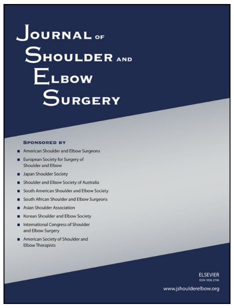


NEW GENERATION OF SUPERIOR SINGLE PLATING VS LOW-PROFILE DUAL MINI-FRAGMENT PLATING IN DIAPHYSEAL CLAVICLE FRACTURES. A BIOMECHANICAL COMPARATIVE STUDY

Tatjana Pastor, MD, Ivan Zderic, Phd, Till Berk, MD, Firas Souleiman, MD, Esther Vögelin, Prof, Frank JP. Beeres, Prof, Boyko Gueorguiev, Prof, Torsten Pastor, MD

PII: S1058-2746(23)00668-7

DOI: https://doi.org/10.1016/j.jse.2023.08.008

Reference: YMSE 6546

To appear in: *Journal of Shoulder and Elbow Surgery*

Received Date: 22 May 2023

Revised Date: 31 July 2023

Accepted Date: 6 August 2023

Please cite this article as: Pastor T, Zderic I, Berk T, Souleiman F, Vögelin E, Beeres FJ, Gueorguiev B, Pastor T, NEW GENERATION OF SUPERIOR SINGLE PLATING VS LOW-PROFILE DUAL MINI-FRAGMENT PLATING IN DIAPHYSEAL CLAVICLE FRACTURES. A BIOMECHANICAL COMPARATIVE STUDY, *Journal of Shoulder and Elbow Surgery* (2023), doi: https://doi.org/10.1016/j.jse.2023.08.008.

NEW GENERATION OF SUPERIOR SINGLE PLATING VS LOW-PROFILE DUAL MINI-FRAGMENT PLATING IN DIAPHYSEAL CLAVICLE FRACTURES. A BIOMECHANICAL COMPARATIVE STUDY

Running title: Dual versus single clavicle plating

Tatjana Pastor, MD[1, 2] Ivan Zderic, Phd[1], Till Berk, MD[3], Firas Souleiman MD [4], Esther Vögelin Prof[2], Frank J P Beeres Prof[5], Boyko Gueorguiev Prof[1], Torsten Pastor MD[5]

[1] *AO Research Institute Davos, Davos, Switzerland*

[2] *Department for Plastic and Hand Surgery, Inselspital University Hospital Bern, University of Bern, Bern, Switzerland*

[3]*University Hospital Zurich, Department of Trauma, Zurich, Switzerland*

[4]*Department of Orthopaedics, Trauma and Plastic Surgery, University Hospital Leipzig, Leipzig, Germany*

[5]*Department of Orthopaedic and Trauma Surgery, Lucerne Cantonal Hospital, Lucerne, Switzerland*

Corresponding Author: *Torsten Pastor, MD, Cantonal Hospital of Lucerne, Department Orthopedic and Trauma Surgery, Spitalstrasse, 6000 Lucerne, Switzerland*

Phone: +41412051111; Email: Torsten.Pastor@Luks.ch

All procedures performed in this study were followed in accordance with relevant guidelines. The donor gave its informed consent inherent within the donation of the anatomical gift statement during his lifetime, as registered by Science Care.

Disclaimers:

Funding: This work was financially supported by the Swiss Accident Insurance Fund (SUVA).

Conflicts of interest: The authors, their immediate families, and any research foundation with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

Acknowledgments: This investigation was performed with the assistance of the AO Foundation.

ABSTRACT

Background: Recently, a new generation of superior clavicle plates was developed featuring the variable angle locking technology for enhanced screw positioning and a less prominent and optimized plate-to-bone fit design. On the other hand, mini-fragment plates in dual plating mode have demonstrated promising clinical results. The aim of the current study was to compare the biomechanical competence of single superior plating using the new generation plate versus dual plating using low-profile mini-fragment plates.

Methods: Sixteen paired human cadaveric clavicles were pairwise assigned to two groups for instrumentation with either a superior 2.7 mm Variable Angle Locking Compression Plate (Group 1), or with one 2.5 mm anterior combined with one 2.0 mm superior matrix mandible plate (Group 2). An unstable clavicle shaft fracture (AO/OTA 15.2C) was simulated by means of a 5mm osteotomy gap. Specimens were cyclically tested to failure under craniocaudal cantilever bending, superimposed with bidirectional torsion around the shaft axis and monitored via motion tracking.

Results: Initial construct stiffness was significantly higher in Group 2 (9.28 ± 4.40 N/mm) compared to Group 1 (3.68 ± 1.08 N/mm), p=0.003. The amplitudes of interfragmentary motions in terms of axial and shear displacement, fracture gap opening and torsion, over the course of 12,500 cycles were significantly higher in Group 1 compared to Group 2, $p \leq 0.038$. Cycles to 2mm shear displacement were significantly lower in Group 1 (22792 ± 4346) compared to Group 2 (27437 ± 1877), p=0.047.

Conclusion: From a biomechanical perspective, low-profile 2.5/2.0 dual plates can be considered as a useful alternative for diaphyseal clavicle fracture fixation especially in less common unstable fracture configurations.

2.7 single superior variable angle locking plates and can therefore be considered as a useful alternative for diaphyseal clavicle fracture fixation especially in less common unstable fracture configurations.

Keywords: midshaft/diaphyseal clavicle fracture, dual plating, mini-fragment plates, biomechanics, motion tracking, implant removal, symptomatic implants

Level of evidence: Basic Science Study; Biomechanics

Fractures of the middle part of the clavicle account for 69% to 82% of all clavicular fractures and for 2.6% to 5% of all human fractures [6]. In patients with significantly displaced fractures, primary operative fixation, as opposed to non-operative treatment of clavicle fractures, promotes a quicker return to function and reduces early residual disability [10]. Plating is a common method for surgical treatment and the standard fixation technique for midshaft fractures using a 3.5mm anatomic Locking Compression Plate (LCP) demonstrated good clinical results and less non-unions on the long term follow-up [8]. However, high implant removal rates due to disturbing hardware of 9 to 64% have been reported [21] and led to a search for alternatives. One approach to reduce soft tissue irritation is using the recently introduced 2.7 variable angle locking compression plate (VA-LCP) for superior placement on the clavicle. The main features consist of a low-profile design with a smoothened plate surface, tapered edges and variable angle locking holes. However, reports in the current literature related to clinical outcomes are still scarce. Another strategy is the use of low-profile dual plates that have already demonstrated good clinical outcomes [2] and theoretically lead to less soft tissue irritation due to the low cross-sectional area of the two plates. The concept of dual plating is an additional way to increase the multiplanar stability of the fracture fixation by using two smaller locking plates instead of a single larger implant and offering a wider choice of screw anchoring sites to enhance construct stability while reducing implant prominence. Therefore, it is especially interesting in locations where prominent hardware disturbs patients after fracture fixation. However, these new plate designs for diaphyseal clavicle fracture fixation have not been subjected to a direct biomechanical evaluation so far. Therefore, the aim of the current study was to investigate the biomechanical competence of the new generation single 2.7 mm VA-LCP superior clavicle plate versus superior-anterior dual plating using two low-profile mini-fragment plates in a human cadaveric bone model.

2. MATERIALS AND METHODS

2.1 Specimens and study groups

Sixteen paired fresh frozen human cadaveric clavicles from 4 female and 4 male donors aged 72.5 years on average (range 48–96 years) were used in this study. The specimens were thawed at room temperature, freed from all soft tissues and subjected to computed tomography (CT) scanning at a slice thickness of 0.63mm (Revolution EVO, GE Medical Systems AG, Switzerland) to calculate volumetric bone mineral density (BMD) within the clavicle bone using a phantom (European Forearm Phantom QRM-BDC/6; QRM GmbH, Möhrendorf, Germany). Subsequently, the specimens were pairwise assigned to two groups for single superior plating in Group 1, or superior-anterior dual plating using two low-profile mini-fragment plates in Group 2, with equal distribution of left and right clavicles in each group.

2.2 Surgical technique

For instrumentation in Group 1, a 2.7 mm VA-LCP Clavicle Shaft Plate (size CS1; length 98 mm; DePuy Synthes, Zuchwil, Switzerland) was used. Each plate was positioned such that the fracture gap was located centrally between the two innermost plate holes 6 and 7, counting from medial. Contouring of the plates to fit the anatomy was not necessary as they fitted well to the anatomy of the 8 donors. Pilot holes of 2.0 mm were predrilled using the VA-LCP Drill Sleeve in bicortical fashion through plate holes 1, 3, 4, 5, 8, 9, 10, and 12, counting from medial after plate fixation to the bone with two repositioning forceps. Final plate securing was achieved via locking screw fixation through these pilot holes using a total of four bicortical 2.7mm variable angle locking screws in each fragment starting with plate holes 1 and 12. Finally, a 1.2 Nm torque limiter was used for screw locking.

For instrumentation in Group 2, one 2.5 mm 9-hole 68 mm long Matrix mandible plate and one 2.0 mm 5-hole 36 mm long Matrix mandible plate (2.5 Matrix mandible 20-hole plate and 2.0 Matrix mandible 20-hole plate; DePuy Synthes, Zuchwil, Switzerland) were considered. Both were cut from 20-hole plates as they are not available in the according length. Whereas the 2.5 mm plate was contoured to fit the anatomy of the anterior aspect of the clavicle, the 2.0 mm plate was pre-shaped to cling to the superior aspect of the clavicle. Both plates were positioned and secured with repositioning forceps such that the middle hole – number 5 of the 2.5 mm anterior plates and number 3 of the 2.0 mm superior plates, counted from medially – was located centrally over the osteotomy gap. Pilot holes of 1.8 mm were predrilled using a Drill Sleeve in bicortical fashion through plate holes 1, 2, 4 and 5 of the superior plate and through plate holes 1, 4, 6 and 9 of the anterior plate. Final plate securing was achieved via locking screw fixation through these pilot holes using a total of two bicortical 2.4mm locking screws in each fragment and plate, starting with plate holes 1 and 5 of the superior plate and plate holes 1 and 9 of the anterior plate. No torque limiter was used, and all screws were tightened according to best knowledge of the surgeon. All instrumentations were performed by one experienced surgeon following the technical prescriptions of the individual implants (*Figure 1*). All implants were made of commercially pure titanium (cpTi)/titanium alloy (TAV/TAN), and were provided by the same manufacturer (DePuy Synthes, Zuchwil, Switzerland).

A 5 mm wide osteotomy gap was created in the mid-shaft region of each specimen using an oscillating saw and a cutting jig to simulate a displaced unstable diaphyseal AO/OTA 15.2C fracture (type 2B according to Robinson's classification). The lateral and medial ends of the clavicles were embedded in collinear cylindric forms using polymethylmethacrylate (PMMA, SCS-Beracryl D28; Suter Kunststoffe AG, Fraubrunnen, Switzerland) with the innermost sites of the cylinders measuring 120 mm in distance between each other. This distance resembled the lowest common denominator allowing secure fixation in each specimen, given the variable clavicle sizes with the shortest one measuring 140 mm. Furthermore, this uniform length allowed consistent loading of each specimen. Finally, two optical marker sets were mounted to the clavicle on both sides of the osteotomy gap for motion tracking.

2.3 Biomechanical Testing

Biomechanical testing was performed on an electrodynamic material testing machine (MTS Acumen; MTS Systems Corp., Eden Prairie, MN, USA) equipped with a 3kN load cell and a test setup adopted from previous work [13,24]. Whereas the PMMA embedding at the sternal side was connected to the machine base via an XY table, the embedding at the acromial clavicle end was fixed to the machine actuator via a cardan joint (*Figure 2)*. A pin placed beneath the specimens medial to the osteotomy gap was used to support the sternal clavicle end and ensure cantilever bending of the plated specimen. The cardan joint was angled at 20 degrees corresponding to 25 mm posterior offset of the machine actuator axis with respect to the axis of the acromial clavicular embedding. This configuration allowed complex loading comprising cantilever bending superimposed with shear and torsional loading, initiated by the actuator [13,24], with the aim to simulate clavicle torsion due to arm swinging during walking, as well as bending and shear loading during breathing induced by the sternocleidomastoid, delta, subclavius, pectoralis major, and trapezius muscles.

The loading protocol commenced with of an initial non-destructive quasi-static compression ramp from 0 N to 30 N at a rate of 5 N/s, followed by cyclic sinusoidal loading pattern with a constant amplitude between 50 N compression and 20 N tension at 2 Hz test frequency over 20000 cycles and was adapted from previous work [5,13,24]. Subsequently, compression and tension were increased at a rate of 0.01 N/cycle until catastrophic failure of the bone-implant construct. The application of progressively increasing cyclic loading has been demonstrated as useful in previous studies [3,15–17] and allows construct failure of specimens with different bone quality to occur within a predefined number of cycles. Peak torque values induced from the posterior offset of the applied load under 20 N tension and 50 N compression, were 0.5 Nm and 1.25 Nm, respectively. According to previously published work [13,24], the test was stopped after catastrophic failure, which was characterized as a 45 mm axial displacement of the machine actuator.

2.5 Data Acquisition and Analysis

Machine data in terms of axial load and axial displacement were acquired at a rate of 32 Hz. Initial construct stiffness was calculated from the ascending load-displacement curve of the quasistatic ramp in the range between 10 N and 25 N compression. Further, the coordinates of the optical markers attached to the tested constructs were continuously acquired throughout the tests at 20 Hz by means of stereographic optical measurements using contactless full-field deformation technology (Aramis SRX; GOM GmbH, Braunschweig, Germany) to assess interfragmentary movements in all six degrees of freedom. Based on the motion tracking data, the following parameters were evaluated: (1) shear displacement, defined as the relative displacement within the osteotomy plane between the two fragments measured at the most inferior aspect lying in the fracture gap; (2) axial displacement, defined as the relative displacement perpendicular to the osteotomy plane between the two fragments measured at the most inferior aspect lying in the fracture gap; (3) torsional displacement, defined as the relative angular displacement between the two fragments within the osteotomy plane; (4) gap angle displacement, defined as the magnitude of fracture gap opening between the two fragments. The outcome values of these parameters were analyzed after 2500, 5000, 7500, 10,000 and 12,500 test cycles under peak and valley loading conditions to assess the evolution of the amplitude over the course of cyclic testing. Furthermore, a margin of 2 mm of shear displacement was defined as clinically relevant criterion for construct failure and the numbers of cycles until fulfilment of this criterion under peak loading condition were calculated. Finally, catastrophic failure modes were evaluated by X-ray imaging and visual inspection of the implant at the end of each test.

Statistical evaluation was performed with SPSS software package (IBM SPSS Statistics, version 27; IBM, Armonk, NY, USA). Shapiro-Wilk test was used to screen and prove normality of the data distribution. Differences in fracture gap movements and their change over time were analyzed with General Linear Model Repeated Measures test. Significant differences between the study groups were identified using Paired-Samples T-tests. Level of significance was set to 0.05 for all statistical tests.

3. RESULTS

3.1 Volumetric bone mineral density

Cortical and trabecular volumetric BMD were respectively 383.9 ± 18.9 mgHA/cm^3 and 349.5 ± 4.7 mgHA/cm^3 in Group 1, as well as 383.4 ± 12.9 mgHA/cm^3 and 349.9 ± 6.7 mgHA/cm^3 in Group 2, with no significant differences between the groups (p≥0.815).

3.2 Initial construct stiffness

Initial construct stiffness was significantly higher in Group 2 (9.28 ± 4.40 N/mm) compared to group 1 (3.68 ± 1.08 N/mm), p=0.003.

3.3 Fracture gap movements

The amplitude at the five intermittent time points over the course of 12,500 cycles for the four investigated parameters shear displacement, axial displacement, gap angle, and torsion are displayed in *(Figure 3)*. For each of these parameters, the amplitude was significantly higher in Group 1 versus Group 2, $p \leq 0.038$. Furthermore, whereas the amplitude for shear displacement, axial displacement, and gap angle remained without significant changes over the cycles in each group ($p \geq 0.232$), it significantly increased for torsion in both groups ($p \leq 0.031$).

3.4 Cycles to clinically relevant failure

Cycles to 2 mm shear displacement were significantly lower in Group 1 (22792 ± 4346) compared to Group 2 (27437 ± 1877), $p = 0.047$ *(Figure 4)*.

3.5 Failure modes

In Group 1, plate plastic deformation in all specimens was followed by screw breakage of up to all 4 screws at the medial side in five specimens. Whereas in two specimens screw breakage occurred at the lateral side, in one specimen all screws remained intact. Main failure mode in Group 2 was breakage of one or two screws of the anterior plate at the medial side in six specimens. In two specimens screw breakage occurred at the lateral side. Plate breakage was not observed in any specimen of both groups (*Figure 5*).

4. DISCUSSION

The current study compared the biomechanical competence of the recently introduced 2.7 mm VA-LCP superior clavicle plate with low-profile dual plate constructs (2.5/2.0) used for the fixation of unstable mid-shaft clavicle fractures. The main findings were a significantly higher initial stiffness and a significantly higher resistance failure of the low-profile dual plate constructs compared to the new 2.7 mm VA-LCP superior clavicle plate. Moreover, the low-profile dual plates were associated with significantly less fracture gap movements in terms of shear and rotational displacement over the first 12,500 cycles. In a clinical setting with a gap fracture as simulated in the current study, less adverse interfragmentary shear movements in dual plate constructs might be beneficial for bone healing, whereas the longer endurance theoretically allows more time for bone healing. In contrast, single plates were associated with more favorable axial movements which theoretically is beneficial for bone healing in bridge plate constructs. However, the single plates demonstrated less resistance to failure. The current study used a worst-case scenario with a gap fracture of 5 mm to maximally stress the plates. Thus, less interfragmentary movements of the single plates should occur in more stable fracture configurations. However, the current study is not able to categorize the amount of interfragmentary movements as beneficial or harmful.

Although the current study cannot compare the biomechanical competence of the new 2.7 mm VA-LCP against the thicker 3.5 mm clavicle plates, it is hypothesized that the reduced thickness to minimize soft tissue irritation comes at costs of biomechanical stability. Since the new plate design has only recently been introduced, it is obvious that reports are scarce in the current literature. However, first clinical reports on the new 2.7 VA-LCP are promising with excellent clinical results although the study included shaft fractures with lateral extension [1]. One advantage of the single plate is the possible use in minimally invasive plate osteosynthesis (MIPO) technique as described by Michelitsch et al in comminuted midshaft fractures [12].

There are several other biomechanical studies available in the current literature comparing the biomechanical competence of dual plate constructs to single plates in midshaft clavicle fractures. In the beginning, thicker dual plate constructs with 3.5 mm reconstruction plates were compared to single 3.5 mm reconstruction plates which led to expectable increased construct stiffness and higher resistance to failure [24]. In a further consequence, dual plate constructs with thinner plates were evaluated biomechanically. Ziegler et al reported similar superior results with 2.7 mm and 3.5 mm dual plate constructs when compared to single 3.5mm plates [26].

Prasarn et al used 2.7 mm plates superiorly and 2.4 mm plates anteriorly and compared them to 3.5 mm reconstruction plates in an artificial bone model and also reported superior biomechanical behavior for the dual plate constructs when compared to 3.5 mm single plates[18]. Kitzen et al also evaluated 2.7 mm plates superiorly and 2.4 mm plates anteriorly and compared them to 3.5 mm single reconstruction plates in a human cadaveric bone model. Again, the authors reported similar biomechanical properties as found in 3.5 mm single plate constructs [7].

The plates used in the aforementioned studies were relatively thick and it is questionable if hardware removal rates can be significantly lowered with their use in clinical practice. Therefore, even thinner plates were recently investigated and compared 2.5/2.0 mm dual plate constructs as well as 2.0/2.0 mm dual plate constructs with conventional 3.5 mm anterosuperior plates in an artificial bone model [13]. The used low-profile plates were initially designed for mandible fractures and although the 2.5/2.0 mm dual plate constructs demonstrated higher initial stiffness and comparable resistance to failure as a 3.5mm single plate, the 2.0/2.0 mm constructs demonstrated comparable initial stiffness. However, during cyclic testing the 2.0/2.0 mm constructs showed significantly lower resistance to failure and might not be considered as valid alternative to 3.5 mm single plating. On the other side, a worst-case scenario with a 5 mm gap fracture was used. The 2.0/2.0 dual plate construct might be sufficient to achieve fracture healing in a near to anatomically reduced fractures.

In the current study main failure mode of the dual plate constructs was screw breakage in the anterior stronger plate at the medial or lateral side of the fracture gap. In a clinical application the additional insertion of screws in this area (screw hole 2 and 8) might even further increase the resistance to clinical failure. Despite the superior biomechanical characteristics of the dual plate constructs, there are several concerns regarding their routinely use in patients. The additional soft tissue dissection around the clavicle due to orthogonal dual plating might be a drawback since it could impair bone healing, however, a recently published meta-analysis compared low profile dual plating with single plating in midshaft clavicle fractures and the authors conclude that dual plating is a safe procedure attaining the same union rates as seen in single plating [19]. Moreover, the dual plate constructs used in the current study were shorter than the 2.7 mm single plates. Therefore, less soft tissue dissection is required on either the superior or anterior side. Furthermore, the amount of surgical exposure required for anatomic reduction rather than the number of utilized plates determines intraoperative exposure in multi-fragmentary displaced diaphyseal clavicle fractures [11]. Another concern of implants with a high initial stiffness are higher non-union rates due to decreased fracture gap movements especially in gap fractures where the bridge plating concept is applied. In contrast, modern low-contact angular stable plate designs to minimize the negative impact on the blood supply have been developed and clinical studies using low-profile dual plate constructs have shown no non-unions so far [2,18]. Furthermore, a systematic review and meta-analysis described high union rates for dual plating (99.5%), and an implant removal rate of only 4.2% investigating 7 clinical studies regarding low-profile dual plating [25]. Another meta-analysis concluded that dual plating seems to have a lower overall complication and re-intervention rate, mostly driven by the lower incidence of implant related complaints [19]. However, when interpreting implant removal rates, one has to keep in mind that they are dependent on several factors like length of follow-up, activity level of the patients (e.g. backpack), individual costs of implant removal in different health care systems and cultural differences. Furthermore, disturbing hardware might also be a subjective feeling in some patients who are disturbed just by the fact of foreign material in their body.

The results of the current study revealed that dual plate constructs offer more initial stiffness, higher resistance to failure and less fracture gap formation and therefore may have a role clinically. However, further clinical trials would be necessary to determine whether low profile dual plate fixation with 2.5/2.0 plate configurations offers improved healing compared to single plate fixation.

Several limitations that inherent to all biomechanical studies done on human cadaveric bones have to be considered when interpreting the findings of the current study. First, using a cadaveric bone model, it was not possible to fully replicate the in vivo conditions following a fracture in a real human with soft tissue swelling and biological reaction. Second, only a limited number of human clavicles were tested, restricting the generalization of the study findings. However, the results deem sufficient, demonstrating significant differences between the groups. Third, the dual plates used in the current study had to be slightly prebent to perfectly fit to the clavicle, which might have influenced their material properties, which was not necessary in the single plate group. However, in an anatomical investigation on more than 100 clavicles Vancleef et al concluded that it is improbable that a clavicle plating system can match the entire population [20]. In consequence, minor adjustments to the implants are virtually always necessary for surgeons to match the patient's anatomy perfectly [20]. New techniques like the application of three-dimensional patient specific surgical guides might further improve fracture reduction and optimal plate positioning [14]. Fourth, the chosen 2mm of shear displacement is an arbitrarily defined criterion for construct failure as this contrasts with Perren`s strain theory. However, the displacement curve demonstrated a sudden drop in stability near this chosen criterion, which was found to be suitable. Lastly, the donors for the specimens of the current study were relatively old and are therefore not the primary target group for surgical treatment of clavicle shaft fractures. However, main failure mode was screw breakage rather than screw pullout. It is therefore expected that the results of the current study can be transferred to younger patients.

The strengths of the current study lie especially in the use of a precise motion tracking system. Furthermore, the failure modes correspond to clinical failures observed during clinical practice, rendering the used test setup and loading protocol clinically relevant. Furthermore, the use of paired cadaveric specimens allowed for a reliable assignment into the two study groups. This biomechanical investigation adds valuable knowledge to the existing literature regarding the groundwork of the relatively new technique of clavicle low-profile dual plating which might reduce the high implant removal rates after midshaft clavicle fractures.

Future research should focus on the optimal implant length of the low-profile dual plates and their clinical evaluation [9]. It is expected that the dual plates can be further shortened to achieve a similar stiffness and resistance to clinical failure as the 2.7 single plates especially in more stable fracture patterns. Furthermore, implant removal rates and patient satisfaction of the two investigated plate designs should be evaluated. Moreover, the major issue with biomechanical studies on the upper extremity is that it remains unclear which construct stiffness and loading thresholds fixation constructs have to withstand in vivo [4]. Up to now there is no data in the literature on how many cycles the constructs must withstand to achieve bone healing. New technologies like continuous implant load monitoring to assess the bone healing status might bring new insights to this problem [22,23].

5. CONCLUSION

From a biomechanical perspective, low-profile 2.5/2.0 dual plates can be considered as a useful alternative for diaphyseal clavicle fracture fixation especially in less common unstable fracture configurations.

REFERENCES

1. Ago E, Thiruvasagam V, Shah N, Badge R. Surgical Fixation of Clavicle Shaft Fractures Using Superior Locking Plates With Lateral End Extension: A Retrospective Study. Cureus. 2022 Oct;14(10):e30054. doi:10.7759/cureus.30054

2. Chen MJ, DeBaun MR, Salazar BP, Lai C, Bishop JA, Gardner MJ. Safety and efficacy of using 2.4/2.4 mm and 2.0/2.4 mm dual mini-fragment plate combinations for fixation of displaced diaphyseal clavicle fractures. Injury. 2020 Mar;51(3):647–650. doi:10.1016/j.injury.2020.01.014

3. Gueorguiev B, Ockert B, Schwieger K, Wähnert D, Lawson-Smith M, Windolf M, et al. Angular stability potentially permits fewer locking screws compared with conventional locking in intramedullary nailed distal tibia fractures: a biomechanical study. J Orthop Trauma. 2011 Jun;25(6):340–346. doi:10.1097/BOT.0b013e3182163345

4. Hulsmans MH, van Heijl M, Houwert RM, Burger BJ, Verleisdonk EJM, Veeger DJ, et al. Surgical fixation of midshaft clavicle fractures: A systematic review of biomechanical studies. Injury. 2018 Apr;49(4):753–765. doi:10.1016/j.injury.2018.02.017

5. 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 Oct;19(7):1013–1017. doi:10.1016/j.jse.2010.03.016

6. Jeray KJ. Acute midshaft clavicular fracture. J Am Acad Orthop Surg. 2007 Apr;15(4):239–248. doi:10.5435/00124635-200704000-00007

7. Kitzen J, Paulson K, Korley R, Duffy P, Martin CR, Schneider PS. Biomechanical Evaluation of Different Plate Configurations for Midshaft Clavicle Fracture Fixation: Single Plating Compared with Dual Mini-Fragment Plating. JBJS Open Access 2022;7(1). doi:10.2106/JBJS.OA.21.00123

8. Lädermann A, Abrassart S, Denard PJ, Tirefort J, Nowak A, Schwitzguebel AJ. Functional recovery following early mobilization after middle third clavicle osteosynthesis for acute fractures or nonunion: A case-control study. Orthop Traumatol Surg Res. 2017;103(6):885–889. doi:10.1016/j.otsr.2017.03.021

9. Luzerner Kantonsspital. Double Plating Versus Single Plating Techniques in Midshaft Clavicle Fractures clinicaltrials.gov; 2022. Available from: https://clinicaltrials.gov/ct2/show/NCT05579873

10. McKee RC, Whelan DB, Schemitsch EH, McKee MD. Operative versus nonoperative care of displaced midshaft clavicular fractures: a meta-analysis of randomized clinical trials. J Bone Joint Surg Am. 2012 Apr 18;94(8):675–684. doi:10.2106/JBJS.J.01364

11. Michel PA, Katthagen JC, Heilmann LF, Dyrna F, Schliemann B, Raschke MJ. Biomechanics of Upper Extremity Double Plating. Z Orthop Unfall. 2020 Apr;158(2):238–244. doi:10.1055/a-0862-6334

12. Michelitsch C, Beeres F, Burkhard MD, Stillhard PF, Babst R, Sommer C. Minimally invasive plate osteosynthesis for clavicle fractures. Oper Orthop Traumatol. 2023 Apr;35(2):92–99. doi:10.1007/s00064-023-00798-7

13. Pastor T, Knobe M, van de Wall BJM, Rompen IF, Zderic I, Visscher L, et al. Low-profile dual mini-fragment plating of diaphyseal clavicle fractures. A biomechanical comparative testing. Clin Biomech (Bristol, Avon). 2022 Apr;94:105634. doi:10.1016/j.clinbiomech.2022.105634

14. Pastor T, Nagy L, Fürnstahl P, Roner S, Pastor T, Schweizer A. Three-Dimensional Planning and Patient-Specific Instrumentation for the Fixation of Distal Radius Fractures. Medicina (Kaunas). 2022 May 30;58(6):744. doi:10.3390/medicina58060744

15. Pastor T, Zderic I, Gehweiler D, Gardner MJ, Stoffel K, Richards G, et al. Biomechanical analysis of recently released cephalomedullary nails for trochanteric femoral fracture fixation in a human cadaveric model. Arch Orthop Trauma Surg. 2021 Nov 8;doi:10.1007/s00402-021-04239-7

16. Pastor T, Zderic I, van Knegsel KP, Beeres FJP, Migliorini F, Babst R, et al. Biomechanical analysis of helical versus straight plating of proximal third humeral shaft fractures. Arch Orthop Trauma Surg. 2023 Feb 23;doi:10.1007/s00402-023-04814-0

17. Pastor T, Zderic I, Schopper C, Haefeli PC, Kastner P, Souleiman F, et al. Impact of Anterior Malposition and Bone Cement Augmentation on the Fixation Strength of Cephalic Intramedullary Nail Head Elements. Medicina (Kaunas). 2022 Nov 13;58(11):1636. doi:10.3390/medicina58111636

18. Prasarn ML, Meyers KN, Wilkin G, Wellman DS, Chan DB, Ahn J, et al. Dual mini-fragment plating for midshaft clavicle fractures: a clinical and biomechanical investigation. Arch Orthop Trauma Surg. 2015 Dec;135(12):1655–1662. doi:10.1007/s00402-015-2329-0

19. Rompen IF, van de Wall BJM, van Heijl M, Bünter I, Diwersi N, Tillmann F, et al. Low profile dual plating for mid-shaft clavicle fractures: a meta-analysis and systematic review of observational studies. Eur J Trauma Emerg Surg. 2022 Aug;48(4):3063–3071. doi:10.1007/s00068-021-01845-3

20. Vancleef S, Herteleer M, Carette Y, Herijgers P, Duflou JR, Nijs S, et al. Why off-the-shelf clavicle plates rarely fit: anatomic analysis of the clavicle through statistical shape modeling. J Shoulder Elbow Surg. 2019 Apr;28(4):631–638. doi:10.1016/j.jse.2018.09.018

21. Wijdicks F-JG, Van der Meijden OAJ, Millett PJ, Verleisdonk EJMM, Houwert RM. Systematic review of the complications of plate fixation of clavicle fractures. Arch Orthop Trauma Surg. 2012 May;132(5):617–625. doi:10.1007/s00402-011-1456-5

22. Windolf M, Heumann M, Varjas V, Constant C, Ernst M, Richards RG, et al. Continuous Rod Load Monitoring to Assess Spinal Fusion Status-Pilot In Vivo Data in Sheep. Medicina (Kaunas). 2022 Jul 6;58(7):899. doi:10.3390/medicina58070899

23. Windolf M, Varjas V, Gehweiler D, Schwyn R, Arens D, Constant C, et al. Continuous Implant Load Monitoring to Assess Bone Healing Status-Evidence from Animal Testing. Medicina (Kaunas). 2022 Jun 27;58(7):858. doi:10.3390/medicina58070858

24. Yanev P, Zderic I, Pukalski Y, Enchev D, Rashkov M, Varga P, et al. Two reconstruction plates provide superior stability of displaced midshaft clavicle fractures in comparison to single plating - A biomechanical study. Clin Biomech (Bristol, Avon). 2020 Dec;80:105199. doi:10.1016/j.clinbiomech.2020.105199

25. You DZ, Krzyzaniak H, Kendal JK, Martin CR, Schneider PS. Outcomes and complications after dual plate vs. single plate fixation of displaced mid-shaft clavicle fractures: A systematic review and meta-analysis. J Clin Orthop Trauma. 2021 Jun;17:261–266. doi:10.1016/j.jcot.2021.03.024

26. Ziegler CG, Aman ZS, Storaci HW, Finch H, Dornan GJ, Kennedy MI, et al. Low-Profile Dual Small Plate Fixation Is Biomechanically Similar to Larger Superior or Anteroinferior Single Plate Fixation of Midshaft Clavicle Fractures. Am J Sports Med. 2019 Sep 1;47(11):2678–2685. doi:10.1177/0363546519865251

FIGURE LEGENDS

Figure 1: Exemplified photographs of two left clavicles instrumented with a 2.7 mm VA-LCP clavicle shaft plate in superior position (A, B), and with a 2.5/2.0 mm low-profile dual plate construct (C, D), shown from superior (A, C) and from anterior (B, D).

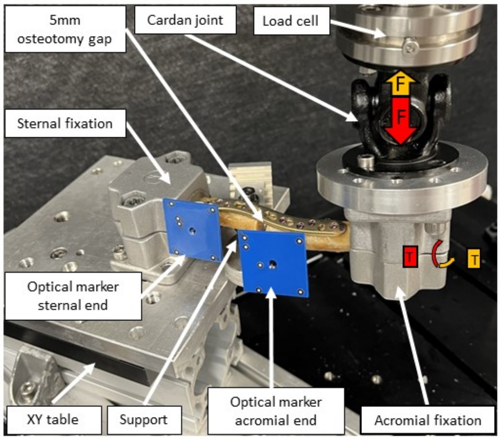
Figure 2: Test setup with a left specimen mounted for biomechanical testing. F indicates loading direction; T indicates passively induced torque via posterior offset of F with respect to the clavicle axis.

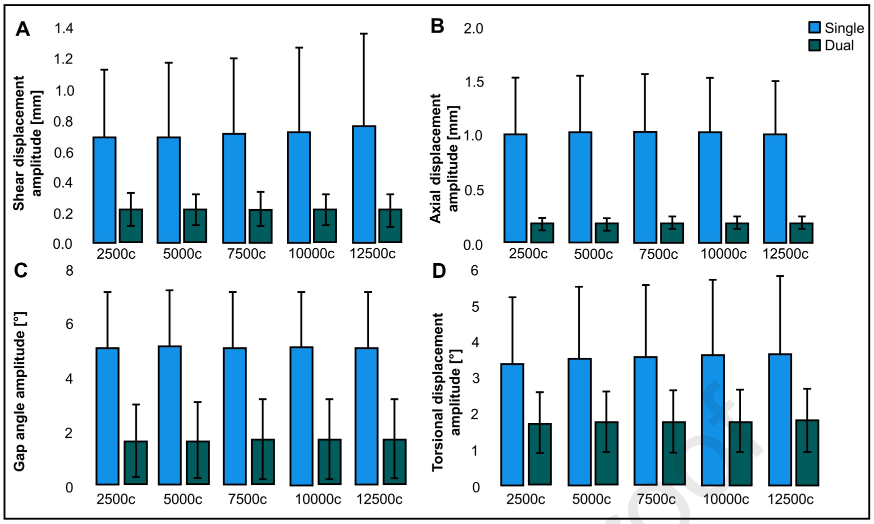
Figure 3: Fracture gap movement amplitudes over the course of 12.500 test cycles, shown for each group separately in terms of mean and SD.

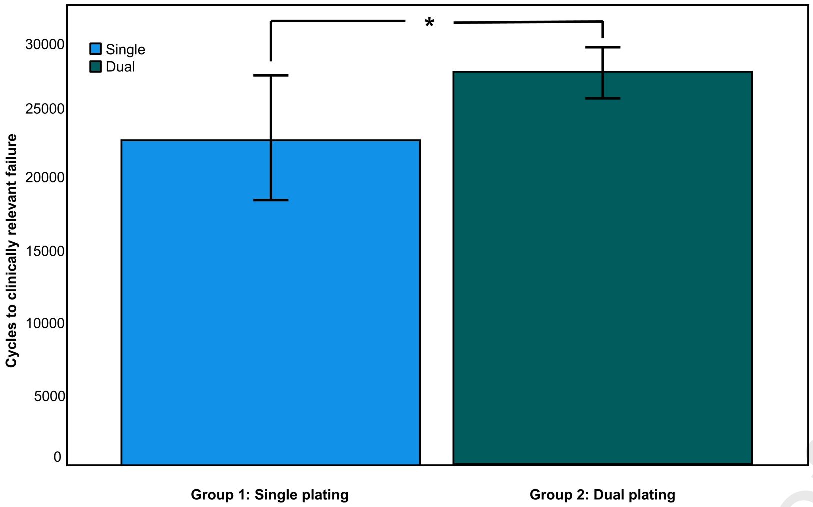
Figure 4: Cycles to clinically relevant failure shown in terms of mean and SD. Star indicates significant difference.

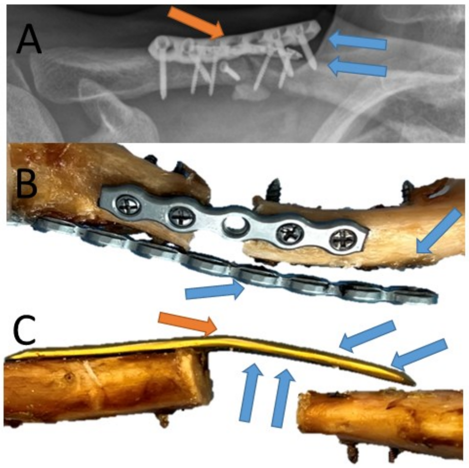
Figure 5: Main failure modes of the investigated specimens. Orange arrows indicate plate deformation. Blue arrows indicate screw breakage or loosening. **A:** X-ray of a clinical failure of a low-profile dual plate construct. View from 40° caudo-cranial to a right clavicle. **B:** View from superior to a right clavicle. The dual plate construct failed via screw breakage of the two medial screws in the anterior 2.5 low profile plate. **C:** View from anterior to a right clavicle. The single plate failed via plate deformation and screw breakage of all 4 medial screws.


A
B
C
D


5mm
osteotomy gap
Cardan joint
Load cell
F
F
Sternal fixation
T
T
Optical marker
sternal end
XY table
Support
Optical marker
acromial end
Acromial fixation


A
Shear displacement amplitude [mm]
1.4
1.2
1.0
0.8
0.6
0.4
0.2
0.0
2500c
5000c
7500c
10000c
12500c
B
Axial displacement amplitude [mm]
2.0
1.5
1.0
0.5
0.0
2500c
5000c
7500c
10000c
12500c
Single
Dual
C
Gap angle amplitude [°]
8
6
4
2
0
2500c
5000c
7500c
10000c
12500c
D
Torsional displacement amplitude [°]
6
5
4
3
2
1
0
2500c
5000c
7500c
10000c
12500c


*
Single
Dual
Cycles to clinically relevant failure
30000
25000
20000
15000
10000
5000
0
Group 1: Single plating
Group 2: Dual plating


A
B
C