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Novel external fixation fracture method with circular locking mechanism compared with the application of dynamic axial external fixator on experimental tibial model ensures better stability in bending and favourable performance in dynamic loads

Arsen Pavic[a,*], Janos Kodvanj[b], Srecko Sabalic[c], Fabijan Cukelj[a], Bore Bakota[d]

[a]University Hospital Centre Split, Surgery Clinic, Department of Traumatology, Split, Croatia
[b]Faculty of Mechanical Engineering and Naval Architecture, University of Zagreb, Zagreb, Croatia
[c]University Hospital Centre "Sisters of Mercy", Clinic for Traumatology, Zagreb, Croatia
[d]General Hospital Karlovac, Department of Traumatology, Karlovac, Croatia

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External fixator
Novel external fixator
Dynamic axial external fixator
Dynamic load
Static load
Cyclic load
Biomechanics
Croatia

ABSTRACT

Objective: The aim of this study was to compare the biomechanical properties of a novel tibial external bone fracture fixator with a circular locking mechanism with standard dynamic axial external fixator.
Material and methods: In order to investigate the prototype usability in experimental conditions, a biomechanical study was performed in which 42 polyacetal tubes set in 14 experimental groups and subgroups represented the fractured tibia that were fixed by a standard dynamic axial external fixator and a novel fixator. Displacements under static and dynamic loads were measured, with static ones corresponding to three directions of fragment movement and dynamic simulating the human gait. Analysis was performed in SPSS v13, with significance set at $P<0.05$.
Results: The novel fixator showed biomechanical superiority in "fragments apart" study groups, while the standard dynamic axial external fixator outperformed the novel one in the situations of bending with "fragments in contact" study groups. There were no significant differences in dynamic load, despite better numerical result of the novel fixator.
Conclusion: The novel fixator is expectedly faster applicable and offers greater extent of external fixation flexibility. Further developments of this model thus seems justified in both construction improvement and on clinical application.

Introduction

External fixation is a process of bone fragment fixation using the elements that rely on external mechanical construction, based on three basic approaches: the pins and wires should avoid damage to vital structures, allow access to the area of injury, and should meet the mechanical demands of the patient and the injury.[1,2] The use of external fixation for tibial fractures became widely accepted over the last 30 years.[3,4] However, various approaches that are used are also linked to some limitations, including technical requirements and complexity of fixator application, possibility for misalignment, exposure to radiation and they are often described as non-patient friendly.[5,6] A recent overview of different methods of external fixation suggested that there is an insufficient amount of evidence that would show that any of the approaches should be favoured[7], suggesting that there is a room for further improvements that could reduce these limitations. Therefore, the aim of this study was to investigate the basic biomechanical properties of a novel tibial fracture fixator with circular locking mechanism, designed for faster application and greater extent of fixator flexibility.

Materials and methods

For this study, a novel prototype of an external tibial fixator was constructed and tested. The basic construction requirements for the fixator were to allow greater flexibility (by providing greater angles and mobility of fixator elements), to reduce the time needed for its surgical application and to reduce the need for pins repositioning. These requirements were met with the development of a circulatory locking mechanism, which is locked by a "butterfly" lever (Figure1). The prototype of the novel fixator was produced from the ISO 5832-1 steel.

Biomechanical properties of the constructed novel fixator were compared to a standard dynamic axial external fixator (Orthofix® SLR, Verona, Italy) in an experimental study design.

Polyacetal models (n=42) simulating tibia were used (30mm in diameter each and 200mm in length each) and fixed with six

* Corresponding author at: Clinical Hospital Centar Split, Spinciceva 5, 21000 Split, Croatia. Tel.: +385981956956; Fax: +38521557300.
E-mail address: arsen.pavic@gmail.com (A. Pavic).

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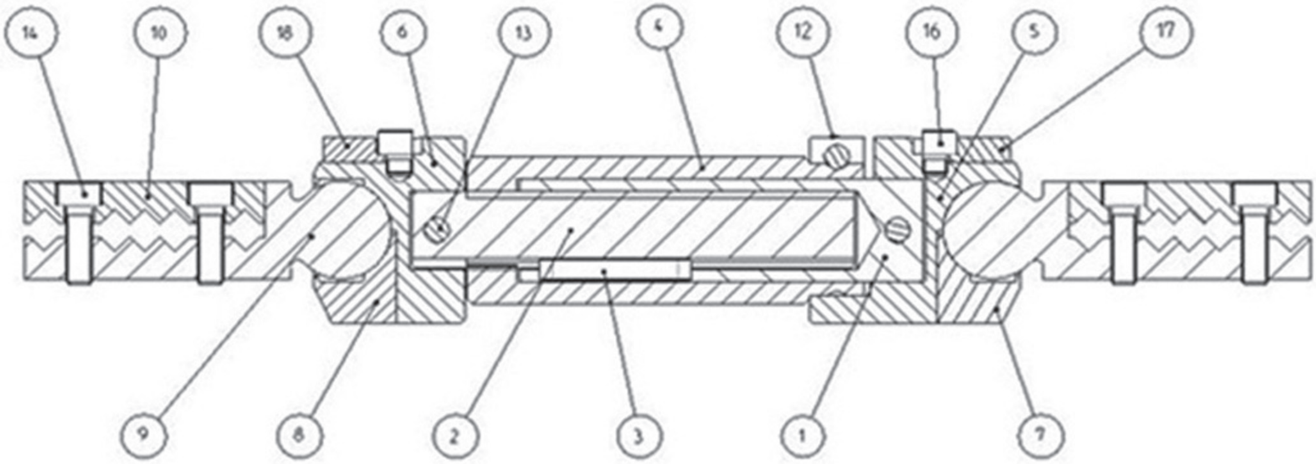

Fig. 1. Schematic cross section of the novel fixator prototype. Elements: 1 fixed rod, 2 moving rod, 3 feather, 4 connecting arm, 5 left joint, 6 right joint, 7 lower left joint, 8 lower right joint, 9 ball, 10 pin holder, 12 arm screw, 13 rod screw, 14 pin screw, 16 securing lever screw, 17 left lever, 18 right lever.

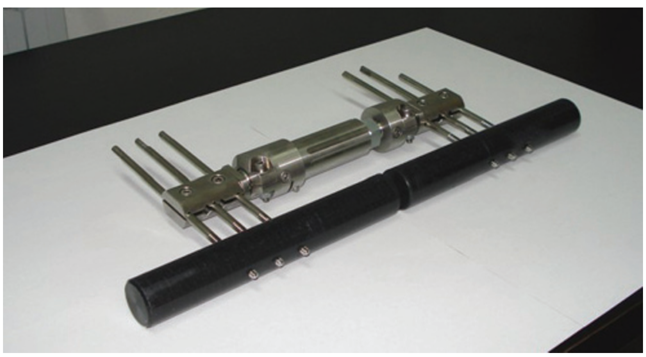

Fig. 2. Model of a novel external fixation fracture method with fragments apart.

Table 1
Fixated tube fragment movements in mm – results from the experimental measurements

Measurement (mm); mean ±standard deviation	Novel fixator	Ortofix® fixator	P (t-test)
Longitudinal movement, bending (y-axis)			
Fragments in contact	0.91±0.01	0.52±0.03	<0.001
Fragments apart	0.85±0.04	1.32±0.03	<0.001
Lateral movement, bending (x-axis)			
Fragments in contact	0.03±0.01	0.02±0.01	0.006
Fragments apart	0.08±0.01	0.81±0.11	<0.001
Forward movement, bending (z-axis)			
Fragments in contact	0.10±0.01	0.09±0.02	0.041
Fragments apart	0.02±0.00	0.06±0.01	0.006
Cyclic loads – Fragments apart	0.78±0.26	0.92±0.05	0.447

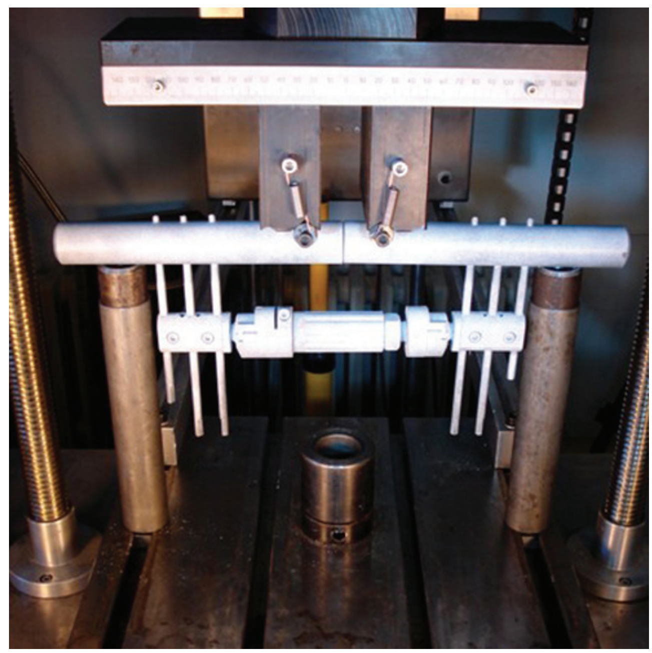

Fig. 3. Dynamic load model- Fragments in contact.

pins (6 mm in diameter each), three at each side of the created fracture.[8] The space between the most inner pins was 186 mm, and the distance between the bone models and the fixator was 40 mm (Figure 2).

Both types of fixators were placed on the bones (polyacetal models) in the same manner and had the same above mentioned characteristics.

Seven groups and subgroups to test were created for each fixator type, with three bones (polyacetal models) for measurements in each group (Table 1).

Two distinct situations were simulated: bone fragments in contact and bone fragments without contact - spaced 10 mm apart (Table 1). Also, two sets of displacement measurements were made; under static and under the dynamic load (Figure 3). The resulting bone fragments displacements were measured in three dimensions (x, y and z), using a screw-drive testing machine Messphysik BETA 50-5 (Messphysik, Austria; Figure 4). The bending tests were conducted with a maximum load of 250N. In all tests the loading and unloading speed was 5 N/s. Dynamic tests were carried out in an asymmetrical fashion, using a servo-hydraulic testing machine LFV-50-HH (Walter Bai, Switzerland; Figure 5), with DIGWIN 2000-EDC120 digital control system. Cyclic tests were perfomed with a sinusoidal loading between 0 and 200N in a force control at 1 Hz for 10,000 cycles. This type of testing simulated human gait (Figure 6).

In the static tests all displacements were determined using the non-contact 3D optical measuring system Aramis 4M (GOM, Germany; Figure 7), with two digital CCD Dalsa Falcon 4M60 cameras, two Titanar lenses, framegrabbers X64CL iPro and Aramis software v 6.2. Measurements were made to correspond to fragment displacement in y, x and z axis. In the cyclic tests the displacements were recorded with the machine's own software (DIONPro+ ver. 4.58). Statistical analysis was based on means and standard deviation calculation, followed by the use of t-test. Analysis was performed in SPSS v13 (SPSS Inc, Chicago, IL), with significance set at P<0.05.