bilateral case) and nine females, aged 33 years old on average (ranging from 17 to 56). Twenty-three fractures were on the right side, whereas 23 fractures were on the left side. Fifty-two percent of the fractures occurred in the patient's dominant limb. Average time between the fracture and the surgery was 8.3 days (ranging from 2 to 21).

We evaluated mechanism of injury, associated injuries, surgical timing and medical discharge.

Patients were medically checked at week 1 and a fortnight after the surgery, and both medically and radiologically at month one, at month two and every two months thereafter until bone healing and sport medical release. X-ray evaluation consisted of anterior-posterior clavicle X-ray and 45°-cephalic inclination clavicle X-ray. Fracture healing was assessed both medically and radiologically (looking for, at least, three healed cortices in both X-ray incidences). Patients were evaluated using the Constant



▲ **Figure 1.** Edinburgh Classification. Mid-diaphyseal fractures.

score and the QuickDASH test,¹³ and remaining pain was evaluated by means of the visual analogue scale (VAS). Abduction strength was assessed with the patient standing, their arm 90° flexed, extended elbow and pronated hand, using the Isobex® dynamometer (Burgdorf, Suiza). We recorded all the complications caused by the surgery and re-operations for any reason. Moreover, we asked the patients if they were able to practice sports again, if it was at the same level as previously, and if they reassumed the same working activities they had carried out before the accident.

Surgical technique

Patients received combined anesthesia (regional block anesthesia plus general anesthesia) and were operated on in supine, 30° beach chair position with a bulk under the ipsi-lateral scapula. We did not include the upper limb in the draping setting. We performed an anterior-inferior approach focused on the fracture. We got to the fracture. We performed reduction with temporal pins, inter-fragmentary screws, stitches or clamps. We inserted the locking plate on the upper aspect of the clavicle.¹⁴

In all cases we used a pre-contoured plate with angular locking (Acumed®; Beaverton, Oregon, USA). We used plates with different numbers of holes and different numbers of screws so as to get six cortices in the main medial fragment and six cortices in the main distal fragment.¹² The plate that we used most was the one with eight holes and six screws, which were half medial to the fracture line and three distal to it. We closed the wound by planes using intradermic stitches.

At the end of the surgery we performed X-ray check-up in the operating room (Figure 2). Patients were discharged on the same day of the surgery or the day after, with sling immobilization.

Results

The main cause of fracture was sport injury, with 15 cases (32.6%); motorcycle and quad rider falls were the second cause in frequency (14 cases; 30.4%) (Table 1). All the fractures were Edinburgh Classification type 2B—32 fractures were sub-type 2B-1, whereas 14 were sub-type 2B-2 (Figure 3). Eight patients had associated injuries, all of them related to high-energy impact (Table 2).

Table 1. Injury mechanism

Number of cases	Mecanism of injury	Percentage	Number of patients with associated injuries
15	Accident in sport activities	32.6	0
14	Motorcycle/Quad rider fall	30.4	4
6	Fall from standing height	13	0
4	Car crash	8.6	4
3	Fall from bicycle	6.5	0
3	Fall from horse	6.5	0
1	Stairs fall	2.1	0



Figure 2. Immediately post-operative anterior-posterior X-ray and cephalic inclination X-ray. Reduction and osteosynthesis with pre-contoured locking plate with eight holes using six screws—three lateral ones and three medial ones to the fracture line. There is also an inter-fragmentary screw for reduction.

Average surgical time was 70 minutes (ranging from 40 to 125). There were no intra-surgical complications. Average follow-up was 30 months (ranging from 12 to 46). Forty-five fractures healed (97.7%) while one patient developed non-union and required a new surgery 13 months after the first one. The average Constant score was 96 (ranging from 56 to 100). The average QuickDASH score was 2 (ranging from 0 to 32). According to the VAS, pain throughout follow-up was 0.3 marks (ranging from 0 to 6).

Out of the forty-five patients, 44 practiced sports before the surgery. Ninety-five dot four percent (42 of 44 patients) were able to reassume sports. The two patients that did not do so suffered injuries associated with the clavicle fracture (one tibial plateau fracture and an ankle fracture). Eighty-four percent of the patients (37 out of the 44 patients) were able to practice the same sport at the same competitive level as previously. Five patients did not get back at the same level or the same sport; three of them for a reason related to the sequel in their clavicle, with low scores in the evaluation methods. In the other two cases, the reason was that they were feeling psychologically unfit or afraid of suffering the same injury, although functional scores were quite good.^{15,16} Ninety-seven dot eight percent of the patients who worked (44 out of 45) were able to retake previous working activities and daily life activities. The rest had suffered an associated injury and were re-allocated to another working activity.

We verified 10 complications in nine patients (21%). Three of them were considered as major consequences (6.5%). The most serious ones were an extrinsic compression of the subclavian vein by a long screw which edged out on the lower aspect of the clavicle. The injury showed as intermittent edema in the upper limb related to the patient's arm raise. Diagnosis was extrinsic compression and treatment consisted of partial removal of osteosyn-



Figure 3. Fifty-four year-old male with injury due to fall while skiing. We can see an Edinburgh type 2B2 fracture—a displaced, segmental and comminute fracture, which represents the more complex pattern.

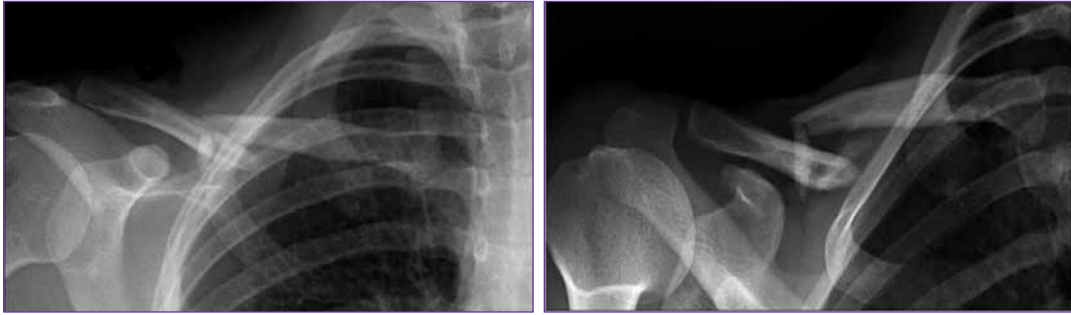
thesis (only the protruding screw). Under anticoagulant treatment for one year, the patient did well and intermittent edema stopped. Another patient suffered bone reduction loss a month after the surgery with implant loosening. We prescribed osteosynthesis revision, but the patient preferred to wait for bone healing under the new circumstances. The patient showed delayed union and, after six month, the fracture healed with bone shortening. Finally, 16 months after the first surgery, we removed the plate because of discomfort on the scar area (second complication). In spite of these complications, 19 months after the initial surgery, the patient showed a Constant score of 100, a QuickDASH score of 0 and remaining pain of 0 on the VAS. The patient reassumed previous sports. The third patient developed non-union and was operated on

Table 2. Associated injuries

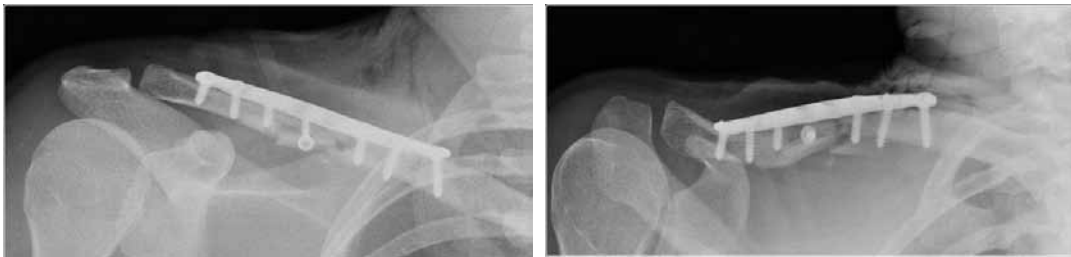
Case	Injury mechanism	Associated injury	Treatment
1	Car crash	Pelvis fracture	Surgical
2	Car crash	Anke fracture	Surgical
3	Car crash	C7 fracture	Orthopedic
4	Car crash	Humera diaphysis fracture	Surgical
5	Motorcycle crash	Fifth finger phalanx fracture	Surgical
6	Motorcycle crash	Cranioencephalic trauma plus brain hematoma	Surgical
7	Motorcycle crash	Tibial plateau fracture	Surgical
8	Motorcycle crash	Rib fracture	Orthopedic

again 13 months after the first surgery. The initial implant was removed, and we performed non-union de-cortication and new reduction and osteosynthesis (Figures 4-6). The remaining six complications, verified in six patients, were

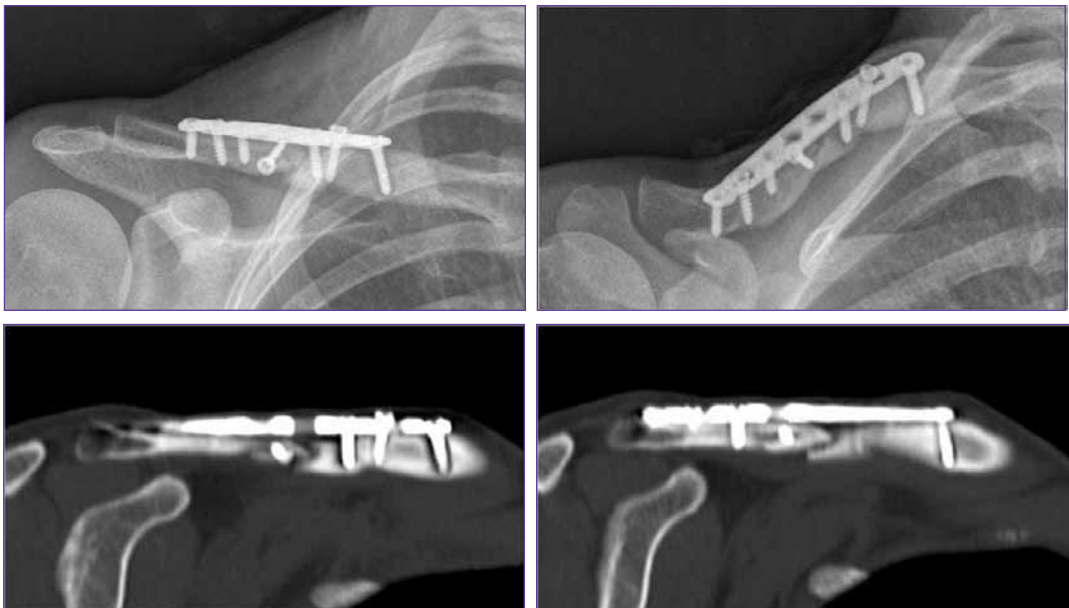
discomfort due to the osteosynthesis material that interfered with daily life; therefore, it was decided to remove it at a second opportunity at average month 23 following the surgery (ranging from 9 to 40).



▲ **Figure 4.** Twenty-seven year-old female who, following a fall from standing height, suffered a displaced, multi-fragmentary and segmental fracture in her right clavicle (Edinburgh 2B2).



▲ **Figure 5.** Immediately post-operative X-ray. Reduction and osteosynthesis with pre-contoured locking fracture and inter-fragmentary screw.



▲ **Figure 6.** One year after the surgery. Major complication: non-union. In X-ray and TC scan images we can see fracture non-union. Note the loosening of the second proximal screw. The patient continued in pain; therefore, it was decided to perform osteosynthesis revision with non-union curettage and bone graft supplementation.

Discussion

In this study, we found out that displaced fractures of the clavicle middle-third treated with locking pre-contoured plates in adult patients are associated with high healing rates and good functional results. The number of major complications is low.

Nevertheless, the treatment of clavicle mid-diaphyseal fractures is under constant revision.¹⁷ In 1960 Neer³ and, then, in 1968 Rowe⁴ produced large series of patients with clavicle fracture treated non-operatively with high healing rates and low non-union rates;⁴ therefore, over a number of years guidelines on this matter were to treat all clavicle fractures with orthopedic techniques. However, these series included all types of fractures and lacked in important data, such as that about symptomatic mal-unions, functional results or return to previous sport or working activities.

Over a number of years, surgical treatment with open reduction and osteosynthesis using different methods did not prove worth in bone healing, and caused numerous complications linked to the surgery; most of them were associated with the implant.

In 2007, the Canadian Orthopedic Trauma Society published a prospective randomized multi-center study in 132 patients which compared conservative treatment with plating reduction.¹⁸ The results that showed significance were: shorter healing time, lower non-union rates and fewer symptomatic mal-unions in the group of patients subject to surgical treatment. Likewise, the Constant and QuickDASH scores were significantly better in the surgery group, not to mention that one year after the surgery patients reported more satisfaction with their shoulder looks. In 2012, Virtanen et al. published a prospective randomized study in 60 patients treated with open reduction and plate osteosynthesis (3.5 reconstruction plate) vs. sling.¹⁹ One year after the surgery, the percentage of non-union was 0% in the surgery group and 24% in the sling group.

In the meta-analysis McKee et al. published in 2012, they analyzed six comparative studies of reduction-and-osteosynthesis surgical treatment (three of them using plate and screws, and three with intramedullary nails) vs. conservative treatment; final results were: lower non-union rates, lower symptomatic mal-union rates and earlier return to daily activities in the group of patients subject to surgical treatment.²⁰

These changes in results of reduction-and-osteosynthesis surgery in clavicle fractures were mainly brought about by two factors—one of them was the study of the fracture epidemiology and the fracture line. Results with conservative treatment in non-displaced fractures were clearly differentiated from those in highly angulated or displaced fractures, and multi-fragmentary fractures. In the latter, open reduction and osteosynthesis are recommended to reestablish anatomy and restore girdle function.^{6,7} In 1988,

Robinson et al. published their work about epidemiology and classification of clavicle fractures in adults, studying more than 1000 patients with clavicle fracture.¹ In the same work they verify intra-observer and inter-observer reproducibility of the classification.

The other important issue is the development undergone by the different designs, even that of some of the implants that are exclusively used for clavicle fracture. In these injuries, the most frequently used types of implants are intramedullary nails and plates plus screws. With respect to intramedullary nails, Yun-feng et al. published a series of 41 patients treated with elastic titanium nails inserted from proximal (beside the breastbone) to distal, with minimal opening at fracture line level.²¹ They reported high rates of consolidation, good medical-functional results and low complication rates. The limitations that they show using this method are that they did not treat OTA type C fractures, i.e., the most complex ones, and that they had to remove systematically all the implants at average 7.2 months after the surgery. Another recent study about intramedullary implants is that of Smekal et al.'s—they compare open reduction plus fixation with an elastic intramedullary nail to conservative treatment.²² In the surgical group there was neither non-union nor was there mal-union vs. three patients with non-union and two symptomatic mal-unions in the sling group; as complications, in the surgical group there were seven proximal migrations in 30 nails that required surgery. Likewise, functional results were better and shortening was less in the group treated with nailing.

Judd et al. in 2009 published another prospective randomized comparative study about intramedullary fixation with “Hagie” nail vs. sling; functional results were similar, but complication rates were high in the group treated with this model of nail.²³ To sum up, intramedullary implant designs can differ in design, they can be inserted laterally or medially, with or without the advantage of minimal fracture line opening and, in general, medical-functional results are very good, but they are associated with limitations because they are not the most adequate ones to treat comminute displaced fractures, and it is necessary to carry out a second surgery to remove the implant.²⁴⁻²⁷

The first plates and screws in clavicle fracture frequently caused complications such as rupture of the plate or the screws, or framework loosening, with subsequent immediate or mediate bone reduction loss. Upon arrival of locking plates, fixation in osteoporotic bone was better, with lower loosening and bone reduction loss rates.²⁸ Then came pre-contoured anatomic locking plates for clavicle fracture, which combined the rigidity of the implant with angular locking with adaptation to the complex anatomic shape of the clavicle, being necessary neither to leave parts of the plate without full bone contact (straight implants) nor to contour them on the operating table to adapt them (reconstruction straight implants) with pos-

sible material fatigue on anchorage spots. Although most of the lab biomechanic studies showed better adaptation to the clavicle anatomic shape without losing properties related to framework rigidity at flexion and torsion forces, we have not found published articles about series treated with these pre-contoured locking plates and their medical results.^{11,12}

The limitations of our study are mainly the ones related to any series of cases: the lack of a comparative group and the retrospective analysis. In our series of patients, we were able to keep high healing rates with only one non-union and one delayed union. Functional scores were good, and the complications related to the implant were low, without rupture or bending of the plate and only one

material loosening with bone reduction loss (the patient with delayed union). It would be necessary to carry out a comparative study with another fixation device were the goal be set on proving the superiority of this implant in comparison with others.

Conclusions

In view of the results seen in this series which, as far as we know, is the first one reported in literature, we can conclude that the treatment of displaced fractures of the clavicle middle-third with pre-contoured locking plates is effective and safe.

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