Fatigue Testing of Medial Plates for Treatment of Distal Tibia Fractures

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Abstract: The focus of the article is the biomechanical analysis of new locking compression medial plates. These types of plates are used in orthopedics and traumatology for internal fixation of fractures of the distal tibia. Low-cycle fatigue analyses were performed by repeated axial loading for non-fused bone with complicated comminuted fractures in the distal metaphysis. This type of fracture represents an extreme situation, where all loads between two fragments of the broken bones are carried by the plate. It is also essential to perform fatigue tests before clinical application in hospitals. From the results of the tests, the durability, loadings and fatigue crack parameters were determined and a reliability assessment was performed.

Keywords: Fatigue testing; Internal fixation; LCP; Fracture; Medial plate; Tibia; Biomechanics, Bone.

1 Introduction

In the past, open fractures and ballistic wounds involving long bone fractures were not amenable to standard fracture treatment. They usually resulted in amputation, disability or even death. Today, hospital doctors perform treatment by means of internal fixation. This is a surgical procedure that stabilizes and joins the ends of fractured bones using mechanical devices such as metal plates, pins, rods, wires or screws.

Internal fixators – which include the medial plates examined here – form an integral part of fracture treatment. Their functionality and reliability are essential not only for medical specialists, but also for patients; the plates help to shorten the duration of treatment and reduce the number of complications. It is therefore important to focus on the development of this type of implant in order to improve the quality of medical care. Among the factors affecting the success of treatment are the reliability and strength of medical implants; in the case of failure, it is necessary to repeat osteosynthesis. Unfortunately it is not possible to achieve 100% success rates. However, failure rates can be significantly reduced via the design and optimization of the implants; see [1]. It is also essential for surgeons to work effectively and to a high standard.

Medial plates are angularly stable implants; they are used primarily for extra-articular and simple intra-articular fractures of the distal tibia partially affecting the diaphysis. An example of the use of a medial plate is given in the CT images shown in Fig. 1. The general advantage of angularly stable plates is that force transfer occurs between the plate and the screws, which eliminates friction between the plate and the bone; see [2,3] and Fig. 2. Current developments are focusing on low-profile anatomically shaped plates, in which the shape and size of the plate and the orientation of the screws are adapted as much as possible to the specific anatomic location of the plate.

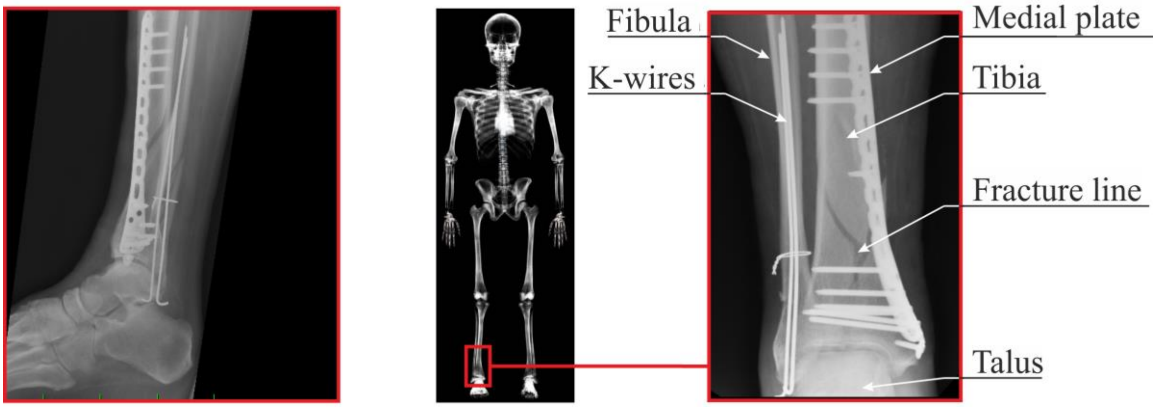


Fig. 1: X-ray images after fixation with a plate.

2 Experiments

The functionality and reliability of medial plates is essential not only for medical specialists, but also for patients; the plates help to shorten the duration of treatment and reduce the number of complications. It is therefore important to focus on the development of this type of implant in order to improve the quality of medical care. It is also essential to perform fatigue tests before clinical application.

The jig used for static and dynamic testing is shown in Fig. 2, including the medial plate fixed to the jig. The plate is fixed to a wooden model using angularly stable screws produced by the company Medin a.s., which were applied using the standard surgical procedure. Based on medical recommendations and surgical practice, the bone was substituted by a jig made of spruce wood, which is the type of wood that best approximates bone tissue. The initial tests were performed using a jig made of beech wood; however, this solution proved problematic due to the properties of the surgical tools and the hardness of the jig (it was not possible to insert the screws into the wood). The shape of the wooden model corresponds with that of a bone surface. Threaded compensation rods were screwed into the model. Thrust washers with spherical joints were screwed onto the protruding ends of the rods. These washers were inserted and fixed into casings. The casings were then clamped into the jaws of the tensile testing machine or pulsator. The jig enables rotation via spherical joints.

A total of three samples were used in order to determine the distribution of total force *Fs* and to perform the subsequent fatigue analysis. In previous experiments, one sample was tested for buckling and stability. The sample was destroyed during the test; the results of the experiment are described in [4].

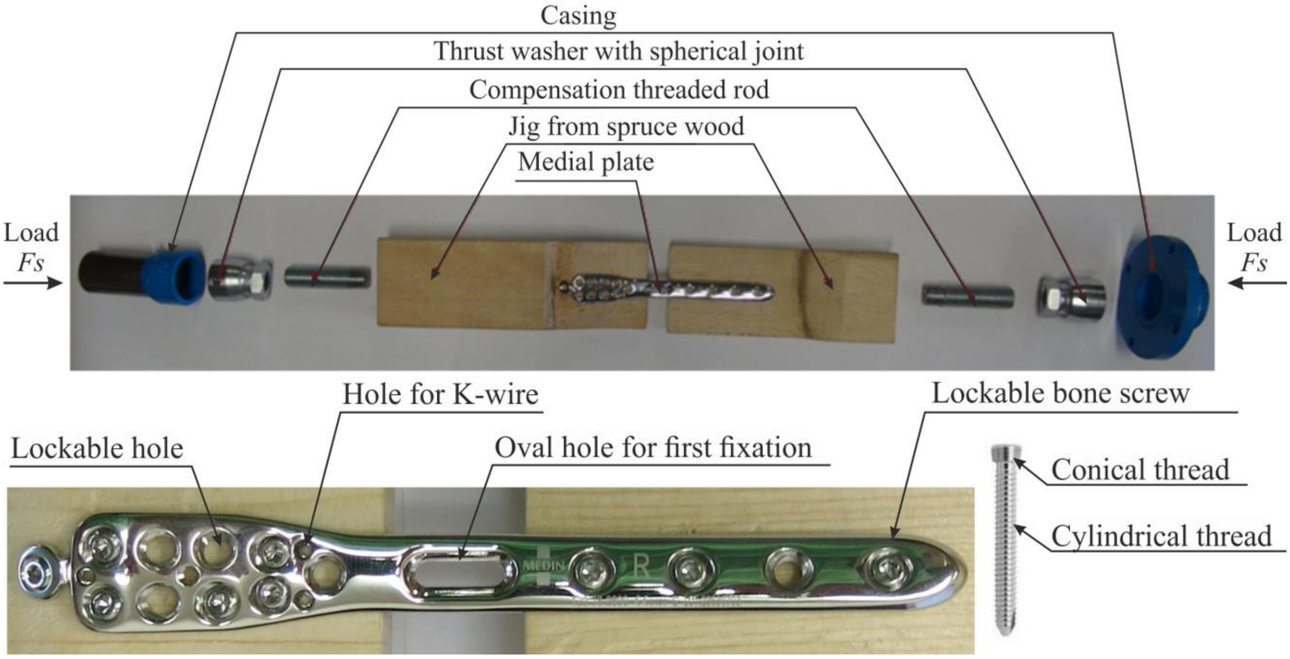


Fig. 2: Medial plate fixed to the jig, lockable screw.

2.1 LOADING OF THE PLATE USING A FORCE SENSOR

In addition to the low-cycle fatigue analysis, the distribution of the total force Fs in the bone and the plate were also analyzed for the possibilities of callus formation in bones (i.e. successful treatment).

First, static measurement was conducted using a tensometric force sensor. It was determined to what degree the total loading Fs was distributed to the bone and the plate after callus formation. The force sensor substitutes the bone at the location of a comminuted fracture; see Fig. 3. Two measurements were taken of each sample. The speed of displacement under loading 0.5 mm/min enabled sufficient control. The force was gradually increased by increments of 50 N up to a maximum value Fs = 400 N. The initial static pressure test (see [4]) indicates that the measurement was conducted in an area of elasticity. Tab. 1 gives an overview of maximum, minimum and mean values for the force transferred via the bone F_K and the force transferred via the plate F_D.

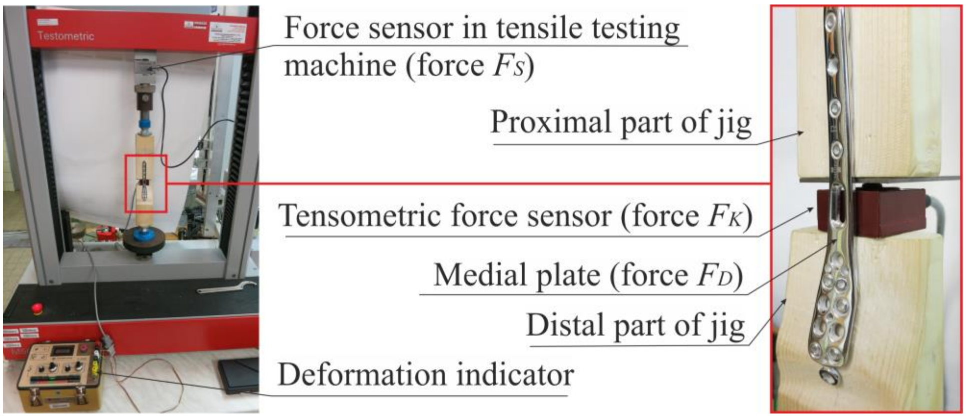


Fig. 3: Loading the plate using a force sensor.

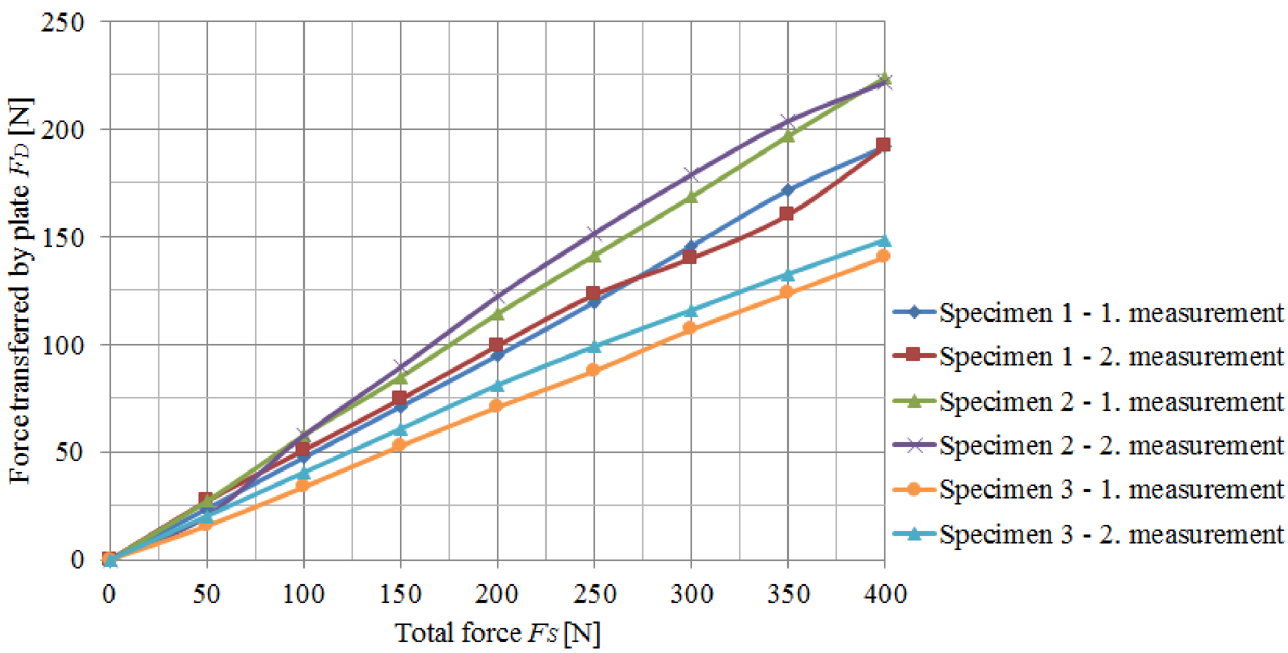


Fig. 4: Loading of the medial plate using a force sensor - Dependency of total force F_S on force in plate F_D.

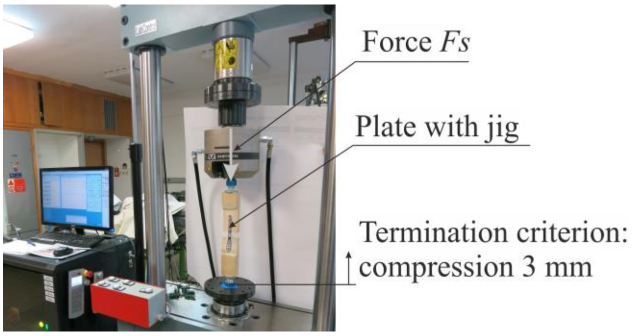
For sample no. 1 the distribution of the total force between the plate and the bone is even ($F_D \approx F_K$). For sample no. 2 more of the force is transferred by the plate, and for sample no. 3 more of the force is transferred by the bone; see Fig. 4 and Tab. 1. These differences are caused primarily by geometric factors, as the individual plates were attached in slightly different ways by the doctor. This corresponds closely with reality; plates are not all applied to the bone identically, because each fracture and each osteosynthesis is different.

Total force F_S [N]	Force transferred by bone F_K [N]			Force transferred by plate F_D [N]		
	Max	Min	Mean	Max	Min	Mean
50	34.3	22.9	27.6	27.1	15.7	22.4
100	66.3	42.3	52.0	57.7	33.7	48.0
150	97.2	60.6	77.7	89.4	52.8	72.3
200	129.2	77.7	102.9	122.3	70.8	97.1
250	162.3	98.3	129.5	151.7	87.7	120.5
300	193.2	121.2	157.4	178.8	106.8	142.6
350	226.3	146.3	185.2	203.7	123.7	164.8
400	259.5	176.0	213.6	224.0	140.5	186.4

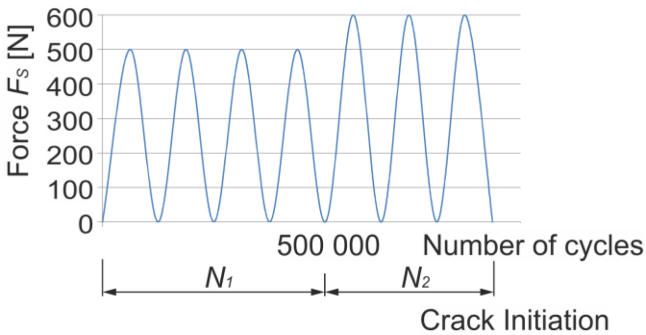
Tab. 1 – Statistical processing of measurement results.

2.2 Fatigue analysis

Fatigue tests of medial plates were conducted using an INOVA ZUZ 100 hydraulic biaxial pulsator; see Fig. 5a. The loading forces applied to the plate were determined from the diagram of the pressure test conducted on the first plate; see [4]. In the first phase, the plate was subjected to cyclical loading by repeated total pressure force F_{S1} = 500 N for the required number of N_1 = 500 000 cycles. If the plate did not fail during the first phase, the loading force was increased to F_{S2} = 600 N; Fig. 5b. This reproduces the real-life situation in which a patient applies increased loading to the bone during the process of rehabilitation. The experiment does not take account of the process of bone healing that occurs during rehabilitation, when part of the loading is gradually transferred to the partially healed bone. The experiment thus reproduces an extreme situation in which the bone callus is not formed and the treatment is unsuccessful (the plate carries the entire load, i.e. (F_D = F_S).



a) Inova ZUZ 100



b) Course of loading

Fig. 5: Fatigue testing of the medial plate.

An example of the fatigue test results is shown in Fig. 6. Cracks appeared at the K-wire holes under the oval hole, and at the oval hole. A total of 3 medial plates for the distal tibia, with 4 holes in the proximal part, were subjected to the experiments. The results were used to determine the distribution of the total force between the bone and the plate and the fatigue resistance of the plate. The individual experiments confirm the high-risk areas, which were also determined by FEM analysis; see [4].

Sample no. 1, which was attached to the jig with only minimal clearance, achieved the best results. Failure did not occur until the second phase, after the force was increased to 600 N. Samples 2 and 3 simulated situations in which the plate does not rest entirely flush with the bone; this geometric difference has a pronounced effect on the fatigue lifespan of the plates. Sample no. 3, which was attached to the jig slightly off the axis, showed greater displacement from the beginning of the experiment; it lasted for approx. 2.6x fewer cycles (N_1 = 161 159 cycles) than sample no. 2, which lasted for N_1 = 422 875 cycles.

In all three samples, cracks appeared at the K-wire holes under the oval hole. A second crack occurred only in sample no. 1 at the oval hole; see Fig. 6. The criterion for terminating the experiment was the compression of the plate by 3 mm. The use of a spruce wood model appears to be sufficient; even in sample 1, which lasted N_1 = 500 000 cycles at 500 N and N_2 = 127 692 cycles at 600 N, the wood showed no signs of wear or failure.

Another similar fatigue analysis or FEM analysis of internal fixators is presented e.g. in [5, 6].

Fig. 6: Results of fatigue test (cracks) for sample no. 1 (locus minoris of the medial plate).

3 Conclusion

This article has presented a fatigue analysis of a medial plate (producer Medin a.s.) for treatment of distal tibia fractures. The experimental data confirm the FEM calculations, see [4], indicating the weakest structural point (locus minoris) of the plate. The experiment also determined the distribution of the loading force in the plate and the bone for cases of successful treatment (i.e. when bone callus is formed and part of the loading is transferred to it).

In all three samples, cracks appeared at the K-wire holes under the oval hole. A second crack occurred only in sample no. 1 at the oval hole; see Fig. 6. In view of the strength analysis (see Fig. 7 and Fig. 8) and the experimental results, alterations to the medal plate were proposed. These alterations should provide greater resistance of the plate to fatigue and loading, as they will remove the stress concentrator at the K-wire holes and enlarge the section at the oval hole.

Future research will focus on fatigue testing of plates produced using various different technologies. Instead of the existing plates – produced by forming and machining – it will be possible to produce plates by 3D printing with titanium powder (using selective laser melting technology).

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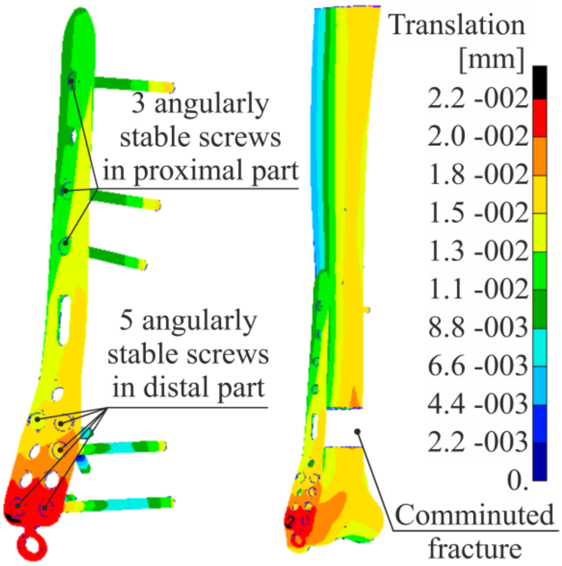

Fig. 7: Course of displacement (non-fused bone, force F = 1 N). [4]

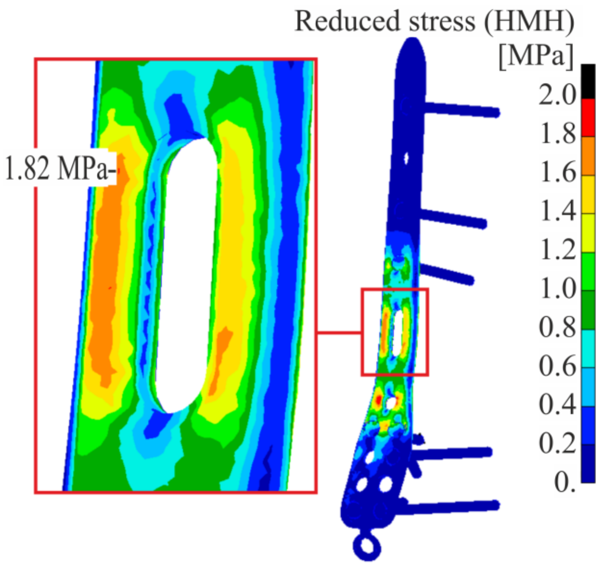

Fig. 8: Reduced stress – HMH hypothesis (non-fused bone, force F = 1 N). [4]

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