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DETERMINING THE STABILITY OF NOVEL EXTERNAL FIXATOR BY USING MEASURING SYSTEM ARAMIS

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Original scientific paper

External fixators are used to treat open and closed fractures of long bones. Stiffness and strength of the fixator greatly affect the final outcome of treatment. An adequate stability of bone fragments provides better fracture healing and early rehabilitation of patients. The aim of this study was to evaluate biomechanical stability of the newly developed unilateral external fixator for proximal tibial fractures. In order to compare the properties of the prototype of the novel fixator and commonly used external fixator Orthofix, static and dynamic tests were conducted. Two different types of static tests were carried out, axial compression test and bending test. In static tests displacements were measured and calculated by using the non-contact optical measuring system Aramis. The results indicated that the novel fixator has better outcomes in bending, while the conventional fixator outperformed the new one in axial compression. There was no significant difference in cyclic test.

Keywords: *external fixator, optical system Aramis, stability*

Određivanje stabilnosti novog vanjskog fiksatora primjenom mjernog sustava Aramis

Izvorni znanstveni članak

Vanjski fiksatori koriste se za liječenje otvorenih i zatvorenih prijeloma dugih kostiju. Krutost i čvrstoća fiksatora uvelike utječu na konačan ishod liječenja. Odgovarajuća stabilnost koštanih ulomaka omogućuje bolje cijeljenje prijeloma i bržu rehabilitaciju pacijenta. Cilj ovog istraživanja bila je procjena biomehaničke stabilnosti novokonstruiranog unilateralnog vanjskog fiksatora za prijelome proksimalne tibije. S ciljem usporedbe svojstava prototipa novog fiksatora s vanjskim fiksatorom Orthofix, koji se često upotrebljava u kliničkoj praksi, provedena su statička i dinamička ispitivanja. Pri statičkom ispitivanju uzorci su opterećeni aksijalno i na savijanje, a pomaci su određeni bezkontaktnim optičkim mjernim sustavom Aramis. Rezultati su pokazali da su biomehanička svojstva nove konstrukcije bolja kod savijanja, dok se konvencionalni vanjski fiksator pokazao boljim pri aksijalnom opterećenju. Pri cikličkom ispitivanju nije bilo značajne razlike u rezultatima.

Ključne riječi: *optički sustav Aramis, stabilnost, vanjski fiksator*

1 Introduction

External fixators are used for simple, rapid and stable fixation of bone fragments or for bone lengthening using pins and wires secured to external frame. There are three basic concepts for safe and effective application of external frames for bony trauma: the pins and wires should avoid damage to vital structures, allow access to the area of injury and meet mechanical demands of the patient and the injury [1, 2]. Nearly all open and closed fractures of the tibial shaft can be successfully treated with an external fixator and is not restricted to any particular group of patients. In order to obtain a successful outcome, it is important that the fixator is applied properly and that much attention is paid to post-operative care [3].

Many studies have focused on the discussion of biomechanical properties and the final outcome of various external fixators [4, 5, 6, 7, 2]. In recent years, intramedullary nailing has become the most popular form of treatment for tibial fractures [3]. The study [8] discussed the outcomes of external fixator and intramedullary nailing of open tibial fractures in relation to time, fracture union, infection rates and complications. The conclusion of this comprehensive review of the literature was that the current literature indicates little evidence to suggest the superiority of one fixation technique over another for open tibial fractures. In contrast, the results of the study [9] showed that the external fixator had the lowest level of stiffness during the compression and three-point bending tests compared to intramedullary nailing, DCP and LCP plates. Intramedullary nailing compared with DCP, LCP is sufficiently strong to fix the tibial proximal fracture. External fixators, compared with internal plates and intramedullary nails, cause less disruption of soft tissues, osseous blood supply and periosteum [10]. Furthermore, external fixators allow adequate adjustability for fracture reduction and the second operation to remove is not required [3, 11]. Both fixation methods, external and internal, with intramedullary nail may represent a definitive treatment of proximal tibial fractures [3]. Therefore, the aim of this study was to evaluate whether the construction of the novel unilateral fixator with circular locking mechanism provides an acceptable biomechanical stability compared to the commonly used external fixator Orthofix® (Orthofix SLR, Verona, Italy). Our hypothesis was that the new construction of the external fixator would show no significant difference in biomechanical stability under static and cyclic loading when compared with Orthofix. Displacements of bone fragments in both cases were determined by using a non-contact optical measuring system Aramis (GOM mbH, Germany), based on digital image correlation. The system is widely used for determination of 3D displacement and strain fields in fracture mechanics [12, 13] and in biomechanics [14, 15, 16, 17].

2 Experimental setup

To test mechanical properties of the novel external fixator, a prototype made of steel ISO 5832-1 was used. The prototype was developed and manufactured by the company Instrumentaria d.d. from Zagreb, Croatia. In order to ensure similar testing conditions, tibial bone fragments were represented by two plastic rods made of polyacetal with a constant diameter of 30 mm, as shown in Fig. 1. The overall length of two bone fragments was set to be 410 mm with a gap of 10 mm half way along, simulating the bone defect. The bone fragments were mounted on the fixator with three 6 mm pins in each bone fragment (Fig. 1).

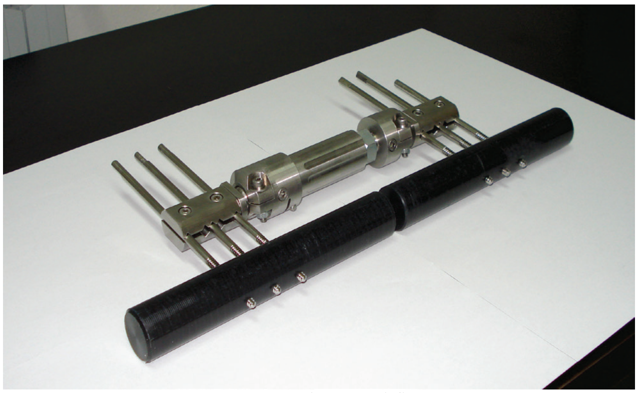


Figure 1 Novel external fixator

2.1 Static test

The static compression test and a four-point bending test were carried out on the Messphysik Beta 50-5 (Messphysik, Austria) screw-drive testing machine. For the axial compression test (Fig. 2) each fixator was mounted vertically in the testing machine. The distance between the simulated bone axis and the longitudinal axis of the fixator was maintained at 60 mm. The quasi-static loading was applied at the bone ending up to the maximum value of 1000 N.

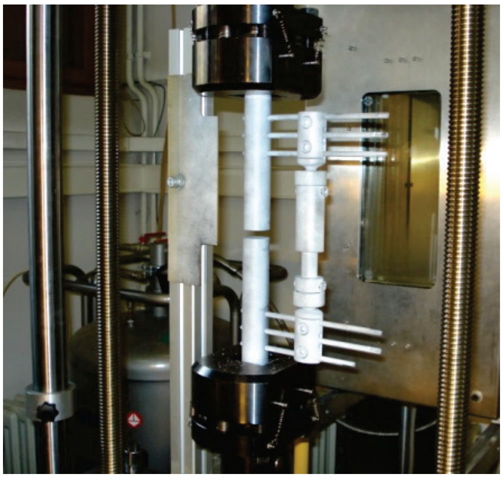


Figure 2 Axial compression test

For the medial-lateral bending tests the four-point bending set-up was used, as shown in Fig. 3. The distance between the supports was fixed at 320 mm and between the loading cylinders at 50 mm. The bending tests were conducted with a maximum load of 250 N. All tests were carried out in force control at a rate of 5 N/s. Each experiment was repeated three times with a new pair of plastic bones in order to avoid the influence of bone models damage on the result of the next measurement.

Displacement fields were determined by digital image correlation (DIC) using the Aramis 4M optical system [18]. The system recognizes the surface structure of the measuring object in digital camera images and allocates coordinates to the image pixels. The first image represents the undeformed state of the object and during deformation of the measuring object further images are recorded. Aramis compares these digital images and calculates the displacement and deformation of the object. In order to measure the displacements and deformation with optical system Aramis, the specimen needs to be prepared adequately. In this case, the specimen was prepared by applying a random spray pattern over the surface in order to clearly allocate pixels in the camera images. This is very important because the surface pattern should show a very good contrast and must be able to follow the deformations of the specimen. The pattern should be small enough to allow a fine raster of calculation facets during evaluation, while on the other hand it should be large enough to be completely followed by the camera.

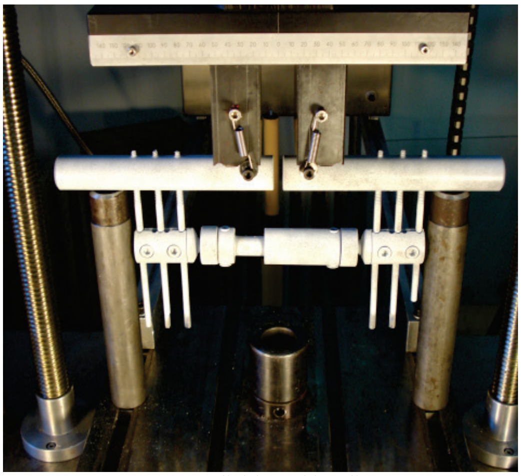


Figure 3 Medial-lateral bending test

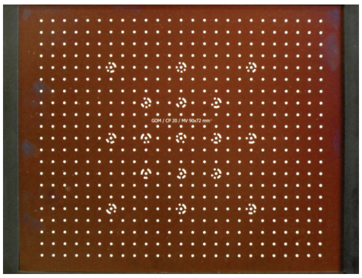


Figure 4 Calibration object

As shown in Fig. 2, a thin unloaded plate with a random spray pattern was fixed on an independent bracket near the specimen. During the measurements, the plate was inside the measurement volume to avoid the error that can occur as a result of unwanted movement of the optical system during the measurement. Before the measurement started the optical system Aramis had been calibrated for the chosen measuring volume by an appropriate calibration object (Fig. 4) [19].

Each model was first recorded in the unloaded state and then recorded every second during loading and unloading. The resulting images were later discretized with square facets (15×15 pixel) that represent the measuring points. Using photogrammetric methods, the 2D coordinates of a facet, observed from the left camera and the 2D coordinates of the same facet, observed from the right camera, lead to a common 3D coordinate.

Optical system parameters that were used at calibration and at measurement were the following:

- lens 50 mm
- measuring volume: 200×150 mm
- measuring distance: 695 mm
- slider distance: 282 mm
- camera angle: 25°.

2.2 Cyclic test

A servo hydraulic testing machine LFV-50-HH (Walter Bai, Switzerland) was used for cyclic testing. The tests were performed with sinusoidal loading between 0 and 200 N in force control at a frequency of 1 Hz for 10 000 cycles. The upper load level was chosen based on previous tests to avoid plastic deformation of the pins. These parameters are common in the literature for cyclic biomechanical testing of the external fixators [4].

The experimental setup was quite similar to the static test except for displacement measurement. In these tests the displacement was recorded with the machine's own software (DionPro+ v4.58).

Statistical analyses were carried out in SPSS 13 (SPSS Inc., Chicago, IL). Differences between the fixators were tested with *t*-test and significance was set at $P<0,05$.

3 Results

The measurement results were analyzed in the measuring system's own software Aramis v6.2. The program interface in the analysis of the results in the bending test is shown in Fig. 5.

Displacements in the vertical direction (*y*-axis, Fig. 5) for both fixators in the bending test are shown in Fig. 6 and in Tab. 1. The results in axial compression are shown in Fig. 7 and Tab. 1. The displacement results in the direction of the *x* and *z* axes show the same tendencies as displacements in the *y* direction and for both fixators and both load cases are shown in Tab. 2 and 3. All these results represent the measured distances between two points, a point on the proximal edge and a fixed point on the distal edge of the fracture gap. Cyclic compression tests were also repeated three times with a new pair of plastic bone fragments like in the static test. The results for the maximum and minimum displacement for one measurement with both fixators after 10 000 cycles are shown in Fig. 8 and the maximum displacements for all three measurements in Tab. 4.

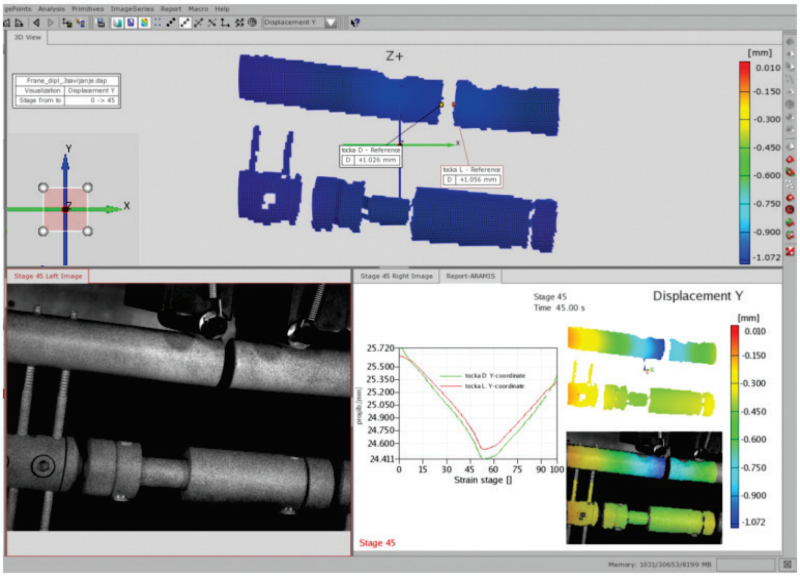
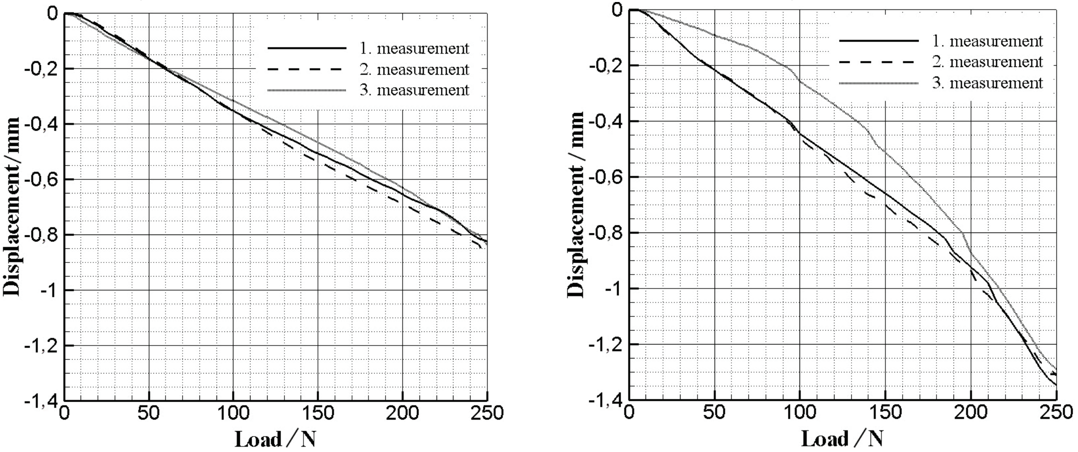


Figure 5 Displacement fields and measuring points in bending test


a) Novel external fixator

b) Orthofix

Figure 6 Vertical displacements during bending test

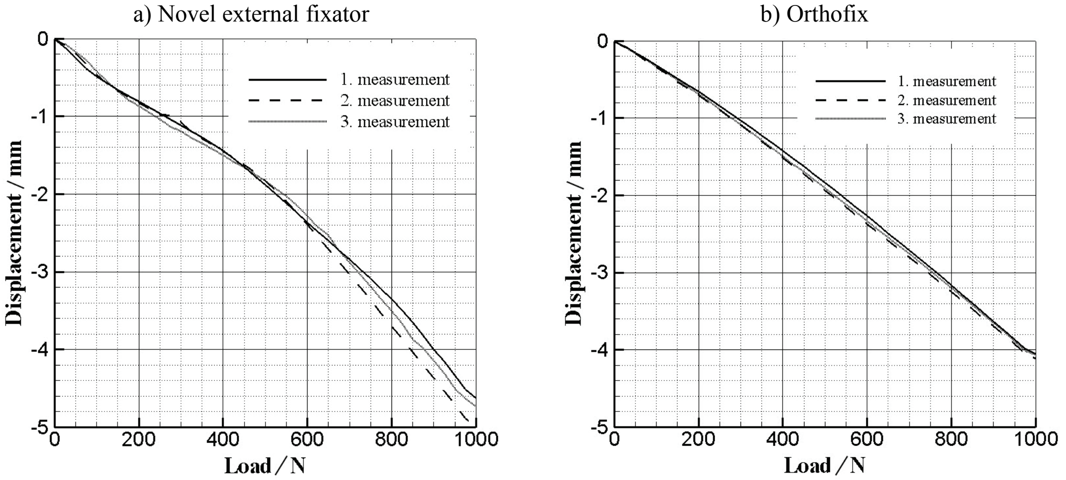

a) Novel external fixator b) Orthofix

Figure 7 Vertical displacement during compression test

Table 1 Maximum displacement in the *y* direction

Measurement	Displacement / mm			
	Compression		Bending	
	N	O	N	O
1.	4,6273	4,0536	0,815	1,348
2.	4,9859	4,1147	0,888	1,309
3.	4,7407	4,0744	0,839	1,291
Mean	4,7846	4,0809	0,847	1,316
St. dev.	0,1833	0,0311	0,037	0,029

N – Novel external fixator, O – Orthofix

Table 2 Maximum displacement in the *x* direction

Measurement	Displacement / mm			
	Compression		Bending	
	N	O	N	O
1.	3,8535	2,0467	0,0668	0,6898
2.	3,8425	1,9678	0,0944	0,8760
3.	4,2703	2,1529	0,0798	0,8761
Mean	3,9888	2,0558	0,0803	0,8140
St. dev.	0,2439	0,0929	0,0138	0,1075

N – Novel external fixator, O – Orthofix

These measurements showed that the digital image correlation using optical system Aramis can be very useful in biomechanical analysis of medical implants.

The repeatability of the measurements is good, even when the measured value is very small.

Table 3 Maximum displacement in the *z* direction

Measurement	Displacement mm			
	Compression		Bending	
	N	O	N	O
1.	3,3091	0,0296	0,0195	0,0767
2.	4,0881	0,0488	0,0219	0,0597
3.	5,4641	0,0333	0,0180	0,0516
Mean	4,2871	0,0372	0,0198	0,0627
St. dev.	1,0912	0,0102	0,0020	0,0128

N – Novel external fixator, O – Orthofix

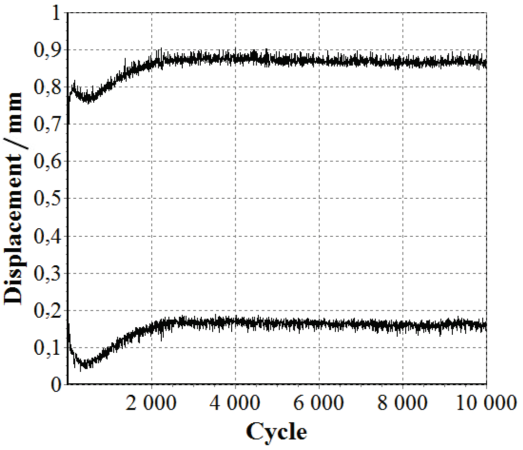
Table 4 Maximum displacement in cyclic test (in mm)

Measurement	Fixator	
	N	O
1.	1,0798	0,9743
2.	0,6634	0,8751
3.	0,5994	0,9188
Mean	0,7809	0,9227
St. dev.	0,2609	0,0497

N – Novel external fixator, O – Orthofix

The results indicate that the prototype has better outcomes in bending. The displacement is less in the direction of all coordinate axes, and the differences are statistically significant: *x* and *y* direction $P < 0,001$; *z* direction $P = 0,006$. Furthermore, a new fixator was also superior in the cyclic test. However, this difference is not statistically significant ($P = 0,447$). The prototype also requires less application time and offers an easier alignment of bone fragments.

a) Orthofix



b) Novel fixator

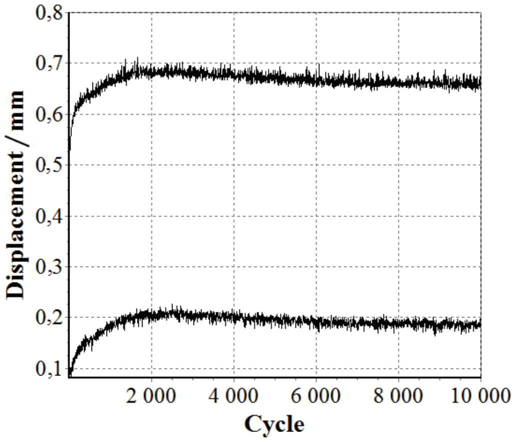


Figure 8 Vertical displacement during cyclic test

In axial compression the novel fixator outperformed the conventional one in all displacements and the differences are as in a bending test statistically significant: *x* direction $P = 0,047$; *y* direction $P = 0,019$; *z* direction $P = 0,002$.

The main drawback of this study is that only a limited number of measurements was made for static and cyclic load. However, the results obtained show that the prototype does not have uniform properties in all positions of the pin clamps, as it is evident from the fragments movement in the direction of the *z* axis in axial compression. These unexpectedly large displacements are probably the consequence of imperfections of the ball-joint.

4 Conclusion

Non-contact optical measuring system Aramis can be successfully used to determine the biomechanical properties of medical implants. A great advantage of this measuring system is that the displacement and strain components of all points within the measuring volume can be determined with a single measurement, which is not possible with traditional measuring devices.

The prototype of the novel fixator does not have the same stability in all positions of the pin clamps which is probably due to imperfections of the ball joint. With additional improvements of the prototype construction and using new materials, a commercially interesting product could be obtained.

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