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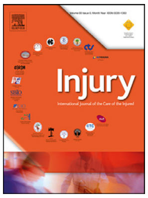

Biomechanical comparison of different cerclage types in addition to an angle stable plate osteosynthesis of distal tibial fractures

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ABSTRACT

Background: Different stand-alone cerclage configurations and their optimal twisting techniques have been investigated over the years. This study tests for the stabilizing effect of different supplemental cerclage materials in combination with locked plating of distal tibia fractures.

Methods: Locking plate fixation of a distal tibial spiral fracture was tested as stand-alone and with supplemental cerclage materials (one cable, two cables, wire, fiber tape). Construct stiffness and fracture gap movements were investigated under quasi-static and dynamic loads and compared to the stand-alone locking plate.

Results: With each of the tested cerclages, stiffness was significantly higher than for a solitary plate osteosynthesis. Most reduction in fracture gap movement was achieved by cable cerclages, followed by double-looped wire and double-looped fiber tape cerclages. Under dynamic loading an additional cable cerclage reduces excessive gap movement.

Conclusion: Compared to solitary plate osteosynthesis all supplemental cerclage materials were generally superior with reduced fracture gap movements whereas cable cerclages showing the greatest stabilizing effect.

Introduction

Cerclage wires have long been used for the fixation of diaphyseal fractures, either alone or in combination with other fixation methods [1,2]. Due to large mechanical stability provided by bone plates and intramedullary nails, nowadays cerclage wires play no important role as solitary fracture fixation device in shaft fractures. However, cerclages are frequently employed as supplementary fixation tools to aid reposition, improve alignment and increase fixation stability. In particular femoral shaft, subtrochanteric and periprosthetic fractures benefit from supplementary cerclage fixation [2–6]. Also in supracondylar femoral shaft fractures, additional wire cerclages proved to be more than just a reposition tool and increased the overall strength of the osteosynthesis construct [7]. Despite promising clinical reports in recent literature [6,8] the use of cerclages for fracture fixation remains controversially discussed. Major concerns include potential metallosis [9,10] or soft tissue damage with periosteal ischemia, which is actually not justified according to a recent literature review [11].

Improved stability of diaphyseal fractures might potentially be beneficial for the fixation of distal tibia fractures. Especially geriatric patients [12] can hardly adhere to post-operative weight-bearing restrictions [13,14] and might benefit from enhanced implant stability due to supplemental cerclage wiring. In a distal tibia fracture model it was recently shown, that in combination to angle stable plate osteosynthesis an additional cable cerclage increases axial stiffness and significantly reduces shear movements to a clinically relevant amount [15]. From a biomechanical point of view, this would allow immediate weight-bearing as tolerated.

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Beside well-known steel cable and wire cerclages, further approaches like suture wires exist as supplemental fixation tools [16–18]. These cerclage materials differ in their locking mechanism and mechanical behavior under induced load. For stand-alone cerclages relevant studies exist, comparing biomechanical performances of different cerclage configurations and their twisting [18–21]. However, none of these studies showed a stabilizing effect in combination with locked plating of the distal tibia.

The aim of this study was to investigate the stabilizing effect of three different supplemental cerclage materials in combination with locked plating in a clinically relevant distal tibia fracture model and compare these results to solitary plate osteosynthesis. We postulate that under clinically relevant loads different types of cerclage materials reduce interfragmentary movements to different amounts, but are generally superior to solitary plate osteosynthesis. Moreover we assume that under cyclic loading a supplemental cerclage prevents from excessive interfragmentary movement and lowers the permanent loss of reduction.

Materials and methods

Synthetic composite tibiae were chosen as bone surrogates for this study (large left tibia, fourth generation, Sawbones Europe AB, Malmoe, Sweden). As described in detail in a recent study [15], a reproducible spiral fracture (AO/OTA 42-A1.1c) was cut at the distal third of the shaft. With a template the fracture was anatomically reduced and stabilized by a metaphyseal locking plate (424.814, DePuy Synthes Companies, Oberdorf, Switzerland) with standard screw configuration by an experienced surgeon (SF) (Fig. 1A). To model imperfect fracture surfaces a gap of 1 mm was left that was subsequently reduced by the cerclage. A reproducible plate-to-bone distance was achieved with a 2 mm spacer at the level of the fracture and guaranteed sufficient space for cerclage wiring.

Eight plate-bone constructs were tested as solitary osteosynthesis (Solitary Plate) and subsequently the following cerclage types and configurations were placed below the plate at the same level of the fracture (Fig. 1): first, a steel cable cerclage (Cable+Plate) (298.801.01, ø 1.7 mm, DePuy Synthes Companies, Oberdorf, Switzerland) was tightened at manufacturer's recommended 50 Nm and closed by crimping. Next, two steel cables of identical type (2Cables+Plate) were looped 10 mm more proximal and 10 mm more distal around the fracture zone. Third, a double-looped steel wire cerclage (Wire+Plate) (291.130, ø 1.5 mm, DePuy Synthes Companies, Oberdorf, Switzerland) was placed. To represent surgical conditions, the wire was tightened manually with pliers under permanent tension and with a torque limiter a consistent torque was provided for all samples. After closure, the symmetrical twist was bent downwards. Finally, a fiber tape cerclage (FiberTape+Plate) (AR-7267T, TigerTape cerclage suture, Arthrex, Naples, FL, US) made of ultra-high molecular weight polyethylene and polyester was looped twice around the fracture zone as recommended by the manufacturer. For closure the cerclage suture was shuttled through the pre-tied knot, tightened at 50 Nm and secured by two alternating half-hitches according to the manufacturer's recommendation.

Mechanical testing was performed on a servo-hydraulic testing machine (Instron 8874, Dynacell, measuring range ±10 kN, accuracy ±2% and ±100 Nm, accuracy ±1%, Instron Structural Testing GmbH, High Wycombe, UK) with cardan joints on the proximal and distal side to avoid constraint forces (Fig. 1F). To mount the sample, the tibia was embedded proximally and distally in polyurethane (RenCast FC 53 A/B + Füller DT 082, Huntsman, The Woodlands, TX, US) with the shaft aligned vertical. Prior to embedding, the plate and the screw tips were sealed with modeling clay to avoid embedding of the implant.

Clinically relevant loads were applied by 750 N axial load and ±7 Nm torsional load acting on the proximal embedding [22]. Positive applied torsion represents external rotation and resulted in fracture gap closing, while negative torsion represents internal rotation and opened the fracture gap. To settle the construct and prior to main testing, a 10-200 N sinusoidal load was applied for 100 cycles at a frequency of 1 Hz. To investigate the effect of different load patterns, the samples were tested under the following quasi-static load scenarios: pure axial loading (750 N), pure positive torsion (+7 Nm) and pure negative torsion (-7 Nm). As the samples were loaded in the linear elastic region, the tibiae were reused for testing of the defined configurations with n = 8 for each group.

Based on quasi-static test results, two groups were identified to be tested under combined axial and torsional dynamic load in a subsequent test series (n = 4 Solitary Plate; n = 4 Cable+Plate). To mimic a physiological and clinically relevant load pattern, axial sinusoidal load started at partial weight-bearing loads between 50 N (valley) and 200 N (peak) at 1 Hz. Additionally, alternating

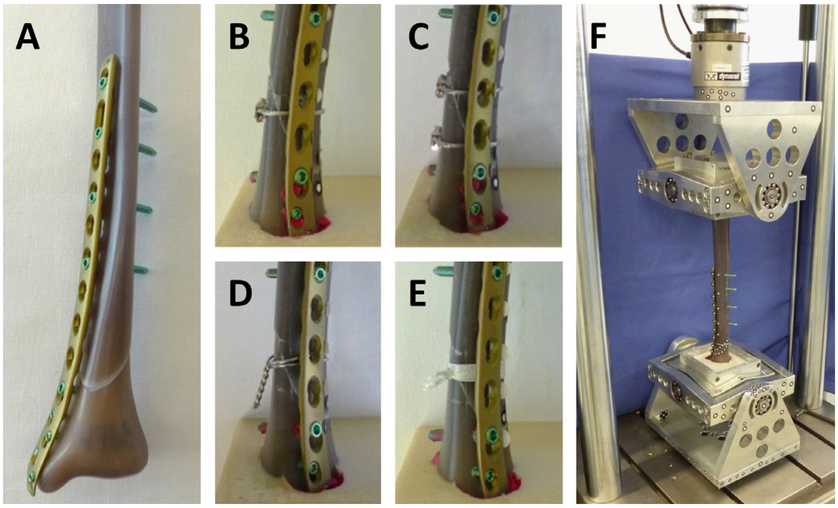

Fig. 1. Sample configuration and test setup: Fractured Sawbones tibia instrumented with a metaphyseal medial locking plate in frontal view (A, Solitary Plate). Medial views on the samples treated with a supplemental cable cerclage closed with a crimp mechanism (B, Cable+Plate), two cable cerclages (C, 2Cables+Plate), a double-looped wire cerclage with the twist bent downwards (D, Wire+Plate), and a double-looped fiber tape cerclage fixed with a knot (E, FiberTape+Plate). Mechanical test setup with proximal and distal cardan joints (F).

positive and negative torsion of ±4 Nm were applied at a frequency of 0.5 Hz. After every 1000 cycles axial peak load increased by 50 N, while torsion remained constant. Termination was defined as either catastrophic failure of the construct or when reaching a peak load of 2000 N.

Both fracture fragments were equipped with adhesive marker points, which were tracked by an optical 3D-motion tracking system (ARAMIS Professional 5M, GOM GmbH, Braunschweig, Germany). Fracture gap was analyzed for translations and rotations based on a coordinate system oriented along the shaft axis representing the vertical axis. Shear movement was defined as movement in horizontal plane. Axial stiffness was calculated by the linear slope of the force-displacement data of the pure axial load ramp. Using the motion tracking software (GOM Correlate Professional, GOM GmbH, Braunschweig, Germany) interfragmentary movements were analyzed at 750 N and ±7 Nm for quasi-static tests and 2000 N after dynamic loading. Plastic deformation after 2000 N was defined as residual movement at 50 N load valley.

For statistical analysis, data were tested for normal distribution with Shapiro-Wilk test. Axial stiffness as well as quasi-static movements were compared to Solitary Plate group using Wilcoxon test and dynamic results were compared using Student's t-tests (SPSS Statistics, Version 26, IBM, Armonk, NY, US). Values are given as mean and standard deviation and alpha level was set to 0.05.

Results

With each tested additional cerclage axial stiffness was significantly larger than for solitary plate osteosynthesis ($p \leq 0.012$; 983 ± 355 N/mm Solitary Plate; 2882 ± 739 N/mm Cable+Plate; 4103 ± 1002 N/mm 2Cables+Plate; 1597 ± 452 N/mm Wire+Plate; 1322 ± 374 N/mm FiberTape+Plate).

Under quasi-static pure axial load, Solitary Plate experienced axial movement of 0.9 ± 0.2 mm and shear movement of 0.3 ± 0.2 mm (Fig. 2). Each additionally applied cerclage reduced axial movement significantly compared to Solitary Plate ($p \leq 0.012$), while shear movements were significantly reduced for both cable cerclage groups only ($p \leq 0.035$).

Under pure torsional loading, largest rotations around the shaft axis occurred for Solitary Plate at gap opening with 7.6°±0.5° (Fig. 3). Gap closing led to compression of the fracture zone with lower rotation of 3.2°±0.7°. Each supplemental cerclage reduced rotational movements significantly for gap opening ($p \leq 0.012$) as well as for gap closing ($p \leq 0.017$). Smallest rotations were measured for both cable cerclage groups, followed by wire and fiber tape cerclages. Shear movements under positive torsion (gap closing) remained rather low for Solitary Plate (0.5 ± 0.2 mm) and were further reduced by more than 50% with each applied cerclage ($p \leq 0.012$). Under negative torsion (gap opening) shear movements increased up to 3.2 ± 0.1 mm for Solitary Plate and were significantly reduced below 0.5 mm for both cable and wire cerclages and below 1 mm for fiber tape cerclages ($p \leq 0.012$).

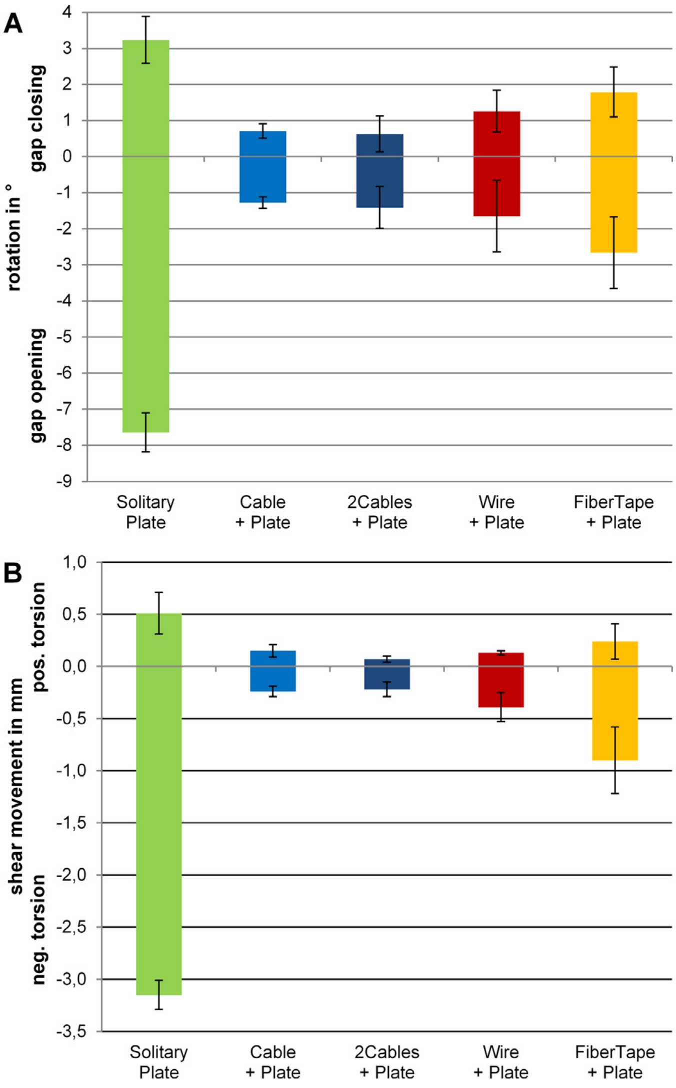

Fig. 3. Quasi-static test results for fracture gap movements under ±7 Nm pure torsional loading. Rotations around the shaft axis (A) are shown by gap closing (positive torsion) and gap opening (negative torsion). Shear movements in horizontal plane (B) are given for positive and negative applied torsion. Values are given as mean ± standard deviation.

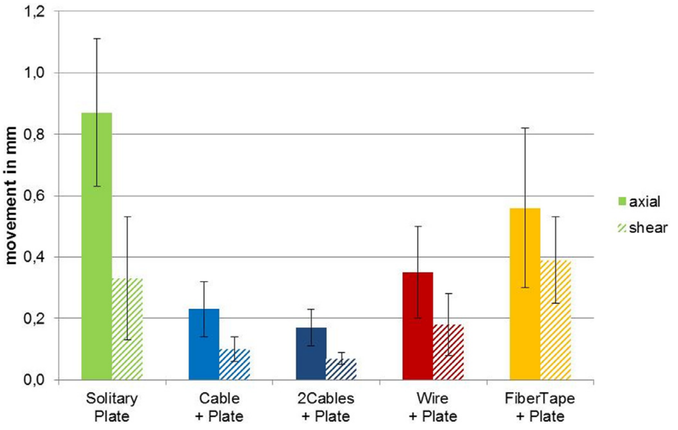

Fig. 2. Quasi-static test results for axial (solid bar) and shear (striped bar) movement under 750 N pure axial loading. Values are given as mean ± standard deviation.

Focusing on cable cerclages only, addition of a second cable reduced shear movements under torsion ($p \leq 0.018$), but had no discernible effect on interfragmentary movement generated by axial loading ($p > 0.05$).

All tibiae survived the dynamic load protocol up to 2000 N (36,000 cycles), except for one Solitary Plate sample that failed at 1950 N due to plate breakage at the most proximal small fragment screw. Under maximum loading, axial and shear movements were significantly reduced by approximately 68% with an additional cable cerclage (axial from 2.5 ± 0.9 mm to 0.8 ± 0.2 mm, $p=0.043$; shear from 1.8 ± 0.3 mm to 0.6 ± 0.1 mm, $p=0.004$) (Fig. 4). Respective amounts of plastic deformation as a measure of loss of reduction were generally low. For the Solitary Plate loss of reduction amounted to 0.4 mm and was reduced by 50% with

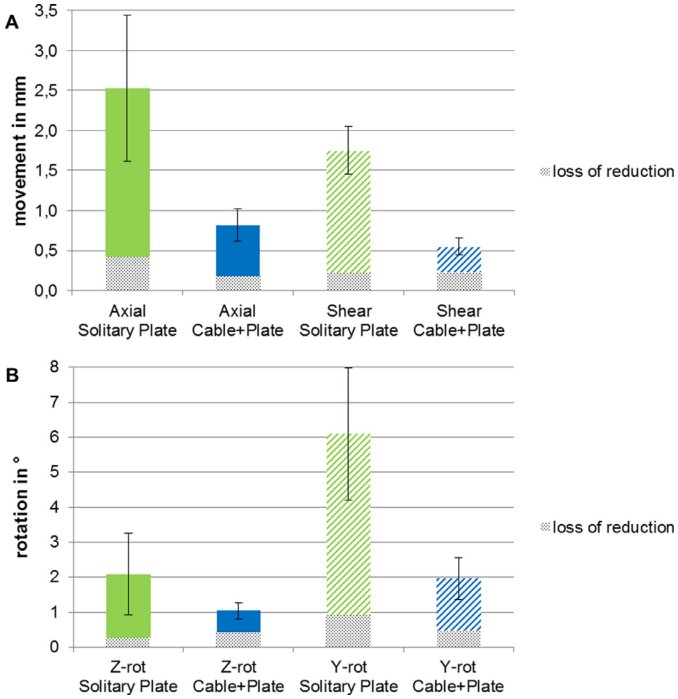

Fig. 4. Results at maximum applied load (2000 N, -4 Nm) following the dynamic load protocol for axial and shear movements (A) and rotational movements (B) around the shaft axis (Z-rot) and the sagittal axis (Y-rot) for Solitary Plate and Cable+Plate groups. Values are given as mean ± standard deviation. Additionally the loss of reduction (plastic deformation) is displayed (dotted proportion).

additional cable fixation. Rotations were highest for Solitary Plate around the sagittal axis with 6.1° ± 1.9° and approximately 1° of permanent loss of reduction. Cable+Plate lowered this rotation by 67% to 2.0° ± 0.6° (p=0.035). Rotation around the shaft axis was minimized to 1.0° ± 0.2° by Cable+Plate and increased by 110% to 2.1° ± 1.2° with Solitary Plate (p=0.221). Plastic deformation remained negligible below 0.4°.

Discussion

This study demonstrates a substantial stabilizing effect of additional cerclage wiring in locked plating of distal tibia spiral fractures. All tested cerclage materials showed different reduction in interfragmentary movement and were generally superior to solitary plate osteosynthesis. Largest reductions in movement were achieved by either one or two steel cable cerclages. While previous studies focused only on stand-alone cerclage configurations and their optimal knot and twisting techniques [19,20] our study provided a comparison of different cerclage types in a clinically relevant fracture model. Since use of cerclage wires as additional fracture stabilizing tools is still controversially discussed, this study provides further information on the understanding of cerclages and their mechanical benefit in combination with locked plating.

Our results demonstrate that limited movements due to additional cerclage wiring come along with increased stiffness. For fracture gaps ≤3 mm, stiffness values above 2500 N/mm are said to promote good healing [23]. In our fracture model with ≤1 mm gap this favorable stiffness was reached in both cable cerclage groups only. However, further research is needed to properly interpret these data for clinical relevant settings. The key to achieve a good surgical outcome and physiological foot loading is a proper fracture reduction with correct three-dimensional restoration of the tibia axis [24]. Furthermore the osteosynthesis should reduce shear movement to a minimum to avoid healing delays and improve callus formation [25,26]. Recently, a similar study demonstrated that supplemental cable cerclages reduce interfragmentary movements to a clinically relevant amount and from a biomechanical point of view immediate post-operative weight-bearing as tolerated is allowed [15]. In the current study significant reduction in shear movement was achieved by all cerclage groups compared to Solitary Plate, except for Wire+Plate and FiberTape+Plate under pure axial loading. From a biomechanical aspect, cable cerclages should be preferred to wire or fiber tape cerclages, as they show highest stiffness and largest reduction of shear movements. Importantly, our findings demonstrated that addition of a second cable cerclage does not improve the mechanical performance but may increase soft tissue irritation and invasiveness.

The superiority of cable cerclages in terms of stiffness and stability compared to wire or fiber tape cerclages might be explained by the difference in material and their twisting. For both steel cerclages (cable and wire) the closing mechanism is supposed to be the decisive factor [20]. While cables are closed at recommended 50 Nm by crimping, wires are tightened manually with pliers and twisted under permanent tension. To achieve a stable and long lasting twist, it was perpendicular bent downwards [20]. Despite this thorough application we observed higher interfragmentary movements for wire cerclages than for cable cerclages, which is in accordance to previous findings [19,20]. This implies that the knot plays a key role in maintaining stability and wires are more prone to loss of pretension. Another decisive factor might be that relatively smooth and flexible cables can adapt more easily to the irregular bone surface and reach higher amounts of bone-cerclage contact [27]. Lenz et al. found that double-looped wire cerclages are comparable to single cable cerclages, which might be true for stand-alone cerclage testing, but in combination with locked plating this finding cannot be confirmed by our results [19].

Least reduction in movement was identified for fiber tape cerclages, which is contrary to previous observations [17,18]. According to Westberg et al. sutures are comparable or superior to wire cerclages in simplified tension tests [18]. Although a standardized knot procedure and tightening at 50 Nm allow comparability to the other cerclage types, we assume that its polyethylene and polyester material facilitates more elasticity. Their mechanical benefit as supplemental fixation tools to plate osteosynthesis at distal tibia fractures should be interpreted carefully and needs further research. Suture cerclages represent common fixation techniques in shoulder arthroplasty [28,29] and cruciate ligament reconstruction [30], but their application in lower limb fractures should be considered with caution [16].

To further investigate the superior stabilizing effect of cable cerclages, they were compared to Solitary Plate group in a stepwise increasing load protocol. Since post-operative management still recommends weight-bearing restrictions, this protocol started at partial weight-bearing loads and covered full and also excessive weight-bearing up to 2000 N. Supplemental cable cerclages reduced excessive movements and contributed to the overall implant stability during cyclic loading. The remaining amount of deformation after loading gives information about loss of reduction and was highest for Solitary Plate in axial movement (0.4 mm) and in rotation around the sagittal axis (0.9°). Against our assumption, a similar loss of reduction was found for Cable+Plate. One possible reason could be the multiple filaments of the cable that marginally realign under tension. To what extent these findings are transferable into clinical settings and whether similar results are achieved by wire or fiber tape cerclages have to be investigated in further studies.

Despite promising results in recent literature, the fear of periosteal ischemia due to impaired blood supply is still a major argument for refusal of supplemental cerclages. However, in a recent review the harmful effect of cerclages on osseous blood supply and impairment of fracture healing could not be affirmed [11]. Other studies confirmed that radially oriented blood vessels are not disrupted by cerclage wiring [31] and depending on bone geometry cerclages have only partial bone contact so that blood supply is compensated by surrounding vessels [27]. Nonetheless, it is recommended to keep the contact area to the bone as small as possible [32] and careful cerclage selection with tissue-conserving approaches using minimally invasive techniques for the application of cerclages are of utmost importance. With non-metallic cerclages the likelihood of vascular disruption is smaller, however this has to be confirmed in future studies [16].

The used synthetic bone surrogate represents idealized bone structure and therefore might limit our study. However, perceptible loosening or migration of cerclages along the conical and slippery synthetic bone as a possible reason for different stabilizing performances was not observed. Further, after cyclic loading, no cut-through or noticeable abrasion of the synthetic cortical layer was found. A reproducible plate-to-bone distance of 2 mm prevented from mechanically induced metallosis and no metal debris was detected after loading. In clinical situations complications including metallosis should be taken seriously when looping the cerclage and selecting and placing the plate [9]. Also when focusing on the mechanical behavior of the cerclage materials under loading, the bone surrogate represents a reasonable alternative to human specimens and further excludes inter-specimen variabilities [33]. While intramedullary nailing is another treatment option for distal tibia shaft fractures, this study focused on locked plating. Although no muscle forces were considered, physiological and clinically relevant load scenarios were defined [22]. Excessive movement of 6° led to plate breakage in one Solitary Plate sample, thus it was analyzed at the inferior load step at 1900 N. This did not affect the reliability or interpretation of data. Finally, cerclage wiring is obviously limited to oblique or spiral fractures and has no further stabilizing effect in transverse or comminuted fractures.

In conclusion, we demonstrated the stabilizing effect of different supplemental cerclage materials in combination with locked plating in a clinically relevant fracture model of the distal tibia. The findings from this study favor a single cable cerclage rather than wire or fiber tape, as it was able to better reinforce plate osteosynthesis in terms of higher stiffness and reduced interfragmentary movements. Whether our results can be transferred into the clinical routine has to be investigated in further clinical studies.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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