



# Management of Clavicular Fracture in Adults by Plating: a Systematic Review

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## Abstract

Fracture clavicle in adults is common, treatment of such fracture is debatable, and in case of surgical treatment, the method of fixation is also debatable. In the current study, we reviewed the literature to bring up the answers for this debatable point, and to focus on the positive and negative results of surgical plating for the fracture clavicle in adults. The search was performed in the following electronic databases: PubMed, SCOPUS, Web of Science, and The Cochrane Library. The search included key words of: clavicle, fracture clavicle, in association with surgical approaches, plating of the clavicle and functional ability or physical activity. The initial search in database yielded 98 articles which match the search key words, by 1st screening, 47 articles were removed as duplicated titles and articles not in English language, 51 articles were re-screened, 40 articles were excluded as they were case reports, studies with unclear description of the outcome and unfound articles, and the remaining articles for final analysis were 11 articles. We recommended using of locking precontoured plate for fixation of the clavicle fractures especially middle third, and anteroinferior approach to perform this fixation; by combination of both, it will be of little complication and high successful rate of union.

**Keywords** Clavicle fracture · Plate · Surgical

## Introduction

One of the commonest fractures is fracture clavicle; it represents 2.6 to 10% of all fractures and about 35 to 45% of shoulder injuries, in addition 2 to 5% of total adult fractures [1, 2].

Regarding the site of fracture, it was reported that the mid shaft fractures are the commonest, 70%, while the medial third fractures are the lowest, 2 to 3%, where the lateral third fracture accounts 25 to 28%, of all fracture clavicle [2]

Trauma is considered the most common cause of fracture clavicle, direct fall on the shoulder, 87%, direct fall on out-stretched hand, 6%, and direct trauma to the clavicle, 7%, while pathological or stress fractures are rare causes [3].

The treatment of fracture clavicle whether conservative or operative is still a challenge; the indication of surgery in patients with fracture clavicle includes the need for rapid and early mobilization of the shoulder, open fracture, flail shoulders and polytrauma patients [4].

There are variable methods of fixation and variable surgical approaches for operative treatment of fracture clavicle [4]. In the current study, we reviewed the different indications and techniques of plating of clavicular fractures also the results and the complications of each technique.

## Materials and Methods

### Data Sources and Search Strategy

The search was performed in the following electronic databases: PubMed, SCOPUS, Web of Science, and The Cochrane Library. The search key words were: clavicle,

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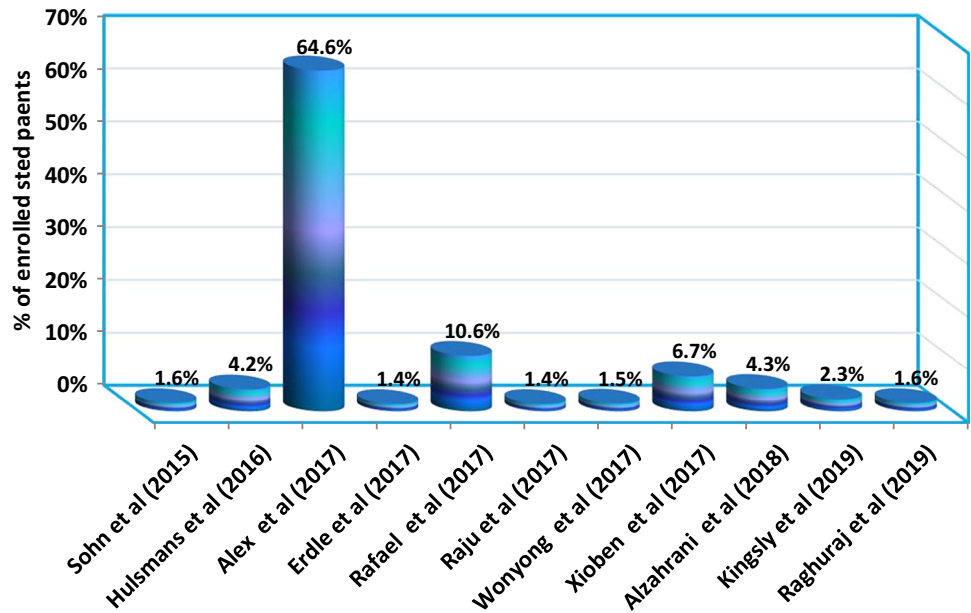
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**Fig. 1** Percentage of patients of enrolled studies of different authors ( $n = 2370$ )



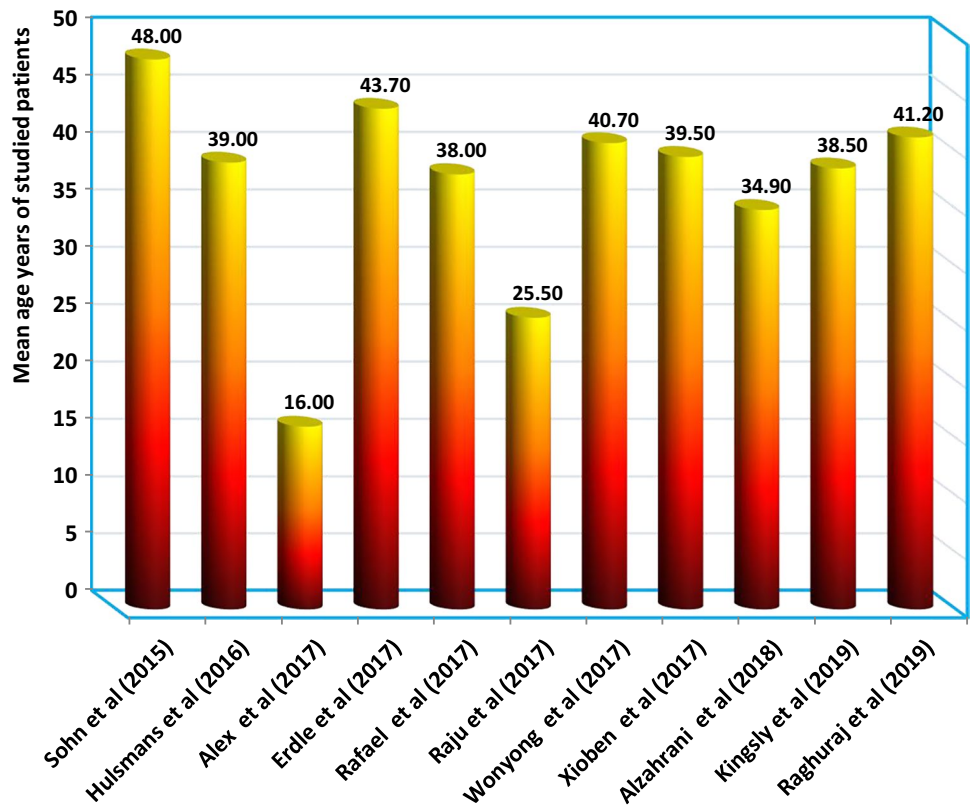
fracture clavicle, in association with surgical approaches, plating of the clavicle and functional ability or physical activity.

- Clinical studies with patients of fracture clavicle.
- Fracture clavicle underwent surgical intervention by plating.
- Articles in English language.

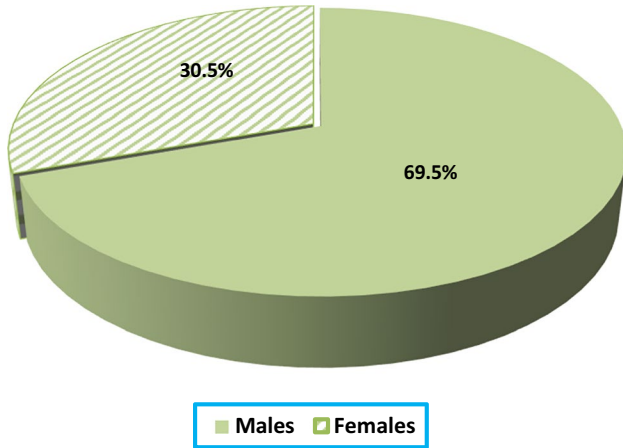
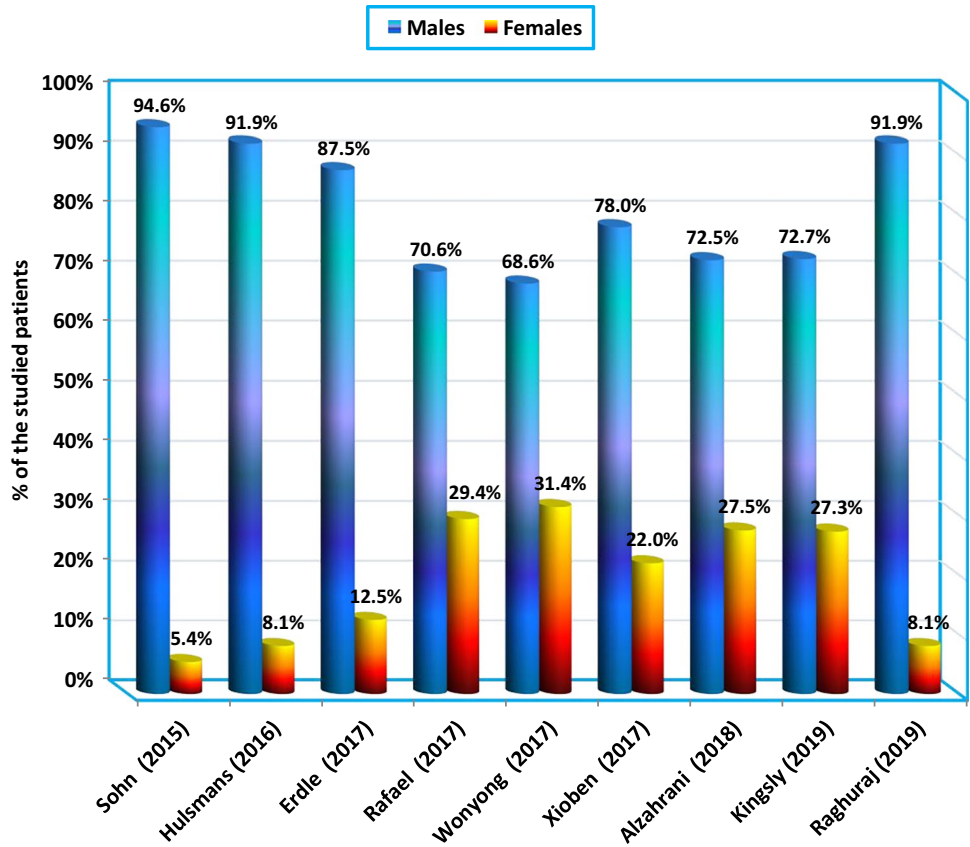
**Selection of Studies and Screening of Titles and Abstracts**

All selected titles are screened to meet the following criteria:

**Fig. 2** Mean age years of patients of enrolled studies of different authors ( $n = 2370$ )



**Fig. 3** Sex of the enrolled studied patients of different authors studies ( $n=2370$ )



**Fig. 4** Sex of the total enrolled studied patients ( $n=689$ )

**Study Characteristics**

The data extraction was performed to obtain the name of the authors, year of publication, types of the plate, the number of patients in each group, age, sex (Figs. 1, 2, 3, and 4), and duration of the follow-up, surgical, and functional outcomes of each intervention (Tables 1 and 2).

**Outcomes of the Included Studies**

The outcome included complications, rate of bony union, advantages of each surgical intervention, and radiological outcome of each method of intervention (Table 3).

**Table 1** Baseline characteristics of the enrolled studied patients

Authors	Year	The enrolled studied patients ( $n=2370$ )		Mean age (years)
		<i>n</i>	%	
Sohn et al. [5]	2015	37	1.6	48
Hulsmans et al. [6]	2016	99	4.2	39
Nourian et al. [7]	2017	1530	64.6	16
Erdle et al. [8]	2017	32	1.4	43.7
Serrano et al. [9]	2017	252	10.6	38
Vaishya et al. [10]	2017	32	1.4	25.5
Lee et al. [11]	2017	35	1.5	40.7
Chen et al. [12]	2017	159	6.7	39.5
Alzahrani et al. [13]	2018	102	4.3	34.9
Kingsly et al. [14]	2019	55	2.3	38.5
Kundangar et al. [15]	2019	37	1.6	41.2

**Table 2** Sex of the enrolled studied patients of different authors ( $n=2370$ )

Authors	Year	The enrolled studied patients ( $n=2370$ )					
		Males		Females		Total	
		<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Sohn [5]	2015	35	94.6	2	5.4	37	1.6
Hulsmans [6]	2016	91	91.9	8	8.1	99	4.2
Nourian [7]	2017	-	-	-	-	1530	64.6
Erdle [8]	2017	28	87.5	4	12.5	32	1.4
Serrano [9]	2017	178	70.6	74	29.4	252	10.6
Vaishya [10]	2017	-	-	-	-	32	1.4
Lee [11]	2017	24	68.6	11	31.4	35	1.5
Chen [12]	2017	124	78.0	35	22.0	159	6.7
Alzahrani [13]	2018	74	72.5	28	27.5	102	4.3
Kingsly [14]	2019	40	72.7	15	27.3	55	2.3
Kundangar [15]	2019	34	91.9	3	8.1	37	1.6
<b>Total</b>		<b>479</b>	<b>69.5</b>	<b>210</b>	<b>30.5</b>	<b>689</b>	<b>100</b>

### Inclusion Criteria

Studies which met these inclusion criteria were considered for the final analysis in the current study:

- 1) Fracture clavicle in adult.
- 2) Open reduction and internal fixation by plate and screws.
- 3) Follow-up duration more than 12 months.
- 4) Age group 18–60 years old.
- 5) Studies using different types of plates.
- 6) Studies using different approaches to the fracture.

Exclusion criteria:

- 1) Studies with languages rather than English.
- 2) Studies with unclear description of results and techniques.

**Table 3** Mode of trauma and the affected third of clavicle among the enrolled studied patients

Authors	Mode of trauma	Anatomical third
Sohn [5]	Motor vehicle accident	Middle third
Hulsmans [6]	Motor vehicle accident	Middle third
Nourian [7]	Motor vehicle accident	Middle third
Erdle [8]	Road traffic accident	Distal third
Serrano [9]	Sports injury	Middle third
Vaishya [10]	Motor vehicle accident	Distal third
Lee [11]	Falling from height	Distal third
Chen [12]	Bicycle related trauma	Middle third
Alzahrani [13]	Bicycle related trauma	Middle third
Kingsly [14]	Road traffic accident	Middle third
Kundangar [15]	Sports injury	Middle third

- 3) Follow-up duration less than 1 year.
- 4) Experimental and cadaveric studies.

### Literature Search (Selection of Studies)

The initial search in database yielded 98 articles which match the search key words, by 1st screening, 47 articles were removed as duplicated titles and articles not in English language, 51 articles were re-screened, 40 articles were excluded as they were case reports, studies with unclear

**Table 4** Different approaches and follow-up duration among the enrolled studied patients

Authors	Approach	Mean follow-up duration (months)
Sohn [5]	Ant. Inf	16.7
	Superior	20.2
Hulsmans [6]	Ant. Inf	27.0
	Superior	21.0
Nourian [7]	Ant. Inf	18.0
	Superior	18.0
Erdle [8]	Anterior superior	54.1
Serrano [9]	Ant. Inf	30.1
	Superior	32.6
Vaishya [10]	Horizontal incision on distal clavicle	18.0
Lee [11]	10 cm on distal clavicle	24.0
Chen [12]	Ant. Inf	12.0
	Superior	12.0
Alzahrani [13]	Transverse incision	12.0
Kingsly [14]	Transverse incision	25.5
Kundangar [15]	Open longitudinal	24.0
	MIPO	24.0

**Table 5** Union rate after plating among the enrolled studied patients

Authors	Approach	No. of patients	Union frequency	
			n	%
Sohn [5]	Ant. Inf	18	18	100
	Superior	19	19	100
Hulsmans [6]	Ant. Inf	39	39	100
	Superior	60	59	98.3
Nourian [7]	Ant. Inf	1140	1106	97.0
	Superior	390	386	99.0
Erdle[8]	Anterior superior	32	31	96.9
Serrano [9]	Ant. Inf	118	117	99.2
	Superior	134	131	97.8
Vaishya [10]	Horizontal incision on distal clavicle	32	31	96.9
Lee [11]	10 cm on distal clavicle	35	35	100
	Ant. Inf	125	114	91.2
Chen [12]	Superior	34	34	100
	Transverse incision	102	100	98.0
Kingsly [14]	Transverse incision	55	55	100
Kundangar [15]	Open longitudinal	16	15	93.7
	MIPO	21	20	95.2
Total patients with union after plating		<b>2370</b>	<b>2310</b>	<b>97.5</b>

**Table 6** Nonunion rate after plating among the enrolled studied patients

Authors	Approach	No. of patients	Nonunion frequency	
			n	%
Sohn [5]	Ant. Inf	18	0	0
	Superior	19	0	0
Hulsmans [6]	Ant. Inf	39	0	0
	Superior	60	1	1.7
Nourian [7]	Ant. Inf	1140	34	3.0
	Superior	390	4	1.0
Erdle [8]	Anterior superior	32	1	3.1
Serrano [9]	Ant. Inf	118	1	0.8
	Superior	134	3	2.2
Vaishya [10]	Horizontal incision on distal clavicle	32	1	3.1
Lee [11]	10 cm on distal clavicle	35	0	0
Chen [12]	Ant. Inf	125	11	8.8
	Superior	34	0	0
Alzahrani [13]	Transverse incision	102	2	2.0
Kingsly [14]	Transverse incision	55	0	0
Kundangar [15]	Open longitudinal	16	1	6.3
	MIPO	21	1	4.8
Total patients with nonunion after plating		<b>2370</b>	<b>60</b>	<b>2.5</b>

description of the outcome and unfound articles, and the remaining articles for final analysis were 11 articles.

## Results

### Follow-up Duration (Table 4)

### Union Rate (Table 5)

### Complications

### Nonunion (Table 6)

### Implant Failure (Table 7)

### Infection (Tables 8, 9 and 10) Score (Table 11)

## Discussion

Several authors had recommended surgical intervention for displaced fracture clavicle with liability for skin penetration, impaired neurovascular, open fractures, patient with poly trauma, and floating shoulder as absolute indication, while nonunion is considered a relative indication for surgical intervention [16].

Many authors advocated that plate osteosynthesis is the standard tool for operative treatment of the fracture clavicle; there are many types of plates as dynamic compression, locked, and reconstruction plates [16, 17].

Recent studies had recommended of open reduction and plate fixation of the mid shaft and lateral fractures of the clavicle to avoid nonunion or mal union of these fractures [7]. Hill et al. had treated 52 patients with displaced fracture clavicle conservatively, 15% had nonunion, and 31% were not satisfied functionally [18]. Zlowodzki et al. had reviewed 2144 midshaft clavicle fractures and they found that 15.1% had nonunion [19], while McKee et al. [20] had evaluated 30 patients of mid shaft fracture clavicle who were treated conservatively; they found that the mean constant score 71

**Table 7** Different approaches, and plating of fracture with implant failure proportion among the enrolled studied patients

Authors	Approach	Type of plate	Implant failure	
			<i>n</i>	%
Sohn [5]	Ant. Inf	3.5 mm titanium locking reconstruction plate	0/18	0
	Superior		1/19	5.3
Hulsmans [6]	Ant. Inf	Locking reconstruction plate	14/39	35.9
	Superior		22/60	36.7
Nourian [7]	Ant. Inf	Precontoured plate	27/1140	2.4
	Superior		43/390	11.0
Erdle [8]	Anterior superior	Hook plate	1/19	5.3
		Locking plate	0/13	0
Serrano [9]	Ant. Inf	3.5 mm plate	5/118	4.2
	Superior	3.5 mm plate	25/134	18.6
Vaishya [10]	Horizontal incision on distal clavicle	3.5 mm locking plate with lateral extension	0/32	0
Lee [11]	10 cm on distal clavicle	Hook plate	0/35	0
Chen [12]	Ant. Inf	Locking plate	4/125	3.2
	Superior	Reconstruction plate	0/34	0
Alzahrani [13]	Transverse incision	3.5 mm reconstruction plate 2.7 mm calcaneal plate	32/102	31.4
Kingsly [14]	Transverse incision	Anatomical locking plate	0/24	0
		Reconstruction plate	3/31	6.7
Kundangar [15]	Open longitudinal MIPO	Locking compression plate	0/16	0
			1/21	4.8
Total patients with implant failure			<b>178/2370</b>	<b>7.5</b>

points, and the mean (DASH) score 24.6 points, indicating substantial disability.

On the other hand, Wijdicks et al. had advocated that the most common complications with plate fixation is implant

**Table 8** Postoperative infection among the enrolled studied patients in relation to approach and type of plate

Authors	Approach	Type of plate	Infection	
			<i>n</i>	%
Sohn [5]	Ant. Inf	3.5 mm titanium locking reconstruction plate	0/18	0
	Superior		0/19	0
Hulsmans [6]	Ant. Inf	Locking reconstruction plate	3/39	7.7
	Superior		3/60	5.0
Nourian [7]	Ant. Inf	Precontoured plate	31/1140	2.7
	Superior		62/390	15.9
Erdle [8]	Anterior superior	Hook plate	0/19	0
		Locking plate	0/13	0
Serrano [9]	Ant. Inf	3.5 mm plate	1/118	0.8
	Superior	3.5 mm plate	1/134	0.7
Vaishya [10]	Horizontal incision on distal clavicle	3.5 mm locking plate with lateral extension	0/32	0
Lee [11]	10 cm on distal clavicle	Hook plate	<b>Not documented</b>	
Chen [12]	Ant. Inf	Locking plate	Not documented	
	Superior	Reconstruction plate		
Alzahrani [13]	Transverse incision	3.5 mm reconstruction plate	4/102	3.9
Kingsly [14]	Transverse incision	Anatomical locking plate	0/24	0
		Reconstruction plate	3/31	6.7
Kundangar [15]	Open longitudinal MIPO	Locking compression plate	0/16	0
			0/21	0
Total patients with postoperative infection			<b>108/2176</b>	<b>4.96</b>

**Table 9** Frequency of union, non-union, implant failure, and postoperative infection among the enrolled studied patients in relation to approach and name of author ( $n=2370$ )

Approach	Author (no. of patients)	The enrolled studied patients ( $n=2370$ )											
		Union patients		Non-union patients		Implant failure		Postoperative infection		Total patients ( $n=2370$ )			
		<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%		
• Anterior inferior	Sohn [5]	(18)											
	Hulsmans [6]	(39)											
	Nourian [7]	(1140)											
	Serrano [9]	(118)											
	Chen [12]	(125)											
• Superior	Sohn [5]	(19)											
	Hulsmans [6]	(60)											
	Nourian [7]	(390)											
	Serrano [9]	(134)											
	Chen [12]	(34)											
• Direct transverse	Erdle [8]	(32)											
	Vaishya [10]	(32)											
	Alzahrani [13]	(102)											
	Kingsly [14]	(55)											
• MIPO	Kundangar [15]	(16)											
	Kundangar [15]	(21)											
<b>Total</b>		<b>2370</b>	<b>2310</b>	<b>97.5</b>	<b>60</b>	<b>2.5</b>	<b>178</b>	<b>7.5</b>	<b>108/2176</b>	<b>5.0</b>	<b>2370</b>	<b>100</b>	

irritation and failure [21], while Wang et al. had found that most of the patients who were treated by precontoured plating for mid shaft fracture clavicle were discomfort and prefer for implant removal because of implant prominence and irritation [22].

In the current study, the most common mechanisms of injury were motor vehicle accident, road traffic accident, sports injury, bicycle related trauma, and falling from height (Table 3) (Figs. 5 and 6). Regarding bony union, we had found that union rate was 97.5% (2310 patients) (Figs. 7 and

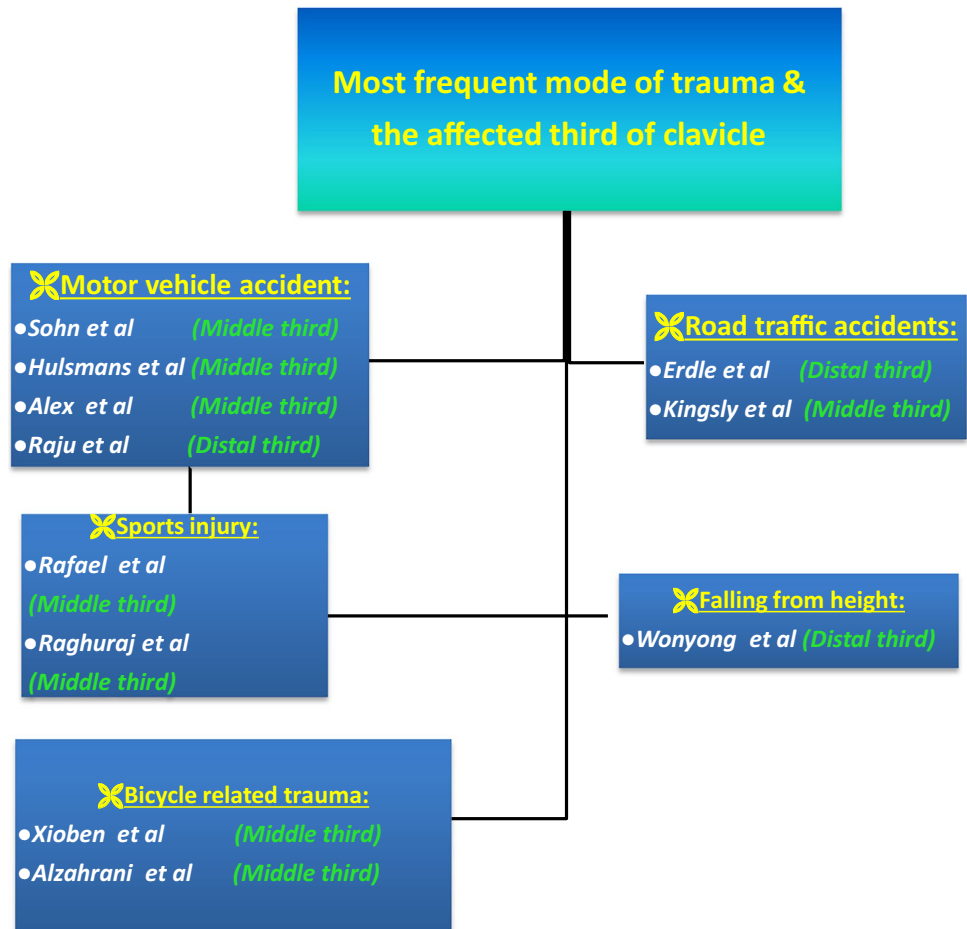
**Table 10** Frequency of union, nonunion, implant failure, and postoperative infection among the enrolled studied patients in relation to type of plate

Type of plate	Author	The enrolled studied patients ( $n=2370$ )									
		Union patients		Non-union patients		Implant failure		Postoperative infection		Total patients ( $n=2370$ )	
		<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
• Non-locking reconstruction plate	Serrano [9]	379	98.4	6	1.6	65	16.9	9	2.3	385	16.2
	Alzahrani [13]										
	Kingsly (31 pt.) [14]										
• Locking reconstruction plate	Sohn [5]	283	95.9	12	4.1	41	13.9	6	2.0	295	12.4
	Hulsmans [6]										
	Chen [12]										
• Locking precontoured plate	Nourian [7]	1551	97.5	40	2.5	71	4.5	93	5.8	1591	67.1
	Kingsly (24 pt.) [14]										
	Kundangar [15]										
• Hook plate	Erdle [8]	66	98.5	1	1.5	1	1.5	0	0	67	2.8
	Lee [11]										
• Locking plate with lateral extension	Vaishya [10]	31	96.9	1	3.1	0	0	0	0	32	1.3
<b>Total</b>		<b>2310</b>	<b>97.5</b>	<b>60</b>	<b>2.5</b>	<b>178</b>	<b>7.5</b>	<b>108/2176</b>	<b>5.0</b>	<b>2370</b>	<b>100</b>

**Table 11** Score among the enrolled studied patients

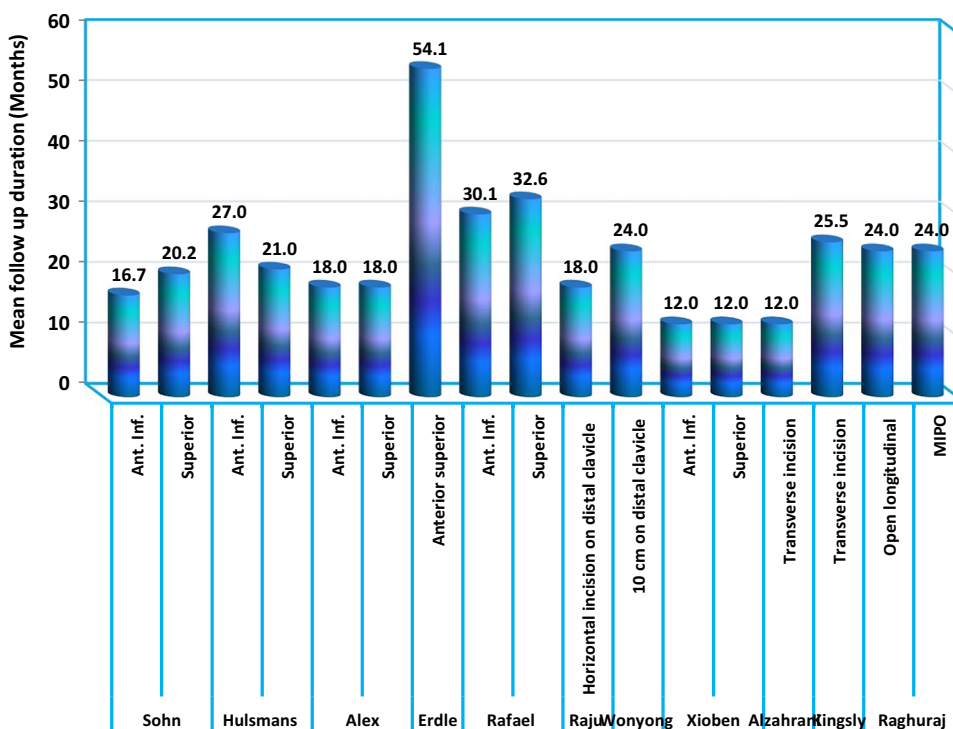
Authors	Outcome measure	Approach or plate type	Score
Sohn [5]	Constant score measure (119)	Ant. Inf	97.27 ± 4.99 point
		Superior	95.75 ± 4.25 point
Hulsmans [6]	Implant related irritation	Ant. Inf	22%
		Superior	18%
Nourian [7]	The mean DASH score (120)	Ant. Inf	5.18 point
		Superior	9.71 point
Erdle [8]	The constant score	Anterior superior	90.3 point
Serrano [9]	Implant related irritation	Ant. Inf	5%
		Superior	25%
Vaishya [10]	The constant score	Horizontal incision on distal clavicle	96.25 point
Lee [11]	The quick DASH score	10 cm on distal clavicle	1.4 ± 0.9 point
Chen [12]	Implant related irritation	Ant. Inf	11.4%
		Superior	21.5%
Alzahrani [13]	The constant score	Transverse incision	95.8 point
Kingsly [14]	Quick DASH score	Anatomical plate	25.44 point
		Reconstruction plate	32.65 point
Kundangar [15]	Quick DASH score	Open longitudinal	4.1 point
		MIPO	4.7 point

**Fig. 5** Mode of trauma and the affected third of clavicle among the enrolled studied patients





**Fig. 6** Mean follow-up duration among the enrolled studied patients of different authors in relation to approach

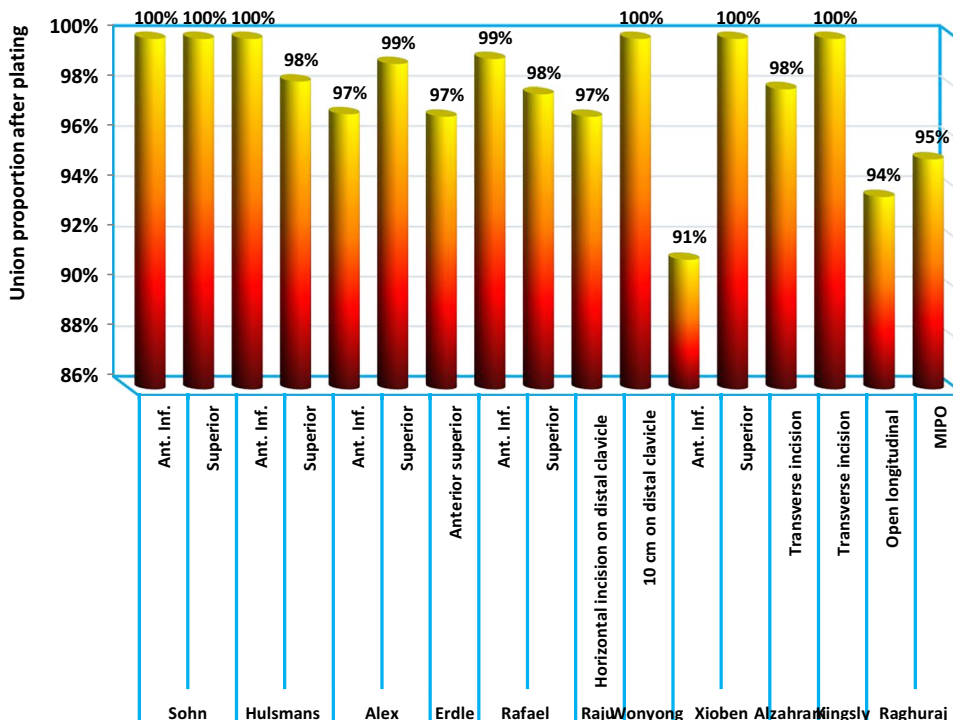


9) while the remaining 2.5% of the whole cases (60 patients) developed nonunion (Figs. 8 and 9) and required another surgery with bone graft which was not briefly discussed by most authors so we could not document that in our study. In addition, we found that malunion can occur secondary to

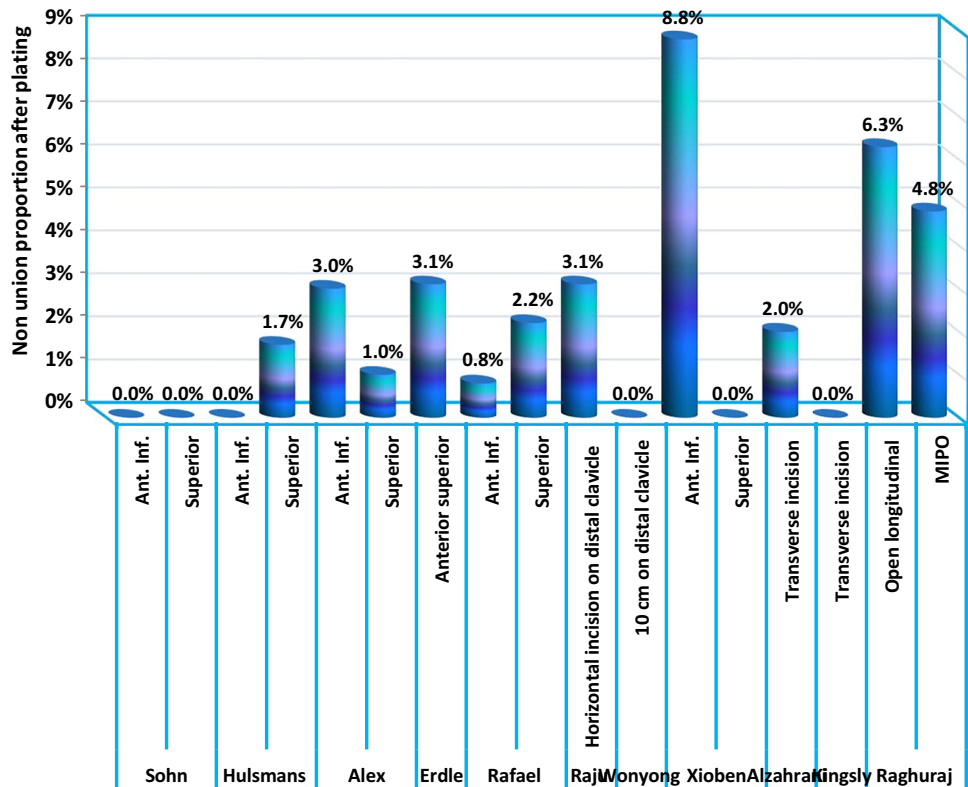
poor plating technique or a loss of reduction postoperatively (Table 5).

One of the most serious complications in this review is implant failure in the form of screw breakage or implant loosening which subsequently affects the reduction of the

**Fig. 7** Proportion of union after plating among the enrolled studied patients in relation to approach



**Fig. 8** Nonunion proportion after plating among the enrolled studied patients in relation to approach



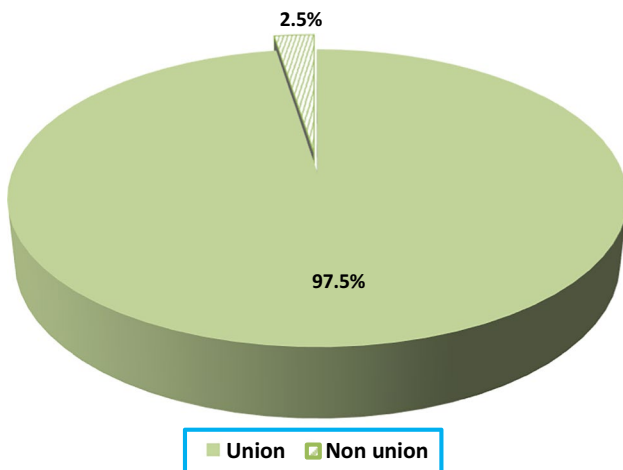
fracture (Figs. 10, 11, and 12). Hulsmans [6] has the most frequency of implant failure in his study (Table 7).

Infection is a very serious complication in the orthopedic surgeries. In fracture clavicle fixed with plates, infection is common due to the subcutaneous position of the implant and poor soft tissue coverage [9]. In this review, two authors, Lee [11] and Chen [12], did not document the infection rate of

their cases. So, the total patient number to study the infection rate will be 2176 patient. The number of infected cases (in the form of wound dehiscence or pus discharge) is 108 patients (4.96%), most of them with the superior approach (9.9%) and with the locking precontoured plate (5.8%) (Figs. 13, 14, and 15). All of these cases were controlled by medical treatment and none of them required a secondary surgery (Table 8).

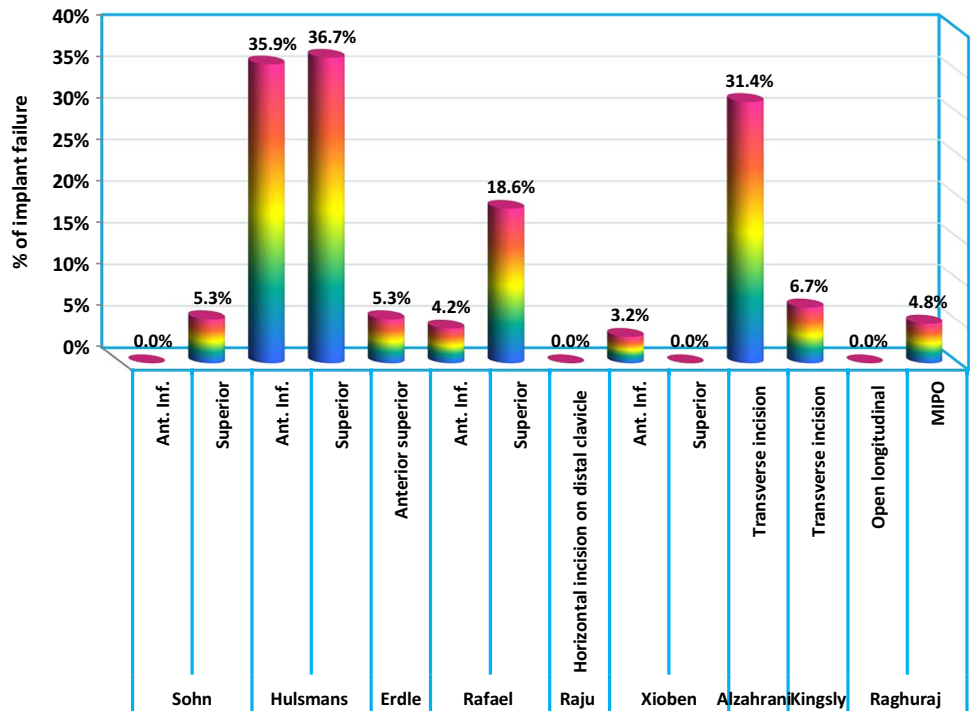
Regarding the surgical approach, we have found that anterior inferior approach (Figs. 6 and 16) was used in 5 studies with total patient number 1440. It is considered one of the best approaches used in the review with the least complication rate (in relation to implant failure and infection) and good union rate (96.8%), while the superior approach was used in 6 studies with total patient number 669. Easy approach to use for fracture reduction and plate fixation. Despite the best union rate (98.6%), it has a very high complication rate according to implant failure (13.7%) and infection rate (9.9%), where direct transverse approach was used in 4 studies with total patient number 240. It is a direct incision across the fracture. Union rate is 98.3%. This approach has the highest implant failure rate by 14.6% and infection rate 2.9% (Table 4 and Table 9).

Minimally invasive plate osteosynthesis (MIPO) was used in only one study with total patient number 21. A difficult surgical approach in controlling the fracture but it preserves

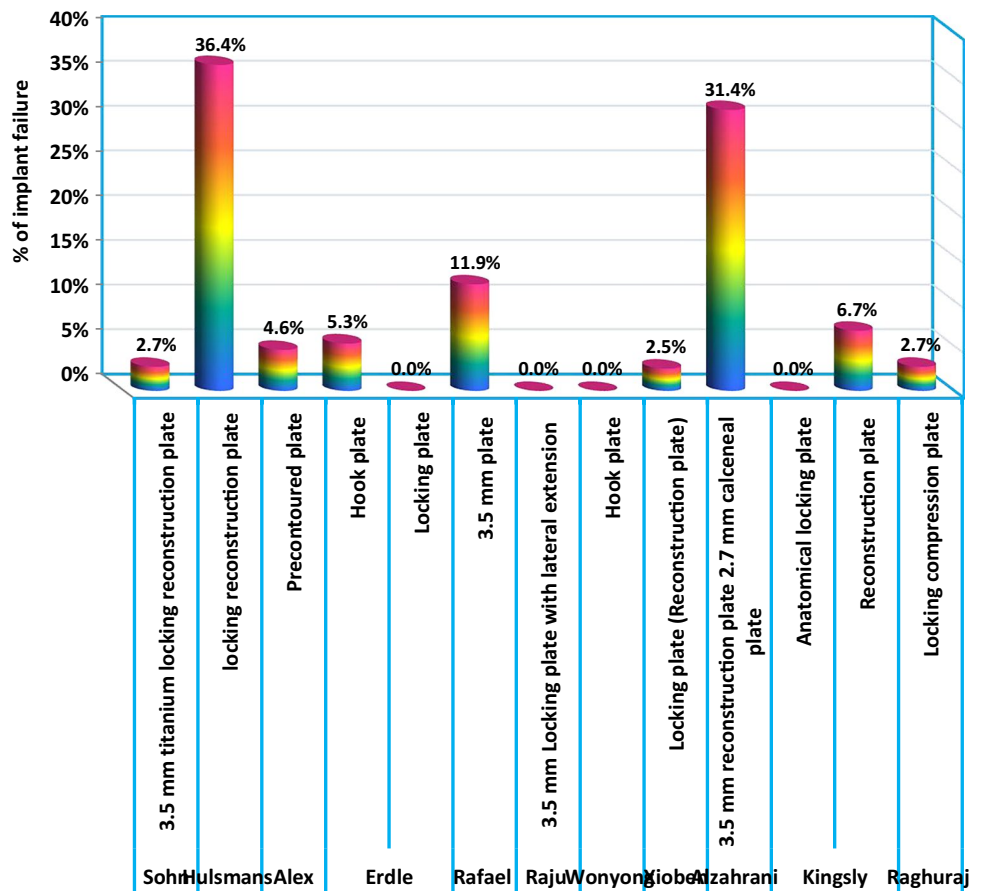


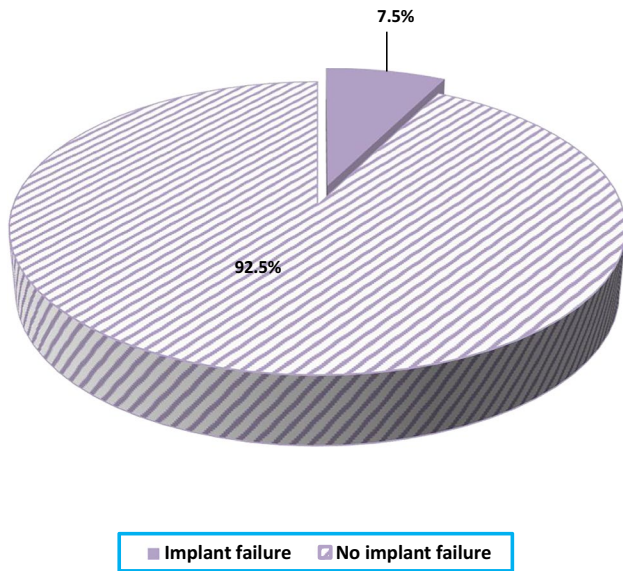
**Fig. 9** Total proportion of union and nonunion after plating among the enrolled studied patients (n = 2370)

**Fig. 10** Implant failure proportion among the enrolled studied patients of different authors in relation to approach



**Fig. 11** Implant failure proportion among the enrolled studied patients of different authors in relation to type of plate (n = 2370)

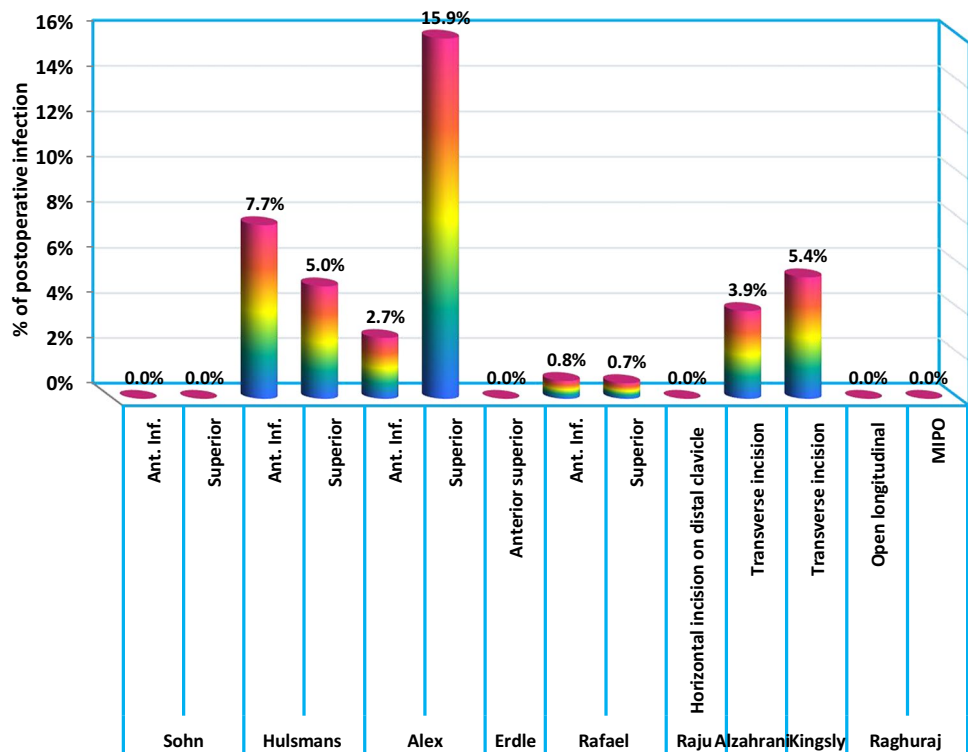




**Fig. 12** Total implant failure proportion among the enrolled studied patients of different authors ( $n = 2370$ )

the vascularity of the clavicle. Union rate was 95.2%. None of the cases has been infected but there is only one case (4.8%) with implant failure (Table 7).

**Fig. 13** Proportion of postoperative infection after plating among the enrolled studied patients in relation to approach ( $n = 2176$ )



Regarding type of plates used in the treatment of fracture clavicle (Fig. 17), it was found that non-locking

reconstruction plate was used in 3 cases series with total patient number 385 and with union rate 98.4%. It was the first plate to be used in the fixation of fracture clavicle but it shows high complication rate. In this study, it has the highest rate of implant failure 16.9% and the infection rate was 2.3%, while locking reconstruction plate was used in 3 papers with total patient number 295 and with union rate 95.9%. It provides more rigid fixation than the non-locking reconstruction plate specially with comminuted fractures so implant failure rate is lower (13.9%) but the infection rate is higher than that of the non-locking reconstruction plate (4.1%) (Table 7).

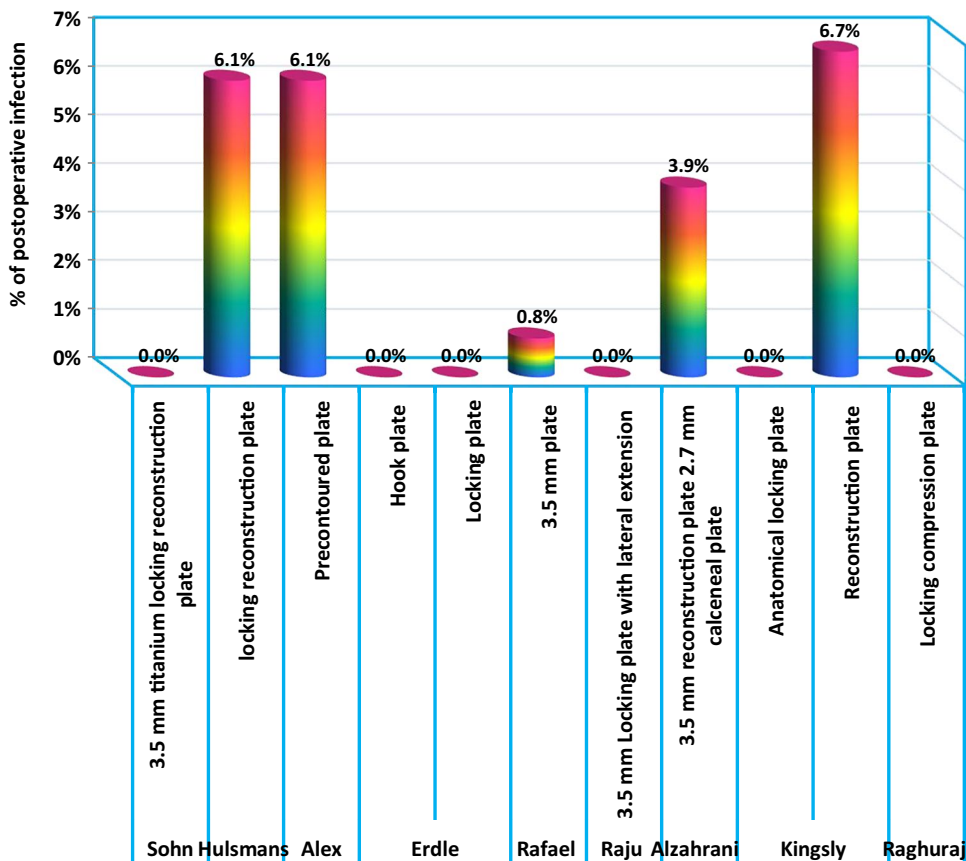
On the other hand, we have found that locking precontoured plate was used in 3 studies with total patient number 1591 and with union rate 97.5%. It is now the most common plate used in fixation of clavicle fractures specially the middle third fractures. The implant failure rate is 4.5% and the infection rate is 5.8% which is the highest rate of infection among all studies in this review (Table 7).

Hook plate, a special plate for the lateral third clavicular fractures, was used in 2 studies with total patient number 67 and with union rate 98.5%. None of the cases has got infection but there is only one case (1.5%) with implant failure (Table 7).

Locking plate with lateral extension, also a special plate for the lateral third clavicular fractures as the hook plate,

was used in one case series with total patient number 32 and with union rate 96.9%. None of the cases has got infection or

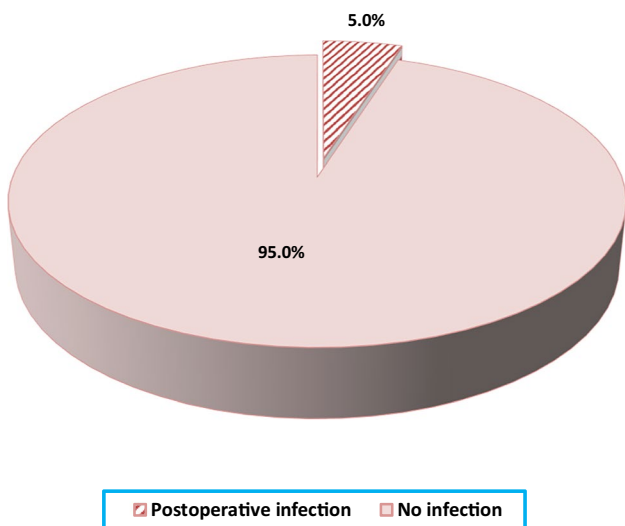
**Fig. 14** Proportion of postoperative infection after plating among the enrolled studied patients in relation to type of plate ( $n = 2176$ )



implant failure. It is just one patient (3.1%) with nonunion (Table 7 and Table 10).

The current study does have some limitations. The direct transverse approach is not as frequently described in the

literature, and there is only one study that compare between MIPO and open technique in fracture fixation; the study presents different surgeons with different plate application which affects the outcome (Table 11).



**Fig. 15** Total proportion of infection after plating among the enrolled studied patients in relation to type of plate ( $n = 2176$ )

### Conclusion

From this review, we recommended using of locking precontoured plate for fixation of the clavicle fractures especially middle third, and anteroinferior approach to perform this fixation; by combination of both, it will be of little complication and high successful rate of union.

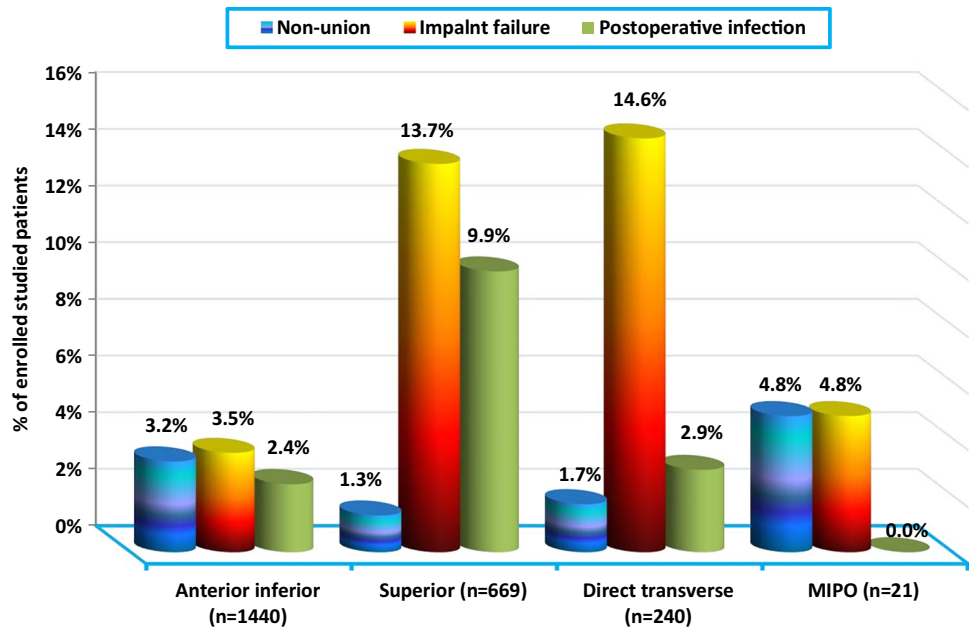
**Author contribution** M.A.M: data collection, manuscript preparation, editing, statistical analysis.

A.M.S: data collection, manuscript preparation, editing, statistical analysis.

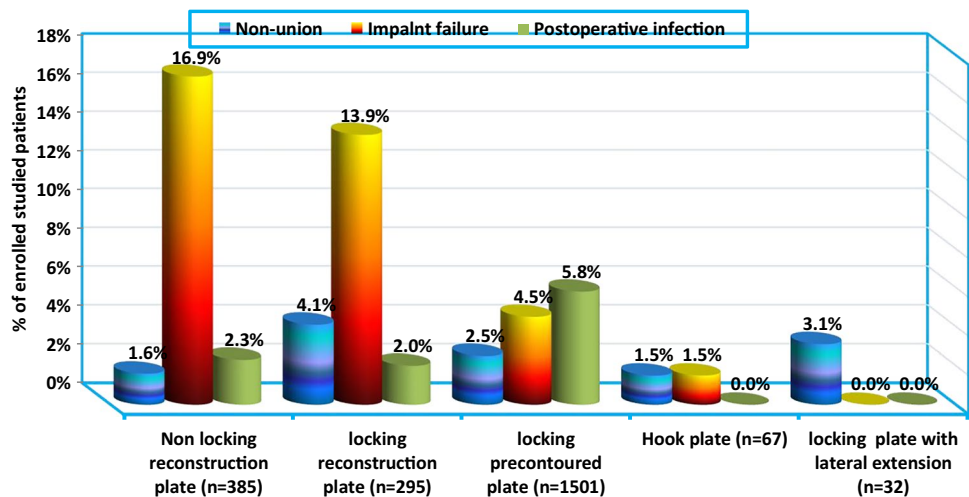
O.M.E: manuscript editing, revision, statistical analysis.

S.A.E: manuscript editing, revision, statistical analysis.

**Fig. 16** Frequency of non-union, implant failure, and postoperative infection among the enrolled studied patients in relation to approach ( $n = 2370$ )



**Fig. 17** Frequency of nonunion, implant failure, and postoperative infection among the enrolled studied patients in relation to type of plate ( $n = 2370$ )



## Declarations

**Ethics approval** The study was approved by the ethical committee of the University and was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

**Conflict of interest** The authors declare no competing interests.

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