https://doi.org/10.1016/j.injury.2016.06.004

Finite element analysis of locking plate and two types of intramedullary nails for treating mid-shaft clavicle fractures

Ming Ni[a,b,†] , Wenxin Niu[c,†], Duo Wai-Chi Wong[d], Wei Zeng[e,f], Jiong Mei[a,*], Ming Zhang[d]

a Tongji Hospital, Tongji University School of Medicine, Shanghai, China

b Pudong New Area People's Hospital, Shanghai, 201299 China

c Yangzhi Rehabilitation Hospital, Tongji University School of Medicine, Shanghai, China

d Interdisciplinary Division of Biomedical Engineering, The Hong Kong Polytechnic University, Hong Kong SAR, China

e CEAS-Biomedical Engineering (BME), University of Cincinnati, 2901 Woodside Dr., Cincinnati, OH 45221, USA

f CEAS-School of Aerospace Systems, University of Cincinnati, 2851 Woodside Dr., Cincinnati, OH 45221, USA

† These authors contributed equally

*Corresponding Author

Jiong Mei

Department of Orthopaedics, Tongji Hospital, Tongji University School of Medicine, Shanghai, China

Tel: +86,139,0187,0631

Email: meijiong@163.com

The manuscript, including the related data, figures and tables has not been previously published and the manuscript is not under consideration elsewhere.

The manuscript has been read and approved by all authors, and each author believes that the manuscript represents honest work.

ABSTRACT

Background: Both plate and intramedullary nail fixations, including straight and anatomic nails, have been clinically adopted for the treatment of displaced mid-shaft clavicle fractures. However, the biomechanical performances of these fixations and implants have not been well evaluated. This study aims to compare the construct stability, stress distribution and fracture micro-motion of three fixations based on finite element (FE) method.

Methods: The FE model of clavicle was reconstructed from CT images of a male volunteer. A mid-shaft fracture gap was created in the intact clavicle. Three fixation styles were simulated including locking plate (LP), anatomic intramedullary nail (CRx), and straight intramedullary nail (RCP). Two loading scenarios (100-N compression and 100-N bending) were applied at the distal end of the clavicle to simulate arm abduction, while the sternal end was fixed.

Results: Under both conditions, the LP was the stiffest, followed by the CRx, and the RCP was the weakest. LP also displayed a more evenly stress distribution for both implant and bone. RCP had a higher stress compared with CRx in both conditions. Moreover, all implants sustained higher stress level under the loading condition of bending than compression.

Conclusions: The plate fixation significantly stabilizes the fracture gap, reduces the implant stress, and serves as the recommended fixation for the mid-shaft clavicle fracture. The CRx is a good alternative device to treat clavicle shaft fracture, but the shoulder excessive activities should be avoided after operation.

Key Words: Biomechanics; Clavicle fracture; Internal fixation; Plate; Intramedullary nailing; Finite element simulation

Level of evidence: III, Case-control study, Treatment Study.

Introduction

Clavicle fractures accounts for around 4% of all fractures and approximately 80% of clavicle fractures occurs at the mid-shaft [1,2]. Clavicle fractures can be caused by falls from substantial height, traffic accidents, or sport injuries [3]. The primary treatment objective is to facilitate reduction of fracture and provide adequate fixation, preferably minimally invasive. Traditionally, non-operative management has been recommended to treat mid-shaft clavicle fracture, regardless of the degree of fracture displacement [4]. However, there is growing awareness that the outcome of conservative treatment is not as satisfactory as expected [5]. Complications (e.g., delayed union, nonunion) and shoulder pain and weakness, were discovered and reported at a high rate with non-operative management [6,7].

Surgical management of middle-shaft clavicle fractures involves various techniques. Plate fixation is considered the gold standard for clavicle fracture since it can provide sufficient reduction and stabilization [8]. However, plate fixation requires a larger exposure and significant soft tissue stripping, which may compromise the blood supply to the clavicle and interfere with bone healing. Intramedullary fixation is another option, which can be accomplished with less soft tissue dissection and more cosmetic incisions. A variety of pin fixation devices, such as Steinman pin, Hagie pin, Rockwood clavicle pins (RCP), and elastic titanium nails， have been utilized so far. However, few of them can provide sufficient stability under physiologic conditions [9]. This could possibly lead to some complications, such as migration of device and soft-tissue irritation due to protruding hardware at the insertion site.

In response to drawbacks with RCP, a new intramedullary device, Sonoma CRx has recently been introduced [10]. It has a flexible shaft allowing itself to accommodate the curvature of the clavicle. The flexible shaft can be activated to become rigid once fracture reduction is completed. The grippers and interlocking screw at two ends can provide additional rotational and axial stability. The device asserted to stabilize the fracture site and control rotation efficiently, thereby reduce the risk of subsequent complications [11]. However, its biomechanical stability has not been extensively investigated, particularly in comparison with traditional intramedullary pins and plate fixation.

Sometimes it is difficult and/or infeasible to assess biomechanical stability of an implant or surgical protocols by means of clinical investigations and cadaveric studies. Finite element (FE) method, as a powerful computational tool, has gained wide acceptance in orthopedics research. FE method is able to quantitatively study the stress distribution of the inner and complex bone structures, adaptation of bone after damage, and optimal design of orthopedic implants [12-14]. In addition, FE analysis allows the control of condition parameters, such as loading forces, fracture type, and fixation implants to better predict the surgical outcomes than experiments using cadaveric specimens.

The purpose of this study includes: 1) to compare the biomechanics of the plate, CRx, and RCP fixation; and 2) to investigate the sensitivity of implant geometry and position on fracture stability by FE method. Construct stiffness, implant stress, and fracture micro-motion would be evaluated. We hypothesized that plate fixation would provide better stabilization, reduce implant stress, and may be potentially suitable for the treatment of mid-shaft clavicle fractures.

Material and methods

Finite Element Modeling

The serial CT images of the clavicle were acquired from a male volunteer (age: 45 years; weight: 60 kg; and height: 176 cm). The slice thickness of the CT images was 0.75 mm in a 512×512 matrix. The DICOM data were imported into Mimics 15.0 software (Materialise, Belgium) to reconstruct the geometry of the clavicle. A threshold of 600 Hounsfield units was used to differentiate between cortical and cancellous bone [15].

Three types of fixation/implants were modeled and simulated: Locking Plate (LP), Sonoma intramedullary nail (CRx) and Rockwood clavicle pin (RCP). The three dimensional models of plate and intramedullary nails were drawn according to the manufacturers' specifications using software Solidworks 2014 (Dassault Systemes Solid-works Corp., USA). The locking plate was modeled from a 3.5-mm plate (Trauson, China) and the screws were modeled as 3.5-mm diameter solid cylinders. The intramedullary implants include CRx (Sonoma Orthopedic Products Inc, Santa Rosa, CA, USA), and RCP (DePuy, Warsaw, Indianan). The CRx was 120-mm long with a distal transverse locking screw on a shaft curved distally at 4.2-mm diameter. The RCP was 4.5 mm in diameter and 110 mm in length.

To simulate clavicle fracture, a transverse gap of 0.5 mm was created on the mid-shaft of the clavicle. The implants were then positioned across the gap. For the LP fixation, the plate was positioned on the superior surface of the clavicle according to recommended surgical guidelines (**Figure 1a)**. The CRx and RCP were positioned as recommended by the manufacturers as demonstrated in **Figure 1b and Figure 1c**.

The models were processed by Geomagic Studio 10.01 (3D System Inc., Rock Hill, SC, USA) and then, were input to the FE software ABAQUS 6.14 (Dassault Systems, Simulia Corp., RI, USA), through which the models were assembled and meshed with four-node tetrahedral three-dimensional elements (C3D4). A mesh convergence test was conducted so that the deviation was less than 2 %.

In this study, the mechanical properties of clavicle and implants were adopted from previous published reports [16,17] (Table 1). All contact pairs were assigned with 0.3 coefficient of friction [18], except that the bone-implant interfaces were tied.

Boundary and loading conditions

Two types of boundary and loading conditions (compression and pure bending) were used based on Favre et al.'s study [19]. Both conditions applied a total force of 100N at the distal part of the clavicle [20,21] as illustrated in **Figure 2**. The sternal end of the clavicle was fixed in all degrees of freedom.

Analysis and Validation

The FE analysis was conducted using ABAQUS 6.14. The construct stiffness was defined by the ratio of applied load to the displacement of the distal clavicle at the load direction [17]. The fracture micro-motion was calculated according to the change of fracture gaps after load-bearing. The Von Mises stresses of the clavicle and implants were also analyzed.

To validate our FE models, the bending stiffness of LP and RCP fixation was normalized to the stiffness of the intact clavicle and then compared to a cadaveric study [22]. In their study, ten fresh-frozen clavicle fractures were randomly fixed by 3.5 mm locking plate, and 4.5mm RCP.

Results

Model Validation

Figure 3 showed the comparison of our predictions with the reported data [22]. The results of bending stiffness in our FE model were agreeable with the existing findings. Both results showed similar trends, but with less than 7% differences among different constructs. This may due to the variations in specimen anatomy and bone quality.

Construct Stiffness

Figure 4 showed the bending and axial normalized stiffness for different constructs. For the intact clavicle, the bending stiffness was about 25% lower than that of the Plate construct. However, the axial stiffness of the intact clavicle was 42% higher than that of the LP constructs. Under both loading condition, the LP construct significantly provided the highest stiffness, followed by the CRx, and the RCP construct was the weakest. The results indicated that fixation style played an important role in the construct stiffness and the LP was more stable than intramedullary fixation for the mid-shaft clavicle fractures.

Stress Distribution

The von Mises stress distributions of the intact and fracture models were shown in **Table 2.** For the intact clavicle, the peak stresses and the concentration at the medial side of clavicle were in agreement with previous reports [16,19]. The peak stresses of the clavicle were 62.77 MPa in the cantilever bending and 10.16 MPa in the axial compression. In both loading modes, the three reconstructions led to higher stresses in bone than intact clavicle. For the cantilever loading, the LP fixation showed lower bone stress (80.76 MPa) than that of the CRx (124.7 MPa) and the RCP (151.4 MPa). For the axial loading, the stress values of the bone were 16.13 MPa, 14.64 MPa, and 17.54 MPa for the LP, CRx, and RCP fixation, respectively.

The stress distributions of the three implants were illustrated in **Table 2**. In both loading conditions, the maximum stresses of all implants consistently occurred around the fracture sites. For the cantilever loading, the stress value of the LP construct was 390.24 MPa, lower than those of the CRx (872.45 MPa) and RCP (1017.91 MPa) construct (**Figure 5**). For the axial loading, the stress of the LP construct was 250.79 MPa, higher than those of the CRx (97 MPa) and RCP (78.02 MPa) construct **(Figure 6)**, respectively.

Fracture Micro-motion

Table 2 shows the micro-motion plot for the clavicle fracture. For the case of bending, the smallest micro-motion was observed in the LP construct (0.25 mm) as compared to the CRx (0.28 mm) and RCP (0.42 mm). The micro-motion was lower during the axial compression. The RCP generated greater micro-motion than the CRx and LP fixations.

Discussion

It is valuable for surgeons to evaluate the biomechanical performance of implants since it can assist to improve the treatment result of displaced clavicle fracture. In this study, a FE model of the mid-shaft clavicle fracture was created for simulation of three fixation styles, followed by comparison with an existing *in vitro* experiment. The three fixation styles, i.e., LP, CRx and RCP, demonstrated large differences on the construct stiffness and stress distributions under compression and bending conditions. This study suggested that plate fixation (LP) could provide better biomechanical performance compared to the intramedullary nails (CRx and RCP) for clavicle fracture.

Boundary and loading conditions affect the accuracy and internal validity of FE predictions. However, the physiological and biomechanical environment of the clavicle remains poorly understood until now. This is probably due to the structural complexity, such as the complex attachment of multiple ligaments and muscles, which makes the measurement of muscle forces nearly impossible. Nonetheless, as the major supporting structure for the shoulder, the clavicle experiences two special loading modes: bending and compressive loads [23]. Iannolo et al [20] measured clavicle forces in cadavers through a load cell mounted to the middle third of the clavicle. Larger force occurred in the clavicle during humeral abduction and the peak compressive and bending force was 34.4 N and 9.8N, respectively. Scepi et al [21] constructed a digital model of the human shoulder to calculate the muscle forces involved in the abduction of arm. The maximum force acting on the clavicle was 100N, which approximated arm abduction as suggested by other literature [24]. In our study, the boundary conditions were defined to replicate arm abduction, and thereby the load magnitude was set as 100 N.

In the viewpoint of biomechanics, the structures of LP and CRx, RCP predominantly provide support in lateral and axial directions respectively. For construct stability, the LP fixation exhibited the highest stiffness and the least micro-motion. These findings were similar to that of Zeng et al [16], who found that plate fixation was significantly stronger than intramedullary nail. The predicted stresses in this study also demonstrated that the LP fixation was less likely to fail under bending since it was exposed to a lower stress level. However, LP fixation was vulnerable under pure compression. The structure and position of the implants would determine the amount of support to the fracture site at different loading modes. Nevertheless, it was worth noting that stress of the LP was concentrated adjacent to the fracture gap in both loading modes, which suggested that the site is prone to failure during shoulder abduction. Clinically, majority of implant also failed at this site [25]. Clavicle plate with a stronger bridging section may reduce the risk of implant failure.

The CRx device has been recently introduced and preliminary clinical outcomes have been satisfactory [10,11]. However, some studies showed a relatively high complication rate about CRx, especially when the shoulder was loaded excessively or reinjured after operation [26]. Most implants failed at the junction between the rigid and flexible portion of the implant [26]. This observation was consistent with our results. According to the FE calculation, the maximum von Mises stress was concentrated adjacent to the fracture site, which is close to the yield stress of stainless steel (750-950 MPa) [27]. Additionally, considering that fatigue failure generally occurred at a stress level well below the yield stress of material, the stress values indicated that the CRx might have a substantial risk of fatigue failure. This suggested that shoulder excessive activities should be avoided after operation.

The RCP is modified from the Hagie pin and introduced in 1975. The RCP intended to provide a less invasive alternative to plate fixation. However, the incidence of complications of RCP was relatively higher, including nonunion, revision surgery, and soft tissue complications [28]. The high complications may be related to the inherent weak biomechanical stability of the RCP.

Renfree [29] et al conducted a biomechanical study with synthetic bones comparing the plate against the RCP. The results demonstrated the RCP was unable to resist small torque and less stiff than the plate fixation. In this study, the RCP also presented a lower stiffness than CRx. This can be attributed to the geometry and positioning of the RCP. The RCP was not accommodative to the curvature of the clavicle. Moreover, it was suggested that the RCP implant would be more sensitive to external force since it was positioned laterally [21]. During bending, the RCP and the lateral clavicle constitute a bending-resisting mechanism to stabilize the fracture, making them highly stressed. The peak stress was up to 1018 MPa and beyond the yield stress of stainless; indicating the use of RCP may result in implant failure.

The fracture micro-motion depended on a greater extent of the fixation types. In this analysis, the clavicle fracture with a small gap was simulated. It was reported that the fracture micro-motion plays an important role in bone healing process [30]. Several studies have demonstrated that micro-movement between 0.15 mm and 0.4 mm can assist in the healing of a fracture gap no more than 3 mm [31]. In our analysis, the relative fracture micro-motions were 0.28 mm and 0.25 mm respectively for LP and CRx under normal shoulder activities. This indicated that *in vivo*, bone regeneration was encouraged with an appropriate gap distance.

There are some limitations in this study. Firstly, only axial and bending loads were applied to the clavicle for FE analysis. The clavicle, in reality, is exposed to various forces and moments during the shoulder movement. Secondly, soft tissues and other neighboring structures were not included in the models. Finally, the material properties of the bone were determined according to the average of a population. Despite certain simplifications, the FE prediction was generally agreeable with previous in vitro study [22]. Further biomechanical and clinical studies are recommended to validate these findings and explore novel protocols.

Conclusion

In summary, this study extensively compared the stabilizing mechanisms of three fixation models. According to the FE analysis, the use of plate fixation could significantly stabilize the fracture gap and reduces the implant stress, making it potentially suitable for the treatment of mid-shaft clavicle fractures. Compared with the RCP, the CRx constructs provided more favorable performance. However, the highly stressed mechanical failure is one major concerns of the CRx.

References

1. Duan X, Zhong G, Cen S, Huang F, Xiang Z. Plating versus intramedullary pin or conservative treatment for midshaft fracture of clavicle: a meta-analysis of randomized controlled trials. *J Shoulder Elbow Surg* 2011;20(6):1008-15.
2. Khan LK, Bradnock TJ, Scott C, Robinson CM. Fractures of the clavicle. *J Bone Joint Surg Am* 2009;91(2):447-60.
3. Nowak J, Mallmin H, Larsson S. The aetiology and epidemiology of clavicular fractures: a prospective study during a two-year period in Uppsala, Sweden. *Injury* 2000;31(5):353-8.
4. Vander Have KL, Perdue AM, Caird MS, Farley FA. Operative versus nonoperative treatment of midshaft clavicle fractures in adolescents. *J Pediatr Orthop* 2010;30(4):307-12.
5. Lazarides S, Zafiropoulos G. Conservative treatment of fractures at the middle third of the clavicle: the relevance of shortening and clinical outcome. *J Shoulder Elbow Surg* 2006;15(2):191-4.
6. McKee MD, Wild LM, Schemitsch EH. Midshaft malunions of the clavicle. *J Bone Joint Surg Am* 2003;85(5):790-7.
7. Nordqvist A, Petersson CJ, Redlund-Johnell I. Mid-clavicle fractures in adults: end result study after conservative treatment. *J Orthop Trauma* 1998;12(8):572-6.
8. Zehir S, Zehir R, Şahin E, Çalbıyık M. Comparison of novel intramedullary nailing with mini-invasive plating in surgical fixation of displaced midshaft clavicle fractures. *Arch Orthop Trauma Surg* 2015;135(3):339-44.
9. Boehme D, Curtis RJ Jr, DeHaan JT, Kay SP, Young DC, Rockwood CA Jr. Non-union of fractures of the mid-shaft of the clavicle. Treatment with a modified Hagie intramedullary pin and autogenous bone-grafting. *J Bone Joint Surg Am* 1991;73(8):1219-26.

10. King PR, Ikram A, Lamberts RP. The treatment of clavicular shaft fractures with an innovative locked intramedullary device. *J Shoulder Elbow Surg* 2015;24(1):e1-6.

11. King P, Ikram A. Intramedullary locked fixation of clavicle shaft fractures: review of early results. *SA Orthop J* 2011;10:67-74.

12. Mei J, Liu S, Jia G, Cui X, Jiang C, Ou Y. Finite element analysis of the effect of cannulated screw placement and drilling frequency on femoral neck fracture fixation. *Injury* 2014;45(12):2045-50.

13. Wang Y, Li Z, Zhang M. Biomechanical study of tarsometatarsal joint fusion using finite element analysis. *Med Eng Phys* 2014;36(11):1394-400.

14. Whitlow CT, Yazdani SK, Reedy ML, Kaminsky SE, Berry JL, Morris PP. Investigating sacroplasty: technical considerations and finite element analysis of polymethylmethacrylate infusion into cadaveric sacrum. *A J Neuroradiol* 2007;28(6):1036-41.

15. Tupis TM, Altman GT, Altman DT, Cook HA, Miller MC. Femoral bone strains during antegrade nailing: A comparison of two entry points with identical nails using finite element analysis. *Clin Biomech (Bristol, Avon)* 2012;27(4):354-9.

16. Zeng L, Wei H, Liu Y, Zhang W, Pan Y, Zhang W, et al. Titanium Elastic Nail (TEN) versus Reconstruction Plate Repair of Midshaft Clavicular Fractures: A Finite Element Study. *PLoS One* 2015;10(5):e0126131.

17. Chen SH, Chiang MC, Hung CH, Lin SC, Chang HW. Finite element comparison of retrograde intramedullary nailing and locking plate fixation with/without an intramedullary allograft for distal femur fracture following total knee arthroplasty. *Knee* 2014;21(1):224-31.

18. Ni M, Weng XH, Mei J, Niu WX. Primary stability of absorbable screw fixation for intra-articular calcaneal fractures: A finite element analysis. *J Med Biol Eng* 2015;35:236-41.

19. Favre P, Kloen P, Helfet DL, Werner CM. Superior versus anteroinferior plating of the clavicle: a finite element study. J Orthop Trauma 2011;25(11):661-5.
20. Iannolo M, Werner FW, Sutton LG, Serell SM, VanValkenburg SM. Forces across the middle of the intact clavicle during shoulder motion. *J Shoulder Elbow Surg* 2010;19(7):1013-7.
21. Scepi M, Faure J-P, Ridoux N, Kamina P, Richer JP. A three-dimensional model of the shoulder girdle. Forces developed in deltoid and supraspinatus muscles during abduction. *Surg Radiol Anat* 2004;26(4):290-6.
22. Drosdowech DS, Manwell SE, Ferreira LM, Goel DP, Faber KJ, Johnson JA. Biomechanical analysis of fixation of middle third fractures of the clavicle. *J Orthop Trauma* 2011;25(1):39-43.
23. Partal G, Meyers KN, Sama N, Pagenkopf E, Lewis PB, Goldman A, et al. Superior versus anteroinferior plating of the clavicle revisited: a mechanical study. *J Orthop Trauma* 2010;24(7):420-5.
24. Van der Helm FC, Veeger HE, Pronk GM, Van der Woude LH, Rozendal RH. Geometry parameters for musculoskeletal modelling of the shoulder system. *J Biomech* 1992;25(2):129-44.
25. Bostman O, Manninen M, Pihlajamaki H. Complications of plate fixation in fresh displaced midclavicular fractures. *J Trauma* 1997;43(5):778-83.
26. Wilson DJ, Weaver DL, Balog TP, Arrington ED. Early postoperative failure of a new intramedullary fixation device for midshaft clavicle fractures. *Orthopedics* 2013;36(11):e1450-3.
27. Sitthiseripratip K, Van Oosterwyck H, Vander Sloten J, Mahaisavariya B, Bohez E, Suwanprateeb J, et al. Finite element study of trochanteric gamma nail for trochanteric fracture. *Med Eng Phys* 2003;25(22):99-106.

28. Mudd CD, Quigley KJ, Gross LB. Excessive complications of open intramedullary nailing of midshaft clavicle fractures with the Rockwood clavicle pin. *Clin Orthop Relat Res* 2011;469(12):3364-70.

29. Renfree T, Conrad B, Wright T. Biomechanical comparison of contemporary clavicle fixation devices. *J Hand Surg* 2010;35(4):639-44.

30. Ramlee MH, Kadir MRA, Murali MR, Kamarul T. Finite element analysis of three commonly used external fixation devices for treating Type III pilon fractures. *Med Eng Phys* 2014;36(10):1322-30.

31. Claes L, Wilke H, Augat P, Rübenacker S, Margevicius K. Effect of dynamization on gap healing of diaphyseal fractures under external fixation. *Clin Biomech (Bristol, Avon)* 1995;10(5):227-34.

FIGURE AND TABLE LEGENDS

Figure 1. Finite element model of mid-shaft clavicle fractures fixed by the locking plate (LP, a), Sonamora CRx (b), and Rockwood clavicle pin (RCP, c).

Figure 2. Diagram showing the boudary and loading conditions.

Figure 3. Construct rigidity of LP and RCP fixation under bending condition compared with the published experimental data. The values obtained for the intact clavicle were set to 100% and served as a reference.

Figure 4. Bending and axial stiffness of three fixation constructs represented as a percentage of the intact clavicle. The LP construct was the stiffest, followed by the CRx, and the RCP was the weakest.

Figure 5. Peak von Mises stress distribution in the LP (a), CRx (b), and RCP (c) during the cantilever bending condition.

Figure 6. Peak von Mises stress distribution in the LP (a), CRx (b), and RCP (c) during the axial loading condition.

Table 1. Material properties of cortical and cancellous bone, and stainless steel.

Table 2. Peak von Mises stresses of implant/bone and fracture micro-motions of the intact model and three fixations.