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A biomechanical comparison of two plating techniques in lateral clavicle fractures

Cyrill Suter[a,*,1], Martina von Rohr[a,1], Martin Majewski[a], Lutz Dürselen[b], Daniela Warnecke[b], Natalie Schild[b], Andrej Maria Nowakowski[a,c]

[a] University of Basel, Medical Faculty, Klingelbergstrasse 61, 4056 Basel, Switzerland
[b] Institute of Orthopedic Research and Biomechanics, Trauma Research Center Ulm, Ulm University - Medical Center, Helmholtzstr. 14, 89081 Ulm, Germany
[c] Orthopedic Department, Spital Uster, Brunnenstrasse 42, 8610 Uster, Switzerland

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ABSTRACT

Background: Neer Type IIb lateral clavicle fractures typically lead to dislocation of the medial fragment. Therefore, most surgeons recommend surgical treatment for such a fracture pattern. The use of a locking compression plate with a lateral extension has produced satisfactory results in various studies over recent years. Double-plate fixation is a common technique in the treatment of complex distal radius fractures. The authors use this technique as a routine procedure in the treatment of Neer type IIb fractures. In this biomechanical testing study, the mechanical properties of the two techniques were compared.
Methods: On 20 clavicles from fresh frozen cadavers a Neer Type IIb fracture-like osteotomy was performed. A cyclic loading test followed by a load-to-failure test was carried out. Parameters for statistical evaluation were the stiffness at cycles 1, 100 and 17,500 as well as the ultimate tensile load and the deformation at the point of failure.
Findings: All specimens withstood the cyclic loading test without any noticeable damage. At cycles 100 and 17,500, the double-plate technique was less stiff. Failure loads were not significantly different from each other, but deformation at the point of failure was significantly greater for the double-plate technique.
Interpretation: Both techniques provided sufficient fixation to the fracture site to endure the cyclic loading test, which is supposed to simulate an incident-free week postoperatively. In summary, the double-plate technique offers biomechanically a feasible alternative to the single-plate technique in lateral clavicle fractures of Neer Type IIb.

1. Introduction

Clavicle fractures, in general, are common, particularly among adolescents and young, active adults. They occur with the greatest incidence in the second and third decades, with an overall incidence of 64 per 100,000 (Donnelly et al., 2013; Postacchini et al., 2002; Zlowodzki et al., 2005). Lateral clavicle fractures account for approximately 18% of all clavicle fractures (Nowak et al., 2000). Finding the best treatment of clavicle fractures remains a greatly debated topic in orthopedic practice. This also extends to lateral clavicle fractures. Historically, clavicle fractures have mostly been treated conservatively with acceptable results (Donnelly et al., 2013). However, to determine whether a lateral clavicle fracture requires surgical treatment, a precise diagnostic workup is crucial, because up to 25% of all cases are unstable (Rieser et al., 2013; Robinson, 1998). Even when the lateral fragment remains in its anatomical position, whether the fragment will shift away or not depends on the forces applied by the arm and on the integrity of the coracoclavicular (CC) ligaments (Bishop et al., 2013). The functionality of the CC ligaments is critical for the outcome of lateral clavicle fractures. Neer Type IIb fracture is believed to occur somewhere in between the CC ligaments, which typically leads to a torn conoid ligament, an intact trapezoid ligament and thus to a displacement of the medial fragment (Neer, 1963).

When such an unstable fracture pattern like the Neer Type IIb is present, surgical treatment is indicated, because up to 28% of such conservatively treated cases result in bony non-union and surgical treatment can lead to a union rate of up to 95% (Good et al., 2012; Schliemann et al., 2013). In addition, delayed surgical procedure can

* Corresponding author.
E-mail address: cyrill_suter@hotmaill.com (C. Suter).
[1] Contributed equally.

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lead to a higher complication rate (Klein et al., 2010).

When surgical therapy is indicated, numerous therapeutic options come into consideration, including Kirschner-wire fixation, CC screws, plate fixation, hook plate fixation and CC sling procedures (Andersen et al., 2011; Badhe et al., 2007; Hessmann et al., 1996; Kalamaras et al., 2008; Neer, 1963; Nourissat et al., 2007; van der Meijden et al., 2012). Many of these lead to high complication rates, including implant failure, non-union and subacromial impingement, or necessitate a second operation for the removal of a hook plate (Carofino and Mazzocca, 2010; Flinkkilä et al., 2002; Kashii et al., 2006; Lyons and Rockwood, 1990; van der Meijden et al., 2012). In recent years, several studies have shown promising results using a precountered, superior clavicle locking compression plate (LCP) with a lateral extension when performing internal fixation of lateral clavicle fractures (Beirer et al., 2014; Schliemann et al., 2013; Tiren and Vroemen, 2013; van der Meijden et al., 2012). In 2010, Kaipel et al. introduced another, new strategy to treat lateral clavicle fractures by using a double-LCP technique similar to the double-plate technique used in fractures of the distal radius (Babst et al., 2003; Kaipel et al., 2010). The plates used for the double-plate technique are significantly smaller than the one used for the single-plate technique, which makes smaller fracture fragments more accessible for adequate plating. This advantage becomes more distinctive in multifragmentary fractures of the lateral clavicle with smaller fragments. Two other aspects that support the use of the double-plate technique are a) plate removal is required less frequently compared to the single-plate technique according to the authors experience and b) the single-plate technique will not infrequently, with its quite bulky plate, visibly mark the treated clavicle, whereas the double-plate technique offers a more discreet solution to this potential problem.

In the retrospective study of Kaipel et al., stable fixation using the double-plate of all treated fractures ($n = 11$), even in small and comminuted distal fragments, was reported (Kaipel et al., 2010). In addition to these clinically satisfying results, it is of interest to compare the biomechanical behaviour of the newly introduced double-plate technique to a time-tested plate-technique. Accordingly, the purpose of this study was to compare the biomechanical properties of the double-plate technique with anteriorly and superiorly administered, not precountered LCP to the single-plate technique, with a superiorly administered, precountered LCP, in lateral clavicle fractures of Neer Type IIb.

2. Methods

2.1. Specimen and preparation

Twenty right human shoulder girdles with intact CC ligaments and acromioclavicular (AC) joint (MedCure, Portland, USA) were obtained (13 male, 7 female, mean age: 66 years) and stored at −20 °C until 2 days before osteotomy. All the clavicles were free of shoulder pathologies according to the patients' available history. In addition, a gross examination was performed to exclude any pathology of the tissue. Subsequently, a Neer Type IIb fracture-like osteotomy was performed. Here, the conoid tubercle served as an anatomical landmark to reproduce the fracture in an anatomically accurate manner. The fractures were sawn lateral of the conoid tubercle through the trapezoid line, as it would occur with a torn conoid ligament and partly ruptured trapezoid ligament. Additionally, a small fragment was sawn into the inferior part of the lateral fragment, once the medial fragment was dissected. This was performed in a similar manner, like in a previous biomechanical study in which the single- and double-plate technique were compared on artificial bones (Fig. 1) (Suter et al., 2017). Subsequently, the twenty fractured clavicles were randomly assigned into two groups for single- and double-plate technique fixation.

One half of the clavicle specimens ($n = 10$, 4 female, mean age: 59 years) was treated using a single-plate technique. Here, a superior anterior clavicle LCP with lateral extension (05.112.012, DePuy

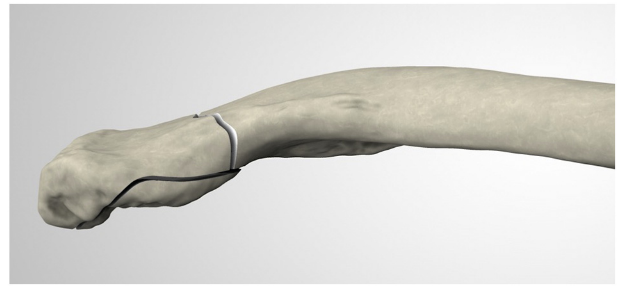

Fig. 1. Schematic diagram of a Neer Typ IIb fracture created with computer-aided design, with an additional inferior fragment. Inferior fracture gaps in cadavers were sawn in a straight fashion with the lateral ending inferior to the AC-joint.

Synthes, West Chester, USA) was fixed using three and six angle-stable bicortical bone screws for the medial and lateral fragments, respectively (3 × Ø = 3.5 mm and 6 × Ø = 2.7 mm, DePuy Synthes, West Chester, USA). The remaining specimens ($n = 10$, 3 female, mean age: 69 years) were treated using a double-plate technique. Here, a locking T-plate (A-4655.15, Medartis, Basel, Switzerland) was positioned on the superior surface and a locking straight eight-hole plate (A-4655.08, Medartis, Basel, Switzerland) on the anterior surface of the clavicle. Both plates were fixed using three bicortical locking screws in each fragment (6 × Ø = 2.0 mm, Medartis, Basel, Switzerland).

The plates used in both techniques were mounted to the clavicles according to their manufacturing manuals. Subsequently, each specimen was again stored at −20 °C until the day before testing.

2.2. Testing procedure

The test setup and the protocol for biomechanical testing were performed according to Madsen et al. (Madsen et al., 2013).

In brief, the custom-made test setup was recreated, which consisted of two parallel, perforated plates, where the scapula was positioned in between and fixed with three threaded rods (3 × Ø = 4.5 mm). Here, special attention was paid, such that the positioning revealed a physiological horizontal alignment of the clavicle. Furthermore, to ensure a physiological alignment, the sternoclavicular joint was mimicked by additionally attaching the medial end of the clavicle to a carbon rod using a cancellous bone screw (length: 32 mm, Ø = 6.5 mm). For testing, the test setup was mounted in a dynamic material testing machine (Instron 8871, Instron GmbH, Darmstadt, Germany) equipped with a 10 kN load cell (Instron 13589, Instron GmbH, Darmstadt, Germany; accuracy ≤0.4%,) 40 mm medially to the fracture gap (Fig. 2).

The testing protocol scheduled a cyclic loading test followed by a load-to-failure test. During the cyclic loading test, a sinusoidal load was applied in the coronal plane for 17,500 cycles at a frequency of 4 Hz ranging between 40 N and 80 N. The number of cycles is an estimate of the arm swinging during the first week postoperatively (2500 strides per day) (Tudor-Locke and Bassett, 2004). According to Lee et al., the 40 N to 80 N range represents the loads acting on the coracoclavicular ligaments due to the weight of the arm during hanging, therefore simulating the arm swinging during walking (Lee et al., unpublished data, 2004) (Lee et al., 2008).

Because no failure of the specimen occurred during the cyclic loading test, a tensile test to failure was subsequently performed. Therefore, a preload of 20–30 N was applied to ensure the same testing conditions at the beginning of each test. Subsequently, the specimen was loaded until failure with a testing velocity of 0.1 mm/s.

For further evaluation, the stiffness at cycles 1, 100 and 17,500 as well as the failure mode, the ultimate tensile load and the deformation at point of failure were determined.

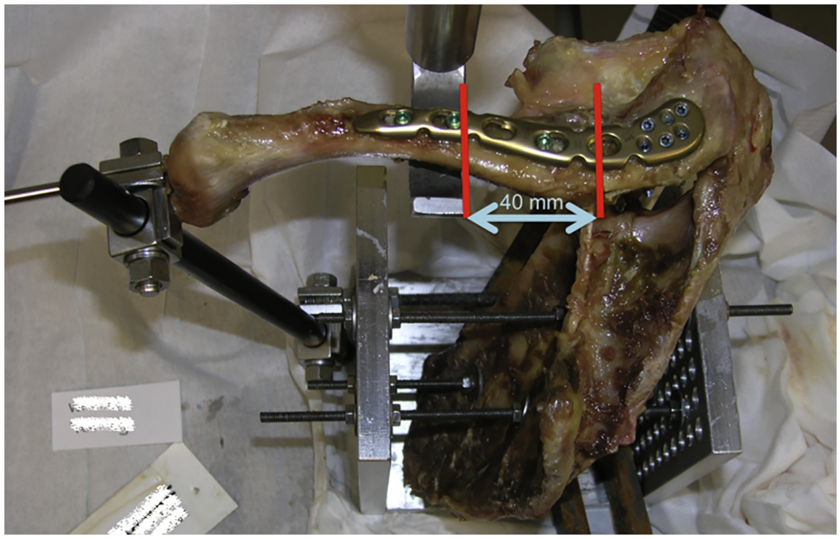

Fig. 2. Illustration of the towing device's position (40 mm medially to fracture) and parallel orientation to the fracture gap.

2.3. Statistics

All means and standard deviations were analyzed for normal distribution using the Shapiro-Wilk test (Shapiro and Wilk, 1965). All further statistical analyses were performed using JMP (Version 13.0.0, SAS Institute Inc., Cary, USA). According to the Shapiro-Wilk test, there was a significant deviation from a normal distribution for stiffness at cycle 1 for the single-plate technique and stiffness at cycle 17,500 for both techniques.

When the data were normally distributed, an unpaired Student's *t*-test was performed. Otherwise, the comparison of the mechanical behaviour of both surgical techniques was performed using the non-parametric Mann-Whitney *U* test. The statistical significant level was set at $P < 0.05$.

3. Results

All 20 specimens were successfully tested within the cyclic loading test without any noticeable damage. At cycle 1, no statistically significant difference regarding the stiffness was found between the two techniques ($P = 0.30$, Table 1). However, during testing, the double-plate technique displayed a significantly lower stiffness for both further evaluation points of cycles 100 ($P = 0.025$) and 17,500 ($P = 0.021$). Failure loads of the double-plate technique were not significantly different compared to the single-plate technique ($P = 0.74$, Table 1 and Fig. 3). However, the deformation at the point of failure was significantly greater for the double-plate technique than in the single-plate technique group ($P = 0.039$, Table 1 and Fig. 3).

The failure mode was recorded by camera and evaluated visually. For the single-plate technique, the failure mode was identical for nine out of the ten specimens. Here, the innermost locking screw appeared to implement a predetermined breaking point in these specimens (Fig. 4). In two of the nine failed specimens, additional pathologies, including a partial tear of the AC-ligament complex and an additional fracture in the lateral fragment, were found after testing. However, it could be observed that these pathologies were not the cause of failure. The other mode of failure seen in the single-plate technique (1/10) was a pull out of the two most medial screws (Fig. 4).

By contrast, there were a broader variety of failure modes in the double-plate technique group. Four specimens failed because of a fracture adjacent to the towing device's position. In a further three clavicles, a fracture gap was found – similar to the most frequent failure mode of the single-plate techniques group – next to the innermost screw (Fig. 5). The other three failure modes in the double-plate technique group were a pull out of the lateral locking screws of the superior T-plate, a displaced AC-joint and a fracture in the superoanterior area between the two plates.

4. Discussion

In order to enhance the comparability of the resulting data of the two different fixation techniques, a pre-existing test setup and loading regime was chosen. Madsen et al.'s test setup and the protocol used for cyclic loading test supposedly simulates one week of incident free rehabilitation (Madsen et al., 2013). At our facility, we allow patients to carry out assisted and active motion in the glenohumeral joint in all directions up to the horizontal level in the first week postoperatively; hence the stress occurring at the fracture site most frequently results from walking and is well simulated by the chosen test setup.

During the cyclic loading test, the single-plate technique displayed a greater stiffness than the double-plate technique. This could have led to the conclusion that single-plate technique is also more resilient in load-to-failure testing. However, this was not confirmed within the subsequent load-to-failure tests. Here, the single-plate technique indeed acted significantly more rigidly at the point of failure than the double-plate technique, but did not withstand significantly higher failure loads.

Table 1
Results of cyclic loading testing (stiffnesses at cycles 1, 100 and 17,500) and the load-to-failure testing (failure load and maximum deformation).

	Single-plate technique (*n* = 10, 4 female; mean age: 59 yrs.)	Double-plate technique (*n* = 10, 3 female; mean age: 69 yrs.)	*P*-value
Stiffness at cycle 1 (N/mm)	72.1 (SD 15.5)	63.9 (SD 6.3)	0.31
Stiffness at cycle 100 (N/mm)	74.0 (SD 15.2)	60.4 (SD 7.8)	0.025
Stiffness at cycle 17,500 (N/mm)	75.5 (SD 13.4)	63.2 (SD 9.1)	0.021
Failure load in N	595.6 (SD 189.6)	563.0 (SD 246.4)	0.74
Max. deformation in mm	15.8 (SD 4.7)	21.0 (SD 5.7)	0.039

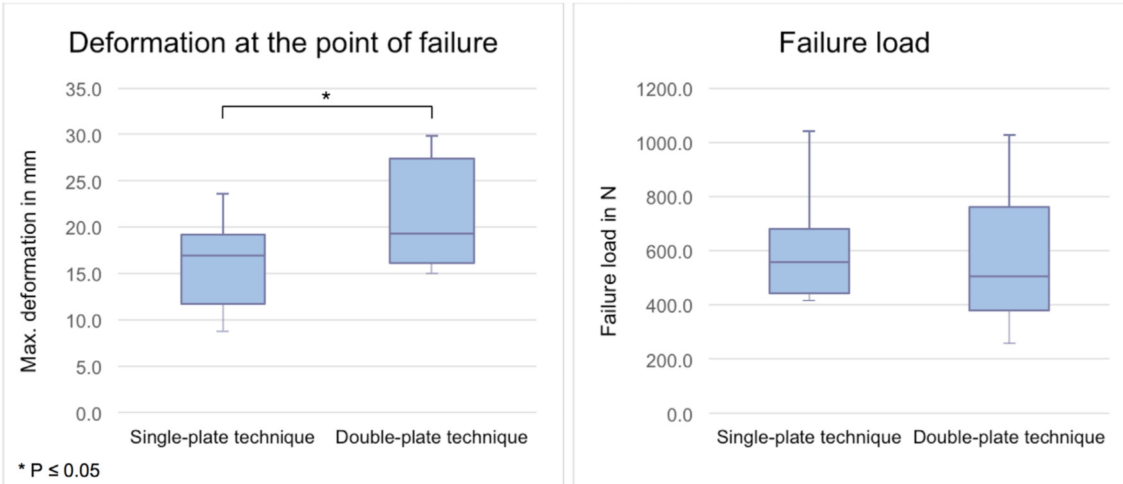

Fig. 3. Box-plots for comparison of "Deformation at the point of failure" and "Load to failure" values.

Therefore, it can be assumed that both techniques provide a stable fixation for Neer Typ IIb fractures during the first week after surgery, if no incident (e.g. a fall) occurs. As seen in the load-to-failure testing, also when an incident, which was similar to our testing set up (e.g. pulling force on the arm), occurs, both techniques presented similar resistance towards failure.

Stiffness at the fracture site is one of many components, which can alter bone healing. It is generally accepted that extremely flexible fixation techniques can lead to a delay in bone healing, compared to rigid fixation. However, a perfect rigidity without movement at the fracture site is hard to achieve (Epari et al., 2007; Mark et al., 2004; Utvåg et al., 2001). A certain amount of motion is additionally helpful for stimulating bone healing.

Nevertheless, the ideal amount of motion (or stiffness respectively) as well as how much motion at what time of fracture healing has not been conclusively identified yet (Augat et al., 1998; Claes et al., 1997; Claes et al., 2002; Epari et al., 2007; Goodship et al., 1993; Kaspar et al., 2005; Krischak et al., 2002; Lienau et al., 2005; Schell et al., 2005). The single-plate technique tested in the current study is a time-tested device, which leads to bony non-union very rarely, as we have found only one case of bony non-union in the literature (Vaishya et al., 2017). With regard to the literature, we feel confident stating that double-plate technique, the more flexible construct, also leads to sufficient stability, because a) constructs with locking plates are believed to lead more likely to too stiff fracture fixation (Bottlang et al., 2009; Gardner et al., 2009; Uhthoff et al., 2006) and b) has shown to achieve regular osseous union in a case series (Kaipel et al., 2010).

However, since we did not measure the motion in the fracture gap during testing, we cannot conclude which fixation technique leads to most adequate stabilisation for bone healing – single or double plate technique. Nevertheless, both techniques lead to a high rate of bony union, which may lead to the assumption that their fixation stiffness

Fig. 4. Modes of failure of the single-plate technique. A) fracture adjacent to the innermost screw (9/10), B) pull out of the two most medial screws (1/10).

Fig. 5. Most frequent modes of failure of the double-plate technique. A) fracture adjacent to the traction device position (4/10), B) fracture adjacent to the innermost screw (3/10).

does not influence bone healing to a clinically significant degree and plate removal shouldn't be performed until.

The failure mode of the single-plate technique can be considered as a limitation of this study. The most frequent failure mode (9/10), a periprosthetic failure, is rarely seen in clinical situations. However, this clinically, rather uncommon failure mode appears to be a well-known problem in the biomechanical testing of clavicle fractures, because it similarly occurred in various other studies (Bishop et al., 2013; Celestre et al., 2008; Demirhan et al., 2011; Eden et al., 2012; Smith et al., 2014). Additionally, the aforementioned failure mode has been reported in two case reports of hook plate fixation (Charity et al., 2006; Haidar et al., 2006). The two most frequent fracture modes of the double-plate technique were fracture adjacent to the traction device position (4/10) and fracture adjacent to the innermost screw (3/10). Because no data were found for the failure modes of the double-plate technique, it could not be determined whether or not the fractures adjacent to the most medial screw represent a typical clinical situation.

Both techniques sufficiently stabilized the actual fracture site, because the most frequent modes of failure did not occur directly at the fracture site (18/20). To be more precise, in the single-plate technique group, all ten specimens failed medial to the fracture site. In the double-plate technique group, seven out of the ten specimens failed medial to fracture site and one lateral to fracture site (displaced AC-joint), which was the clavicle with highest failure load in this group (1027 N).

When combining both techniques, almost all failures occurred at the same site (17/20), which underlines a good reproducibility of the testing setup.

Comparing our test results with those of two studies using a similar test setup, we can conclude that the results of the current study for failure loads and deformation at the point of failure are not inferior, although our specimens displayed less stiffness (Bishop et al., 2013; Madsen et al., 2013). For example, in the study of Madsen et al., the superior LCP failed at a mean load of 401.3 (SD 172 N), resulting in a mean maximal deformation of 7.6 (SD 2.8 mm) and displayed a stiffness of 80.9 (SD 7.8 N/mm). Bishop et al. compared the superior LCP with the hook plate technique, and no significant difference in the biomechanical strength could be determined between these two groups. The superior LCP group withstood a mean of 487.8 (SD 230 N) (Bishop et al., 2013).

Within a previous biomechanical study, the mechanical properties of these two techniques – single and double plate - were compared. In contrast to the current study, testing was carried out using a cantilever bending test and Neer Type IIb fractures were produced on artificial bones. The failure loads seen in the previous testing were substantially lower to the ones in this test series, which might be due to the difference in the test-setup. Double plate technique withstood a failure load of 134.6 (SD 9.45 N), whereas single plate technique failed at a load of 112.1 (SD 12.39 SD). The main findings were a) double plate technique offered a slightly more stable fixation to the fracture as it withstood higher failure loads and more cycles in cyclic loading test and b) also in this test setup single plate technique acted more rigid (Suter et al., 2017).

We are aware that such comparisons only allow very restricted conclusions, because small incongruities (e.g. in length of the lever arm) can already lead to noticeable discrepancies between two observed values. Nonetheless, it is the only way to receive feedback about the validation of the biomechanical performance of a new fixation technique.

An aspect not addressed in this study concerns the fixation of the CC ligaments. In the study of Rieser et al., the single-LCP technique was compared to the single-LCP technique combined with the AC TightRope system for coraclavicular fixation and to the AC TightRope system alone. The combined solution of the single-LCP technique and AC TightRope system displayed the greatest biomechanical stability (Rieser et al., 2013). Additionally, Madsen et al. stated that the single-LCP technique combined with suture anchor CC fixation results in more stable fracture reduction than the single-LCP technique alone. Depending on the integrity of the CC ligaments, additional CC fixation in Neer Type IIb fractures should, therefore, be considered.

Some additional limitations should be noted in the current study. The first applies to the loading regime chosen for the cyclic loading test. The number of cycles applied in this testing setup is an estimate of the arm swinging during the first week postoperatively (2500 strides per day) (Tudor-Locke et al., 2013). However, it takes approximately six weeks until bony union is achieved (Rammelt et al., 2004). Consequently, it would also be of interest to investigate the material's behaviour of both techniques over an equivalent simulated loading regime of up to 105,000 load cycles.

Another limitation concerns the lack of variety of biomechanical test setups. Iannolo et al. performed valuable measurements of the forces acting within the middle part of the clavicle during glenohumeral joint motion (Iannolo et al., 2010). They found that the greatest force occurs on the clavicle during abduction of the arm in the axial direction. Therefore, an additional test setup should be included in a further study to investigate the axial compression.

A further limitation practically inherent in a study of this kind is the fact that it is almost impossible to consider all of the components that are involved in the movement of the arm (e.g. muscle tractions) or in the healing process of a fracture site. By reproducing an established test setup, we hoped to gain an insight as to whether our tested techniques exhibit similarly to techniques tested in the same test setup.

A final limitation of our study concerns the sample sizes, which may have resulted in too low a power for assessing minor differences between the two techniques (e.g. stiffness at cycle 1). Nonetheless, we observed significant differences in the stiffness between the two techniques at cycles 100 and 17,500 and in the deformation at the point of failure. The *P*-value obtained from the comparison of failure loads indicates that a significant difference for failure loads could not be stated with more power.

5. Conclusion

Our results clearly demonstrated that the double-plate technique offers a treatment option, which although biomechanically less stiff than the single-plate technique, nevertheless withstands similar failure loads and numbers of cycles. Both techniques provided sufficient fixation to the fracture site to endure the cyclic loading test, which is supposed to simulate an incident-free week postoperatively. Compared to the results data of similar testing setups, both techniques overcame higher failure loads in load-to-failure testing.

When considering the biomechanical properties shown in this testing setup, the lower plate-removal rate and the frequently more satisfying cosmetic outcome of the double-plate technique provides a valuable option for instable lateral clavicle fractures, particularly when smaller and multiple fragments are present.

Further clinical research on the use of the double-plate technique and biomechanical testing, in general, in unstable lateral clavicle fractures are desirable, because there is only very limited data available on this topic.

Author statement

C.S., M.v.R., M.M., L.D. and A.M.N. conceived and planned the experiments. C.S., M.v.R. and N.S. contributed to the sample preparation. M.v.R., D.W. and N.S. carried out the experiments. C.S. and D.W. analyzed the data. All authors contributed to the interpretation of the results. C.S. led the writing of the manuscript; all authors contributed. All authors had full access to all the data and take responsibility for the integrity and the accuracy of the data. All authors have approved the final version of the manuscript.

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