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REVIEW

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Management of clavicle shaft fractures with intramedullary devices: a narrative review

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ABSTRACT

Introduction: Displaced and shortened clavicle fractures are frequently treated surgically. Although extramedullary fixation using a plate and screws is most commonly used, intramedullary nailing has become increasingly popular over the last decade. Traditional intramedullary nailing is usually associated with a high risk of hardware migration as well as hardware irritation at its entry point. Newer devices, however, seem to mitigate these problems. The aim of this narrative review is to provide an overview of clavicle shaft fractures and treatment with intramedullary nails, in particular the newer, locked devices.

Areas covered: In general, this review covers current literature related to clavicle shaft fractures with a specific focus on the treatment of displaced and shortened fractures with intramedullary nails.

Expert opinion: Clavicle shaft fractures can be effectively treated with an intramedullary nail. The risk of hardware migration when employing the newer, improved designs appears to be minimal. The advantages of using intramedullary fixation include smaller incision sizes as well as the avoidance of routine procedures generally associated with the removal of prominent subcutaneous hardware as per extramedullary fixation.

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1. Epidemiology of clavicle fractures

Clavicle fractures are common and comprise 2.6% to 4% of all adult fractures whilst accounting for 35% of injuries to the shoulder girdle [1]. The annual incidence of clavicle fractures varies between 29 and 64 per 100 000 per year [1]. Nowak *et al*. ascertained the annual incidence of clavicle fractures to be 70 per 100 000 in males and 30 per 100 000 in females [2]. Postacchini *et al*. noted, in their series of 535 isolated clavicle fractures, that 68% of these occur in men with the left clavicle being affected in 61% of patients [3]. In addition, they ascertained that clavicle shaft fractures account for 81% of clavicle fractures with 48% being displaced and 19% comminuted. Robinson *et al*. reported that shaft fractures comprise 69% of all clavicle fractures [4] with the mean age at time of injury being 33 years. The male to female ratio is 2.6 to 1 and the ratio of left to right clavicle fractures is 1.28 to 1. They identified the highest incidence of fractures in males, 13 to 20 years of age [4]. Stanley *et al*. noted that the first, and highest, peak of clavicle fractures occurs in males younger than 30 years. The second peak occurs in females aged 80 years and older [5] and is, in all probability, osteoporosis related.

The mechanisms of injury which result in clavicle shaft fractures can be divided into direct and indirect trauma. Indirect trauma to the clavicle occurs when an individual falls onto an outstretched hand or, more commonly, falls onto the point of the shoulder. These fractures generally occur during sporting activities which include mountain biking and horse riding. Direct trauma inflicted by a blunt, or penetrating mechanism, is commonly a secondary result of interpersonal violence. Postacchini *et al*. identified motor vehicle accidents as the main mechanism of injury [6]. Stanley *et al*. noted that fractures which occur in the elderly generally happen secondary to low energy falls from the standing position [5]. Nowak *et al*. identified bicycle accidents as the most common mechanism of injury with sporting injuries resulting in most clavicle fractures in males [2]. Zhu *et al*. reported that the vast majority of fractures in an urban Chinese population could be ascribed to road traffic accidents [7]. Studying a series of 2 035 fractures over a period of 35 years, Nordqvist *et al*. noted a significant increase in the incidence of clavicle fractures during the review period [8].

An interesting study in China identified alcohol abuse, increased age, smoking, lack of sleep and a history of a previous fracture as risk factors which heighten the possibility of sustaining a clavicle fracture [9]. High energy injury mechanisms are associated with an increase in: fracture comminution, associated injuries and open fractures [10,11].

In developing countries, information pertaining to the epidemiology of these commonly encountered fractures remains limited. In first world populations, however, the epidemiology has been widely studied [5,8]. However, it remains unclear whether the data are applicable to populations in developing countries.

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2. Anatomy of the clavicle

The clavicle, which is much thicker in its middle 3/5th than in the lateral and medial fifths [12], consists of cancellous bone enveloped by cortical bone. The configuration of the clavicle presents a double curvature with a convex anterior curve in the medial half and a concave anterior curve in the lateral half. It has an apex superior curvature located in the medial half of the clavicle [13]. The cross-sectional anatomy of the clavicle differs in shape along its length. Distally the outer third is virtually flat, the medial third is prismatic and the middle third is circular in shape [12].

The clavicle is the first bone in the body to ossify (5th week of fetal life) and the only long bone to ossify by intramembranous ossification without going through the cartilaginous stage [12]. The medial growth plate of the clavicle is the last growth plate in the body to close, usually between 22 and 25 years of age [12]. The clavicle articulates medially with the sternum at the sternoclavicular joint and laterally with the acromion at the acromioclavicular joint.

2.1. Anatomical variations of the clavicle

Based on gender and age, the clavicle can vary substantially in size and shape [12]. Andermahr *et al*. reported that the female clavicle is generally shorter, less curved and contains a lower concentration of calcium [14]. Daruwalla *et al*. reported, based on 3D computer tomography reconstructions, that the male clavicle bone is generally longer, wider, and thicker than that of the female [13].

Through the use of computer tomography, Bortier *et al*. evaluated 90 clavicles and reported an average length of 163 ± 11 mm [15]. They also noted that right and the left side clavicle length tends to differ by 1.2% whilst, on average, clavicles were 9% longer in males. In line with this, Bortier *et al*. further reported that the sternal (18%) and acromial curvature (4%) were substantially less pronounced in females than in males [15]. In line with previous studies, King *et al*. reported differences in length between the right and left clavicle. In this study, however, no curvature differences were noted between the right and left clavicle [16].

2.2. Clavicle anatomy and intramedullary fixation of clavicle shaft fractures

Andermahr *et al*. analyzed 196 cadaver clavicles to determine anatomical variations in the medullary canal and its suitability to intramedullary fixation [14]. They ascertained the narrowest portion of the canal to be at the midpoint of the clavicle 6.7 ± 2.6 mm in diameter. They also discovered the cortex to be at its thinnest at the dorsal aspect of the lateral clavicle and the ventral aspect of the medial clavicle. This represents the insertion points for commonly used intramedullary devices, but also areas at risk for cortical perforation.

Based on a computer tomography study of clavicle anatomy, King *et al*. reported that the size of the medullary canal was adequate to accommodate most intramedullary devices [16]. This study describes, in some detail, the height and width of the intramedullary canal on the lateral, middle and medial end of the clavicle in relation to the clavicle curvatures. The study further notes that, in most cases, the medullary canal is sufficiently wide and extends deep enough into the lateral and medial components of the clavicle to accommodate an intramedullary device [16]. Only 1.4% of male clavicles had a medullary canal smaller than 4 mm in diameter whilst 31% of female clavicles had a medullary canal smaller than 4 mm at the midpoint of the clavicle. In these individuals, it would be very difficult to pass regular intramedullary devices (Rockwood nail, Hagie pin, Sonoma CRx) over the fracture site. However, in the majority of cases, the smaller TEN's nails might still be usable. The authors advised that an alternative fixation device (extramedullary device) should be available in theater when treating fractures in females by intramedullary fixation [16].

The curvature of the clavicle varies and therefore it can affect the length of the implant to be inserted, particularly if said implant is rigid and does not allow to follow the curvature. To determine whether rigid fixation devices can be effective in treating this complex 3-dimensional anatomy, Bachoura *et al*. scanned 22 clavicles and used a CT model to evaluate the length and cross-sectional area of the clavicle [17]. They simulated IM fixation by superimposing a straight cylindrical corridor in a lateral-to-medial direction. The authors considered stable fixation as the ability to bypass the midpoint of the clavicle (assumed fracture site) by two cortical diameters with the straight corridor. They also ascertained that the midpoint of the clavicle had the smallest cross-sectional area and were able to simulate rigid IM fixation successfully in 15 of the 22 clavicles [17]. This seems to suggest certain limitations when using rigid devices, particularly in addressing complex fractures or fractures not located at the midpoint of the clavicle. If the fracture extends medially to the midpoint of the clavicle, secondary to comminution, an adequate bridging of the fracture site with the device to thus create stability could be virtually impossible. Additionally, if the device is not length stable, comminuted fractures can potentially result in loss of clavicle length.

3. Classification of clavicle fractures

Various classification systems for fractures of the clavicle have been described including the Allman, Neer and Craig classifications [1]. Allman based his classification of clavicle fractures solely on the anatomical location of the fracture. He thus classified fractures as occurring in the medial third, the middle third, and the lateral third [18]. Neer subclassified fractures occurring in the lateral third of the clavicle and Craig further subclassified fractures of the lateral and medial third [1]. The Edinburgh (Robinson) classification system describes clavicle shaft fractures in accordance with their displacement and degree of comminution [4]. O'Neill *et al*. have shown that the Robinson classification has the greatest prognostic value for clavicle shaft fractures whilst Craig's classification holds the greatest prognostic value for distal third fractures [19]. The AO/OTA classification scheme has been expanded to include

the clavicle. The clavicle is segment 15 and it is divided into metaphyseal, diaphyseal, and lateral metaphyseal fractures. Currently, no classification system exists which guides the surgeon or offers options as to specific implant choices in the treatment of fractures. No help is thus afforded in distinguishing between fractures which should be managed surgically or those which should be treated non-surgically.

4. Treatment of clavicle shaft fractures

Various treatment modalities, including both operative and non-operative options, exist for dealing with clavicle shaft fractures. However, the optimal treatment for displaced clavicle shaft fractures remains a widely debated and controversial topic [1]. Historically, clavicle shaft fractures were thought to be benign fractures and were treated non-surgically [20,21]. However, a landmark study by McKee *et al*. challenged this belief [22].

A growing number of recent studies have indicated significantly higher complication rates in certain fracture types when these are treated conservatively with a sling or figure-of-eight bandage [22,23]. Non-randomized, non-comparative, pooled data across all studies which compare conservative treatment with plating of clavicle shaft fractures have shown a nonunion rate of 2.5% in the operatively treated fractures compared to a nonunion rate of 5.9% in the conservatively treated group [24]. When the displaced group of fractures is viewed in isolation, the nonunion rate increases to 15.1% [24]. In 1997, Hill *et al*., in a retrospective study of 52 non-operatively treated clavicle shaft fractures, demonstrated that displaced fractures with initial shortening of >20 mm were associated with a higher risk of nonunion and poor clinical outcomes [23]. McKee's landmark study was the first to indicate inferior outcomes in non-operatively treated fractures in 132 displaced middle-third clavicle fractures when compared to non-operative treatment with primary plate fixation [22]. McKee *et al*. showed superior functional outcomes, lower rates of malunion and nonunion and a shorter time to union in the plating group [22].

Eskola *et al*. demonstrated that malunion of a middle-third clavicle fracture with shortening of the clavicle may alter the position of the glenoid fossa which, in turn, may affect glenohumeral mobility and scapular rotation leading to unsatisfactory results and loss of function [25]. Lazarides and Zafiropoulos investigated 132 patients with united fractures of the clavicle shaft after they had received conservative treatment [26]. In their study, 25.8% of the patients were dissatisfied with their treatment result. Final clavicle shortening of more than 18 mm in males and 14 mm in females was associated with these unsatisfactory outcomes.

Operative treatment of displaced clavicle shaft fractures is associated with significantly improved Constant Shoulder and DASH scores when compared to fractures which were treated conservatively [22].

It is widely accepted in the literature that un-displaced or minimally displaced clavicle shaft fractures can, and should be treated conservatively, either in a sling or figure-of-eight bandage [1,27,28]. No difference was noted in the outcomes of patients treated with a sling or figure-of-eight bandage. The figure-of-eight bandage, however, is difficult to apply and causes more complications [29,30].

To further exacerbate the situation, recent reviews are once again questioning whether the operative treatment of displaced clavicle shaft fractures does, in fact, lead to better results. A 2018 Cochrane review [31] concluded that only low-quality evidence exists to prove that surgical treatment holds additional benefits in terms of function, pain, and quality of life when compared to conservative treatment. In terms of adverse outcomes, they could not ascertain any differences between the two treatment options. The reviewers suggest that treatment should be individualized and patient specific to thus better balance the risks of non-operative treatment (symptomatic malunion and shoulder stiffness) with the risks of operative treatment (wound infection, wound dehiscence and hardware irritation) [31]. In a retrospective study, Napora *et al*. found complications and/or poor outcomes rate of 30% in both, patients with displaced fractures who were treated conservatively or who were treated surgically [32]. In a meta-analysis, Woltz *et al*. found that plate fixation does reduce the risk of nonunion but does not, however, provide clinically relevant better outcomes when compared to conservative treatment [33]. Additionally, secondary operations were found to be common in both groups. They concluded that literature does not support routine operative treatment by plating for all patients with displaced clavicle shaft fractures [33]. In a prospective randomized controlled trial of 160 patients, the same authors [33] discovered that operative treatment with plating significantly reduced nonunion rates, but that secondary operations were common in both groups. The functional outcomes of the two groups were similar. Robinson *et al*. noted a reduced rate of nonunion in operatively treated fractures in addition to better functional results [4]. They, however, proposed that operative treatment is more expensive and yields a higher rate of implant-related complications. They concluded that routine operative treatment of displaced clavicle shaft fractures, by extramedullary plate fixation, is unsupported [4].

The operative versus non-operative treatment of clavicle shaft fractures remains a controversial issue [34]. A recent, high-quality prospective randomized trial found that surgical treatment, using a plate and screw construct, yielded better functional and radiological outcomes, with minimal complications, when compared to conservative management [35]. Patel *et al*. also concluded that surgical treatment yields superior results [36]. A very recent current concepts review by Hoogervorst *et al*. concluded that the choice of optimal treatment strategy is not clear-cut [37]. They found that operative treatment leads to improved short-term functional results, increased patient satisfaction, earlier return to sport activities and lower rates of nonunion. They also concluded surgical treatment to be more cost effective. However, they noted that operative treatment yielded more complications and higher re-operation rates. They found the long-term shoulder function of the two groups to be similar. Their final

conclusion was that a shared decision-making model should be used to tailor-make an optimal treatment strategy in accordance with the patient's specific needs and expectations [37]. This seems to be the common thread in most of the recent literature.

4.1. Indications for operative treatment

Indications for surgical treatment of clavicle shaft fractures can be divided into absolute and relative indications [38]. Absolute indications include: open fractures, overlying skin compromise, neurological deficit or associated vascular injury [27,38]. Relative indications include polytraumatized patients, painful malunions and nonunions as well as a floating shoulder. Relative indications have also been expanded to include fractures with 15–20 mm of shortening, complete displacement and comminution [38]. As suggested by Zenni *et al*., these indications have been expanded to include patients who cannot tolerate prolonged immobilization of the upper limb, for example, patients suffering from Parkinson's disease and neuromuscular disorders [27].

4.1.1. Treatment options

Operative treatment options consist of external fixation and internal fixation. External fixation can be achieved through monoplaner devices or ring fixators. Internal fixation comprises open reduction and internal fixation using locked or non-locked plates. Alternatively, open or closed reduction with internal fixation using intramedullary rods, wires or nails, can be used [1,24].

4.1.2. External fixation

Numerous papers describe the external fixation of displaced clavicle fractures [39,40]. Each of these has shown fairly good results, comparable to plate fixation, and superior to non-operative treatment. In cases of soft-tissue compromise, this technique has yielded good results [41]. However, the technique is rarely used as it holds significant drawbacks including prominent bulky hardware and pin tract problems.

4.1.3. Plate fixation

Plate fixation has predictable union and low complication rates and allows for early mobilization of the shoulder [1,38]. Anatomically contoured locked plates are currently the most widely used mode of treatment. The superior approach, in which the plate is placed superiorly, is most commonly adopted [1]. This plate position has also been shown to be biomechanically superior. Neurovascular structures, however, are at greater risk during drilling and the plate is more prominent under the skin [42]. An alternative is the anterior-inferior approach which makes use of appropriately shaped plates. Biomechanical studies have shown that when mono-cortical screw fixation is used there is no difference between the load to failure of locked and non-locked plates [43,44]. When bicortical screws are used, both constructs have significantly improved loads to failure [43]. A percutaneous plating technique, as described by Lee *et al*., has yielded good results [45] with theoretical advantages including less surgical dissection, smaller scars and quicker recovery following surgery [45].

4.1.4. Intramedullary fixation

Intramedullary (IM) fixation presents an alternative to plate fixation for clavicle shaft fractures. This procedure includes the potential advantages of a smaller incision, less soft-tissue disruption, and less prominent implants. Numerous intramedullary fixation devices for the treatment of middle-third clavicle fractures are available on the market and commonly used [1,46] These devices include Knowles pins, Hagie pins, Rockwood pins, and minimally invasive titanium nails [38,47]. Techniques include antegrade insertion through an entry point on the anteromedial surface of the clavicle or through a postero-lateral entry point in the lateral fragment. In the majority of cases, both these techniques necessitate the opening of the fracture site to reduce the fracture. Intramedullary fixation of displaced clavicle shaft fractures is associated with a significantly reduced nonunion rate when compared to conservative treatment [24]. Thyagarajan [33] recommended intramedullary fixation of displaced middle-third clavicle fractures over plating and conservative treatment. He reported no nonunions, scar-related complications nor prominent hardware in the nailing group.

Previously, intramedullary fixation devices could not be reliably locked and thus axial rotation and length were difficult to control when these devices were used [48,49]. Smaller incision sizes and less periosteal stripping are potential positive outcomes in fixating clavicle fractures as the clavicle has a periosteal blood supply. Less soft tissue dissection would potentially preserve blood supply and enhance healing whilst smaller incision sizes would potentially preserve the supraclavicular nerves, thus avoiding loss of sensation of the anterior chest wall. It would be expected that since the device is positioned in the medullary canal there would be no problematic superior subcutaneous hardware as often observed with plate fixation [46]. However, some implants have prominent hardware protruding from the lateral entry point (Knowles, Rockwood, Hagie pin and TEN nails) [46].

Biomechanical studies have shown that the risk of refracture following removal of the intramedullary device is smaller than after plate fixation. The plate-fixated clavicles were predictably vulnerable to fracture through the vacant screw hole after removal of the plate and screws [50]. Removal of the plate following successful union is an invasive procedure with known complications [51].

4.1.5. Kirschner wire fixation

K-wire fixation of clavicle shaft fractures was first described in 1940. Recent studies still report good outcomes with the use of this technique. Bokata described good results using a two-wire technique and found this technique to be safe [52]. Coppa *et al*. reported that intramedullary fixation using K-wires had superior outcomes when compared to conservative management and found the procedure to be safe [53,54]. A recent meta-analysis found less revision and hardware-related complications following K-wire fixation than in the

case of plate fixation. However, inferior functional post-operative results after K-wire fixation were noted [55]. Rollo *et al*. reported on patients developing symptomatic nonunions after open or closed reduction and K-wire fixation. A proportion of these patients had septic nonunions [54]. Concerns regarding the migration of the wires exist. Case reports have been published which describe the intrathoracic, aortic and even spinal cord migration of wires [56,57].

4.1.6. Clavicle pins (Hagie and Rockwood pins)

Hagie and Rockwood pins are nearly identical devices and, as such, are commonly confused. Both devices are made from solid stainless-steel with a terminal-threaded end to obtain bone purchase. Both devices have two locking nuts, one to provide compression over the fracture and the other to keep the compression nut in place. They also differ as to the position of the trochar point. The Rockwood pin can be placed from either the medial or the lateral end of the fracture whilst the Hagie pin can only be placed from the lateral end. To place the device the fracture site is opened, and the medial and lateral medullary canals prepared. The device can then be inserted via an anteromedial approach, close to the sternoclavicular joint, or via a lateral approach, close to the acromioclavicular joint. The fracture is held in the reduced position whilst the pin is advanced over the fracture. The lateral end of the pin is then cut under the skin. Both these devices need to be removed after fracture union.

Some studies have described good results in using both these devices, but more recent reviews have noted high complication rates. Payne *et al*. reported a union rate of 97%, but a complication rate of more than 80% [58]. The main complication noted was painful hardware at the lateral end, but loss of shoulder range of movement, infections, and hardware failure were also reported [58]. Millett *et al*. reported a union rate of over 90% using Hagie pins and a lower complication rate of 25% [59]. However, painful lateral hardware was once again noted as the most common complication. Judd *et al*. reported a higher union rate using the Hagie pin in a study which compared Hagie pin fixation to non-operative treatment [60]. The complication rate was, however, higher in the Hagie pin group and no difference in functional outcome was noted between the two groups at 12 months follow-up. In smaller studies, Mudd and Strauss found unacceptably high complication rates and warned against the use of these devices [61,62]. In a recent literature review, Eichinger *et al*. concluded that the complication rate when using these devices is unacceptably high and that alternative fixation devices should be used [46].

4.1.7. Titanium elastic nail (TEN) fixation

Titanium elastic nail fixation was first described in 2003 by Jubel [47]. The technique is fairly simple, and the device can be passed over the fracture in an open or closed technique. An anterograde or retrograde technique can be used. The nails are often removed after fracture union due to prominent subcutaneous hardware at the entry point. Jubel reported a very high union rate and relatively low complication rate [47]. In two randomized controlled trials, the complication rate was noted as much higher [63,64], although excellent union rates were achieved. Similar results were recorded in the van der Meijden study with patients treated by TEN and plating. In the van der Meijden study, the complication rate was inflated as the second surgery to remove the implant was noted as a complication. This procedure generally regarded as routine when using a titanium elastic nail [64].

4.1.8. Intramedullary screw fixation

Solid or cannulated intramedullary screws have been described in a few studies detailing the treatment of clavicle shaft fractures. Good results were reported in these studies with high union and relatively low complication rates. The screws can be placed from medial or lateral. In the case of a medial approach, the screw head is prominent medially under the skin and the device needs to be removed following union. Khalil *et al*. showed a union rate of 100% and found the technique to be both simple and affordable [65]. In other studies, where a lateral to medial screw trajectory was used, the problem of prominent subcutaneous hardware was avoided [66, 67]. No hardware had to be removed and excellent union rates were recorded [68]. The same anatomical problems associated with the use of Hagie or Rockwood pins would presumably apply to intramedullary screws. A rigid straight implant is placed over the fracture in a bone with an s-shaped curve in the axial plane as well as a curvature in the coronal plane. As described previously [17], in certain cases the accurate placing of the device, with solid fixation over the fracture site, has proved problematic.

4.1.9. Flexible locked nail

An alternative device, which attempts to address the biomechanical challenges presented by traditional devices, namely, lack of rotational and length stability, has recently become available. The Sonoma CRx^{TM} device consists of a solid straight hub, a flexible tubular medial section and an internal fixation system [66]. The device is inserted into the medullary canal following the reduction of the fracture. The medial flexible portion of the device follows the axial and coronal curvature of the clavicle. Once properly seated in the medullary canal, and accurate fracture reduction has been achieved, the internal assembly is activated. Upon activation, the flexible section transforms into a rigid nail and grippers at the medial end are deployed. The grippers lock the medial end of the device providing rotational and axial stability. Laterally the device is locked with an interlocking screw [67]. In a prospective study comparing the device to minimally invasive plating, similar functional outcomes were observed between the two groups. However, a shorter time to union in the nailing group was noted. King *et al*. conducted a randomized controlled trial in which anatomical contoured locked plating was compared to the Sonoma intramedullary nail [66]. This study reported that the Sonoma nail was at least equally as effective as the anatomical contour plate, while Cohen effect sizes favored the Sonoma nail above the anatomical contour plate [66]. In this study, hardware failure was experienced in one case in the

nailing group and in one case in the plating group [66]. This low rate of hardware failure is contradictory to results obtained in other studies using the device where high rates of hardware failure were reported [69,70]. Similarly, Calbiyik *et al*. made no reference to hardware failures in a paper describing their initial experience with the device [71]. King *et al*. described the surgical technique which should be used to insert this device in order to avoid hardware failure [66].

4.2. Intramedullary versus extramedullary fixation of clavicle fractures

4.2.1. Functional outcome and union rate

A systematic review and meta-analyses comparing intramedullary and extramedullary fixation found no statistically significant difference between the two treatment modalities regarding union rate and functional outcome [72,73]. Retrospective and prospective studies comparing intra- and extramedullary fixation have presented similar outcomes where union rates and functional outcomes have been compared [74,75]. Ferran *et al*. compared plating of displaced middle-third clavicle fractures to intramedullary fixation using a Rockwood pin and noted no difference between the union rate, Constant Shoulder score or the Oxford Shoulder score of these two groups [76]. However, in this study, all the Rockwood pins and 53% of the plates had to be removed due to infection or soft tissue irritation [76]. In a meta-analysis and systematic review, prominent hardware in the plating group resulted in complications in most cases [72,73]. A recent meta-analysis noted an increase in reoperation and refracture rates after the removal of plates, post-extramedullary fixation, but no difference in union rate or functional outcome was evident [72]. Two very recent meta-analyses ascertained that intramedullary fixation might be the treatment modality of choice, citing the high reoperation rate due to prominent subcutaneous hardware in the plating group as reason for this conclusion [77,78]. A recent Cochrane review declined to recommend one specific fixation technique suitable for midshaft clavicle fractures, citing the inadequacy of available evidence [79].

4.2.2. Secondary operations following union of the fracture

A very high proportion of fractures treated with plate fixation requires a second operation to remove the plate. This procedure has to be done through the original skin incision and results in additional scarring and soft tissue compromise. The second surgery also increases the risk of supraclavicular nerve injury leading to reduced patient satisfaction [51]. When intramedullary devices and plates are removed, following union of the fracture, these clavicles have a higher load to failure which, in turn, decreases the risk of a fracture shortly after removal of said fixation device [50]. Houwert *et al*. also noted higher refracture rates following hardware removal in plated clavicles when compared to those treated with intramedullary fixation [72]. Intramedullary nailing of the clavicle employs a percutaneous operative technique which results in minimal periosteal stripping and no bone/plate compression interface; thus, the periosteal blood supply is preserved promoting union [38,74]. Fixation of the fracture can be achieved through a much smaller wound than that needed to accommodate fixation using a plate and screws [28,38,74,79,80,81].

4.2.3. Complications

Millett *et al*. noted a major complication rate (nonunion, malunion, and infection) of 8.6% when using intramedullary fixation. In addition, they ascertained that superficial skin infections and skin erosions were present in 15% of cases [59]. Multiple case reviews have described migration of nonlocked intramedullary fixation devices into the lungs or other structures in the thorax [57]. Wijdicks *et al*. noted that intramedullary fixation yielded a lower post-operative complication rate when compared to patients treated by plating [82]. Early nail failure when using the Sonoma CRx intramedullary device has been described [66,69]. Early failure is commonly associated with incorrect placement of the device during initial fixation of the fracture [66]. A recent meta-analysis found a lower complication rate in terms of refracture rate, prominent hardware, and reoperation rates in patients treated with intramedullary fixation [83]. Prominent subcutaneous hardware at the lateral entry point remains problematic with traditional implants as this procedure requires routine removal of implants once fracture union has been achieved [56].

4.2.4. Financial considerations

Currently, there is no literature available which compares the cost-effectiveness of intra- and extramedullary fixation of clavicle shaft fractures. Some intramedullary devices, such as TEN nails, are fairly inexpensive, but a routine operation is required to remove the hardware and this adds to the per case costs. Extramedullary devices vary in costs depending on whether the device is anatomically contoured and whether locking screws are employed. Yet again, a second procedure to remove the prominent subcutaneous hardware is frequently required. As the patient needs time away from work to recover, this procedure exerts further financial strain. High-quality research is necessary to thus assess the most cost-effective modality of treatment. This research should take into consideration the cost of each device, surgical time needed to implant the device and the need for a second procedure to remove the device.

5. Expert opinion

Historically, clavicle shaft fractures were considered benign injuries and good results were reported with conservative treatment. Modern studies, which focus on functional outcomes and patient satisfaction, propose a more aggressive approach to the treatment of displaced and shortened fractures. The topic remains controversial with numerous systematic reviews and meta-analyses reaching conflicting conclusions. The literature seems to have come full circle. At one stage the available evidence seemed to clearly indicate that displaced and shortened clavicle shaft fractures should be

treated surgically. However, some recent reviews seem to be challenging this belief. Current consensus seems to hold that each patient should be individualized in terms of fracture configuration and functional demand.

What has become clear is that clavicle shaft fractures constitute complex injuries. It is thus unlikely that a single set of surgical indications could, or should, provide a definitive blueprint for treatment. The risks associated with operative fixation versus the risk of complications secondary to mal- and nonunion should be carefully weighed. In addition, the patient's age and functional demand should be taken into consideration.

Prospective, randomized multi-center studies which differentiate between patients' unique functional demands, levels of physical activity, and occupation are needed. Conclusions drawn from treatment studies could possibly be strengthened by studies describing the functional and cosmetic disabilities of patients who have been treated conservatively and who consequently developed nonunions and malunions. Prospectively gathered data, which describe the functional and cosmetic disabilities suffered by individuals with displaced and shortened fractures developing non- and malunions, need to be analyzed in well-structured trials. The effect of the anatomical deformity of the shoulder girdle due to shortening of the clavicle needs to be assessed innovatively. Yet again, one needs to distinguish between physically active, young individuals, and more sedentary elderly individuals.

It remains unclear which operative treatment modality is considered most effective. Recent high-quality research studies maintain that there is no difference in outcomes between intra- and extramedullary fixation. The literature clearly addresses the unsuitability of K-wire and external fixation. The remaining modalities show similar effective outcomes with various positive and negative aspects associated with each.

As both extra- and intramedullary devices are effective in treating displaced and shortened clavicle shaft fractures, future research studies should focus on determining patient and fracture variables which could guide the choice of a specific treatment modality and thus facilitate superior outcomes. Patient factors would include: age, expectations regarding cosmetic result, speed of return to normal activity, occupation and functional demands. Fracture variables, including the specific position of the fracture within the clavicle shaft as well as fracture comminution, should be studied to determine whether they play a role in determining outcomes, when different fixation devices are compared.

Limited research has been conducted regarding the effectiveness of the new and novel concept nails, such as Sonoma CRx device. Although early results of these types of nails are encouraging, there remains a dearth of long-term reviews and studies comparing this device to the current gold standard of treatment – extramedullary anatomically contoured locked plate fixation. The surgical wound, when implanting an intramedullary nail, is generally smaller than the wound when implanting an anatomically contoured plate. The smaller surgical wound would likely improve cosmetic results. Similarly, the absence of prominent subcutaneous hardware when using an intramedullary device may also positively impact cosmetic results.

A high rate of secondary operations to remove hardware is commonly described in studies where both intra- and extramedullary treatment modalities are used. In the case of intramedullary devices, reasons for device removal include prominent subcutaneous hardware at the insertion site and the risk of hardware migration. Neither of these complications is encountered when using the Sonoma device. The use of the Sonoma device could thus potentially negate the need for a second operation. Surgical time is expensive and limited in resource constrained environments. In the context of such settings, a second operation to remove prominent hardware is considered a non-feasible luxury. As valuable theater time must be utilized with great discretion, intramedullary fixation using the Sonoma device may hold the positive aspect of negating a second operation.

In conclusion, literature shows that both anatomical contoured locked plating and intramedullary nail fixation can be used effectively to treat displaced and shortened clavicle shaft fractures. Use of the intramedullary nails is beneficial in that it yields better cosmetic results and, as secondary operations to remove hardware are mitigated, makes economic sense.

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