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Assessment of the effect of hybrid implant systems in the Ilizarov fixator on the stability of fragments of the femur subjected to elongation

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Possible ways of improving the stability of the fragments of the femur under elongation by introducing hybrid implant systems (the Kirschner wires and the Schanz screws) into the Ilizarov fixator structure were explored. Laboratory studies were conducted on physical models with the fixator mounted on a pipe section modelling the femur shaft. Ten modifications of the Ilizarov fixator were developed and tested. The designs differed in the kind and configuration of implants. The effect of the developed Ilizarov fixator designs was examined by comparing the coefficients of axial, transversal and torsional rigidity of the structures. The research results clearly show that the Ilizarov fixator's rigidity (particularly transversal rigidity) coefficients can be considerably increased by replacing the Kirschner wires with the Schanz screws or using hybrid systems of these implants. As a result, the stability of the femur fragments improves and so does the quality of the regenerated bone, which makes it possible to reduce the treatment time to a minimum.

Key words: Ilizarov external fixator, femur elongation, mechanical characteristics

1. Introduction

In clinical practice, the external Ilizarov fixator is used in the treatment of complicated fractures and false joints, the correction of limb axis and the elongation of limbs. The fixator is circular and its body is joined to the bone fragments by means of the Kirschner wires, 1.8 mm in diameter. The fixator has a modular design which allows one to create various configurations suited to the needs of treatment. Regardless of its design, each fixator's function is to take over load bearing from the bone and to ensure the dynamization of the bone union site. It is beneficial to the bone tissue growing in the fracture region if axial micromotions of the bone fragments occur. Such micromotions naturally stimulate the callus formation and growth [6], [12]. Whereas relative transverse displacements of the bone fragments affect adversely bone regeneration. Such displacements generate shear stresses in callus which damage the forming bone structure.

Though external long-bone fixators have been used in clinical practice for a long time, treatment is not always fully successful. In the clinical literature, one can find numerous cases of complications associated with limb elongation [8], [10], [11], particularly the elongation of the femur. In such cases, the bone fragments often displace uncontrollably. It is difficult to correct this phenomenon which prolongs treatment.

A proper course of elongation depends on several factors which can be classified in two groups [1]:

- factors associated with the action of the soft tissues during elongation,
- factors associated with the spatial configuration of the fixator.

The effect of the action of the soft tissues on the stability of the Ilizarov fixator–femur fragments system is discussed more extensively in [2] and [7]. Here, the relationships between the fixator's mechanical properties and the stability of the bone fragments are investigated with the focus on the shaping of the characteristics through incorporation of the hybrid Kirschner wires–the Schanz screws systems into the Ilizarov fixator design.

2. Research goal

The goal of the research presented here was to investigate the possibility of improving the stability of the bone fragments by the use of hybrid systems of thin (the Kirschner wires) and thick (the Schanz screws) implants. This need arises from clinical practice: as the thigh bone is subjected to elongation, its upper fragment often displaces uncontrollably to the outside of the thigh when the elongation is performed in the proximal part or the lower bone fragment shifts backwards when elongation is performed in the distal part. This is due to the response of the soft tissues (muscles, skin, blood vessels, etc.) stretched together with the elongated bone and the insufficient rigidity of the fixator at the upper or lower base (a base is an assembly consisting of a ring or half-ring and implants attached to it). As a result, the bone's axis is deformed necessitating additional corrections and prolonging the treatment. One way of preventing such adverse effects can be the application of hybrid implant systems (consisting of both the Kirschner wires and the Schanz screws) at the upper and lower base levels. This problem discussed Caja et al. [4]. Their study show that mechanical characteristics of hybrid fixators make them interesting for clinical use. The use of the Schanz screws at the upper base level enables the introduction of implants into the bone at the place where otherwise it would be impossible to fix them (figure 1). The way of fixing the implants here is different. In the case of a Kirschner wire, both its ends are affixed to the ring (or half-ring). To limit the deflection of this implant under a normal force, the latter is pretensioned with a force of 800–1200 N. In the hip joint region, the Kirschner wires are introduced into the bone in a narrow zone within an angle of 25°–30° whose bisector is within the sagittal plane. In the case of the Schanz screws, one end of the implant is affixed to the ring (or half-ring) and the other end is screwed into the bone. This allows one to introduce implants in a different zone which harmonizes with the anatomy. This zone extends from 90° to 100° and the bisector of the angle between the implants located at its edges coincides with the frontal plane (figure 1a).

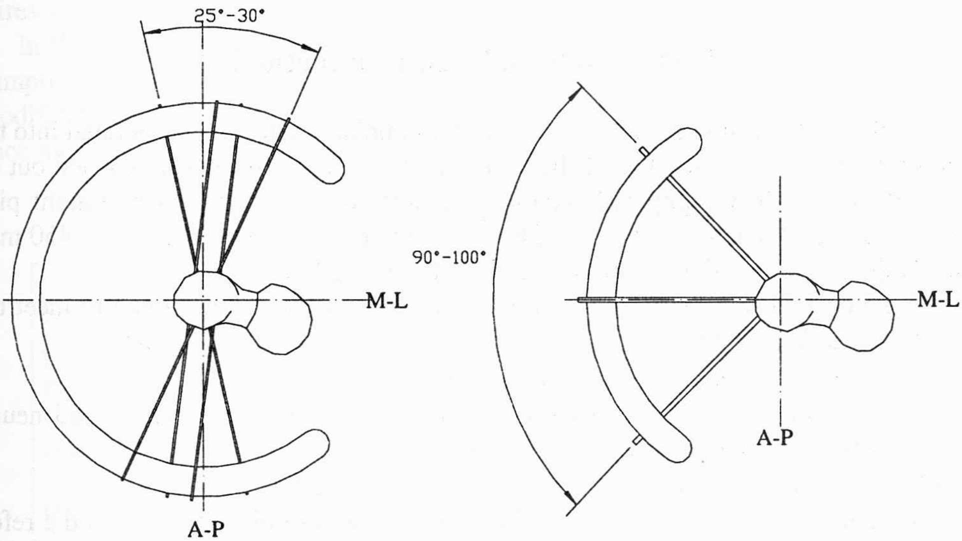


Fig. 1. The Kirschner wires and the Schanz screws introduction into the femur at the upper base levels

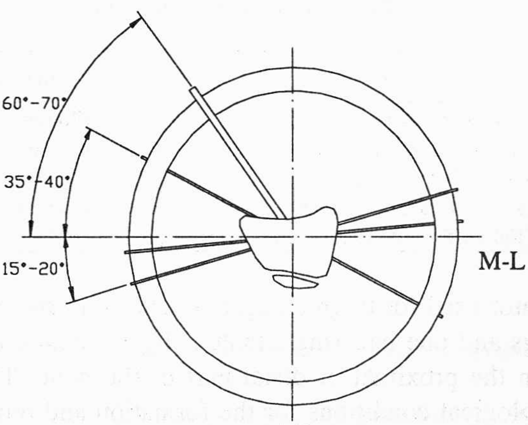


Fig. 2. The Kirschner wires and the Schanz screws introduction into the femur at the lower base levels

In the case of the lower base located in the distal part of the thigh, 3–4 Kirschner wires are introduced into the bone in a zone (having a span of ±30°) situated symmetrically to the frontal plane. If the Schanz screws are used, the implants can be introduced into a much wider zone of 60–70°, but only backwards from the frontal plane (figure 2).

It should be noted that when the Schanz screws are introduced into the Ilizarov system, the number of elements or tools do not have to be increased – standard connectors are used.

3. Materials and research method

In order to determine the effect of the hybrid implant systems incorporated into the Ilizarov fixator on the stability of the bone fragments, some tests were carried out on physical models. The compared fixator structures were mounted on a straight pipe made of Araldit LY554 epoxy resin. The pipe's dimensions were: length $L = 450$ mm, outside diameter $d_z = 30$ mm and inside diameter $d_w = 20$ mm.

Nine modified Ilizarov fixators were prepared for the tests. They had to meet the following requirements:

- be made up of typical Ilizarov system components,
- ensure no collision of its components with the main cardiovascular and neural arteries in the considered region of the thigh,
- have the same overall dimensions as the original fixator.

The standard Ilizarov fixator with the Kirschner wires only was used as the reference. Its geometric parameters are given in table 1. It is a typical design which is commonly used in patients subjected to thigh elongation.

Table 1. Geometric parameters of the standard Ilizarov fixator

Parameter	Value
Radius of half-ring	140 mm
Radius of middle ring	100 mm
Radius of lower ring	100 mm
Diameter of the Kirschner wires	1.8 mm
Initial tension of the Kirschner wires	1000 N

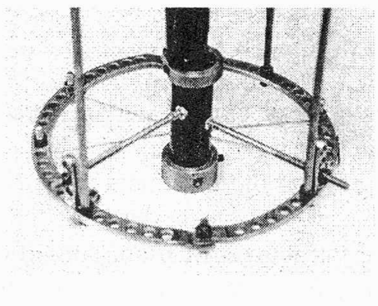
The Ilizarov fixator used for thigh elongation has an asymmetric design. It usually consists of two rings and one half-ring situated slightly below the hip joint. Elongation is performed in the proximal or distal part of the bone. This means that much more favourable biological conditions for the formation and remodelling of bone tissue are in the regions of the proximal and distal metaphyses. The long bone shaft consists of mainly compact bone which has no such high bone-forming potential [8], [10], [11]. Therefore we deal with two situations differing in the location of the bone cut, i.e. in the proximal part (denoted as P – *proximalis*) and in the distal part (denoted as D – *distalis*). Since physical models, which represent both situations, are characterized by high structural asymmetry, the coefficient of rigidity was determined separately for two locations of the cut.

First the case of the proximal fracture (P) was studied. In conformity with the above requirements, two other designs beside standard design P-4k0s (table 1) were investigated. In the fixator denoted as P-0k3s, the Kirschner wires in the upper base were replaced with three Schanz screws, while in the one denoted as P-2k2s, two Schanz screws and two Kirschner wires were used. In both designs, the Kirschner wires were left at the middle and lower base levels as in the reference model.

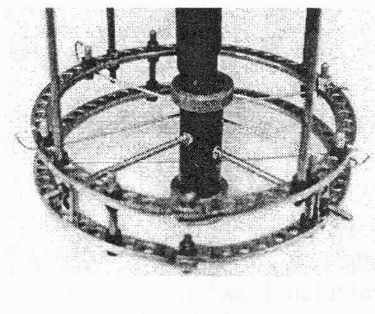
In the case of the distal fracture (D), design alternatives based on the same assumptions as above were developed. Their characteristics are given in table 2. In all modifications, the Kirschner wires were left at the middle base level as in the reference model.

Table 2. Modifications of fixators tested – signs and construction

Sign	Specification
D-1s2k	One Schanz screw and two Kirschner wires fixed to the one ring
D-1s3k	One Schanz screw and three Kirschner wires fixed to the one ring
D-2s2k	Two Schanz screws and two Kirschner wires fixed to the one ring
D-2s1k	Two Schanz screws and one Kirschner wire fixed to the one ring
D-2-0s5k	Five Kirschner wires fixed to the two rings (two to the upper ring and three to the lower ring)
D-2-2s2k	Two Schanz screws and two Kirschner wires fixed to the two rings (two screws to the upper ring and two wires to the lower ring)
D-2-2s3k	Two Schanz screws and three Kirschner wires fixed to the two rings (two screws and one wire to the upper ring and two wires to the lower ring)



D-2s2k



D-2-2s3k

Fig. 3. Implant configuration at the lower base levels

The models were loaded with axial force P_A, transversal force $P_{M\text{-}L}$ in the frontal plane, transversal force $P_{A\text{-}P}$ in the midline plane and by torque moment M_R according to the schemes shown in figure 4. For each of the loading cases an appropriate characteristic, i.e. axial rigidity $k_A = P_A/x$, transversal rigidity $k_{M\text{-}L} = P_{M\text{-}L}/y$ in the frontal plane, transversal rigidity $k_{A\text{-}P} = P_{A\text{-}P}/z$ in the midline plane and torsional rigidity $k_R = M_R/\alpha$, was determined.

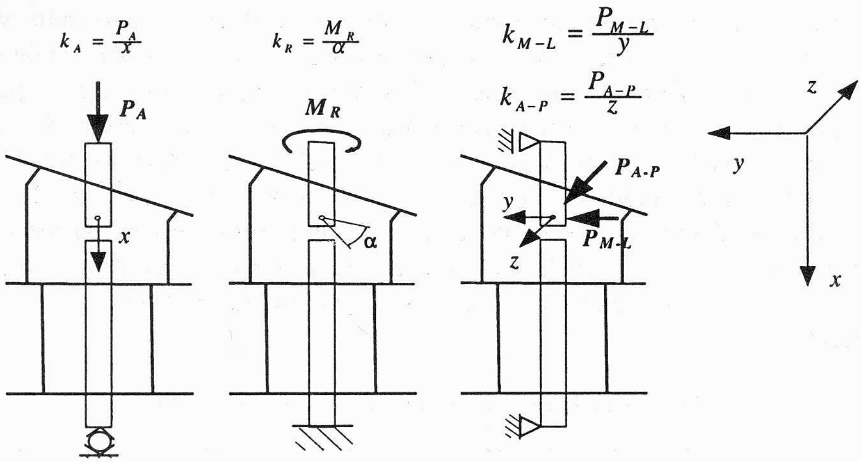


Fig. 4. Schemes of loading systems

The loading modes were realized by means of an MTS MiniBionix testing machine. To determine the axial and transversal rigidity, excitation in the form of displacement was applied in an appropriate direction at a constant rate of 10 mm/min. until it reached 10 mm. At the same time the values of the bone fragment displacement and the values of the applied force were recorded. The torsional rigidity was determined at the rate of loading of 2°/min. The measurement was repeated five times for each of the cases.

4. Results

Illustrative bone fragment displacement versus load curves are presented. The curves have nonlinear character. The coefficients of axial (k_A), transversal ($k_{M\text{-}L}$, $k_{A\text{-}P}$) and torsional (k_R) rigidity were calculated (as a ratio of the maximum force (torque) value to the corresponding linear (angular) displacement) on the basis of the measurements. It should be noted that this procedure introduces a certain simplification: the calculated coefficients of rigidity are for a specific force value (they are different for other force values). This is due to the nonlinearity of the force–displacement relations determined from the measurements. This simplification was made to obtain better clarity of the results. Plots of axial k_A, torsional k_R and transversal $k_{M\text{-}L}$, $k_{A\text{-}P}$ rigidity for different implant systems at the upper base level are shown in figure 5. The variation in the rigidity coefficients representing elongation in the distal part is

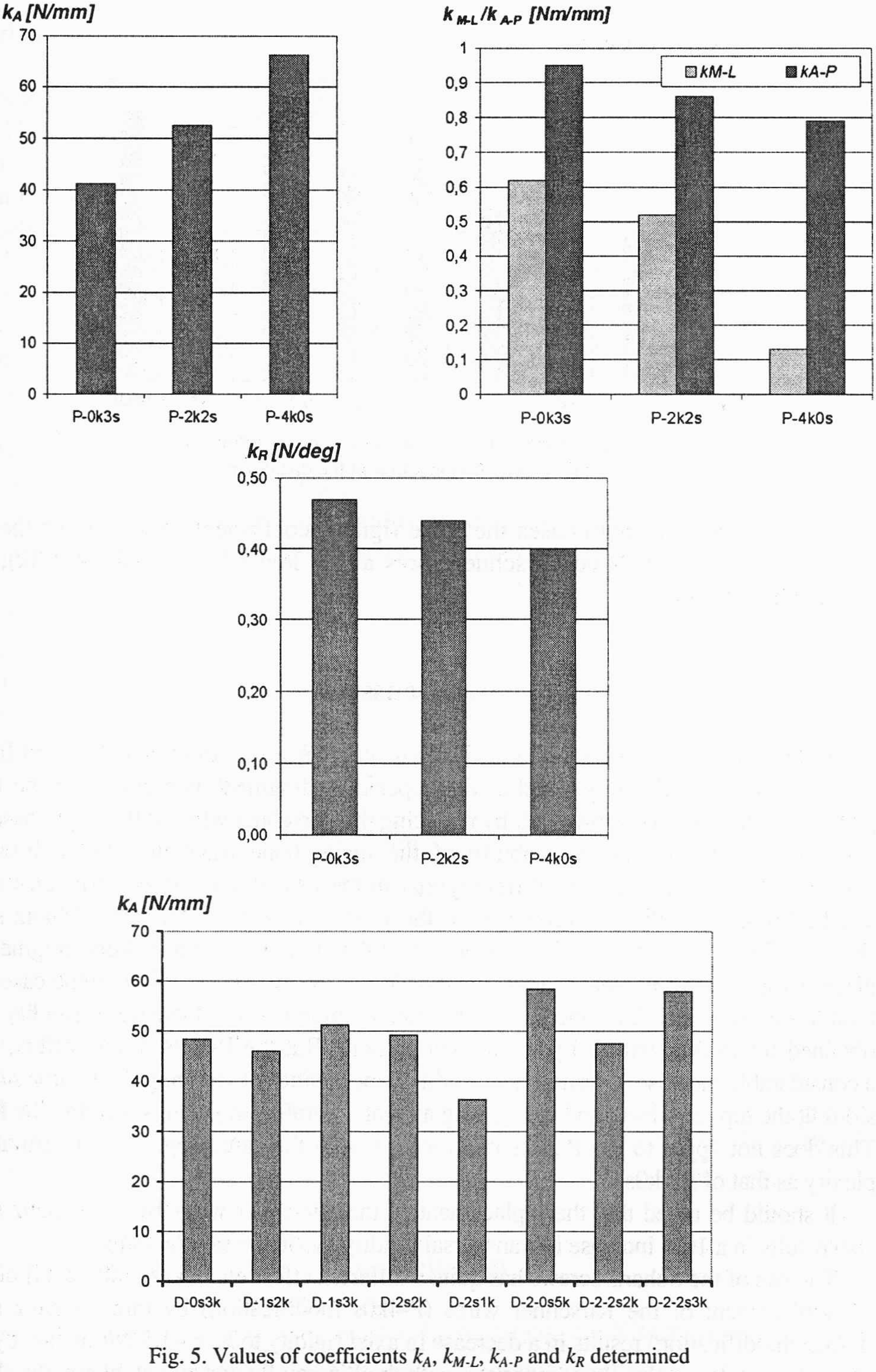


Fig. 5. Values of coefficients k_A, k_{M-L}, k_{A-P} and k_R determined in the case of elongation in the proximal part

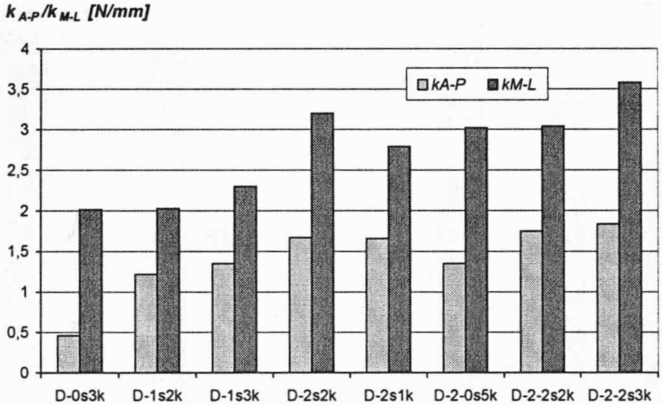


Fig. 6. Values of coefficients k_{M-L}, k_{A-P} determined in the case of elongation in the distal part

shown in figure 6. In both cases the same rigidity coefficient values as for the standard design, i.e. with three Kirschner wires at the lower base level (D-0s3k), were used as the reference.

5. Discussion

When elongation is performed in the proximal part of the thigh, the standard Ilizarov fixator does not sufficiently stabilize the upper bone fragment, particularly in the frontal plane. The studies have shown that by replacing the Kirschner wires at the upper base level with the Schanz screws the stability of the upper bone fragment can be improved: a 4.9-fold increase in transversal rigidity k_{M-L} in the frontal plane in comparison with the standard design (P-4k0s) is obtained for the modified fixator with three Schanz screws (P-0k3s). This means that in the case of the P-0k3s fixator, the upper bone fragment displaces by a given value under the action of a force 4.9 times greater than in the case of the fixator with only the Kirschner wires. An equally high (4-fold) increase in rigidity k_{M-L} is obtained for P-2k2s with a hybrid implant system. But the P-0k3s design offers, beside a considerable increase in transversal rigidity, a possibility of reducing the fixator's dimensions at the hip joint level and thus giving a greater comfort to patients wearing the fixator. This does not apply to the P-2k2s modification with the same degree of structural complexity as that of P-4k0s.

It should be noted that the replacement of the Kirschner wires by the Schanz screws also results in a 16% increase in transversal rigidity k_{A-P} in the sagittal plane.

The use of the Schanz screws has quite a different effect on axial rigidity coefficient k_A: the replacement of the Kirschner wires (P-4k0s modification) by three Schanz screws (P-0k3s modification) results in a decrease in axial rigidity to $k_A = 41.5$ N/mm, i.e. by 37%. This is a very low value. In comparison with the Ilizarov fixator mountable on the shank it is nearly 2.5 times lower [5] and it is as much as five times lower than in the case of such designs as Hoffman-Vidal or Orthofix [9]. As a result of the reduction in the fixator's axial rigidity the range of micromotions of the bone fragments increases. It is reported by WOLF et al. [12] (experiments conducted on sheep) that micromotions of the bone fragments within the range of 0.4–0.8 mm have a beneficial effect on the intensity of bone forming and on mechanical properties of the bone formed. But micromotions which exceed 2 mm adversely affect bone regeneration [6]. The figures quoted apply to the treatment of fractures. It is difficult to estimate the degree to which this factor influences the formation and remodelling of bone tissue during bone elongation when the gap between the bone fragments is as wide as 4–6 cm. No reports on this have been found in the available literature.

The smallest effect of the replacement of the Kirschner wires by the Schanz screws is observed for torsional rigidity k_A which increased by about 15% in P-0k3s in comparison with P-4k0s.

The modified Ilizarov fixator designs significantly affect rigidity values also when elongation is performed in the distal part of the thigh. Particularly interesting is the substantial increase in transversal rigidity in the midline plane. Even if only one Kirschner implant is replaced by a Schanz screw (D-1s2K), a 2.5-fold increase in rigidity $k_{A\text{-}P}$ is obtained. If two Schanz screws are used (D-2s1k), the increase is 3.4-fold. A similar increase in rigidity $k_{A\text{-}P}$ is obtained in D-2s2k modification with four implants. This confirms the results of the previous studies [3], [7] which show that the Kirschner wires introduced into the bone in one plane affect rigidity $k_{A\text{-}P}$ only slightly. A similar observation can be made when D-2-2s2k and D-2-2s3k modifications are compared. To obtain a comparable increase through the use of the Kirschner wires only, their number must be increased to at least five and they should be arranged on two coupled rings as in design D-2-0s5k (a 2.8-fold increase in rigidity in comparison with reference version D-0s3k). But in this solution, the place of bone fracture must be removed from the epiphysis towards the bone shaft where conditions are less favourable for bone formation and remodelling [8], [10], [11].

As regards the transversal rigidity $k_{M\text{-}L}$ in the frontal plane, a substantial increase of 45-70% is obtained in the modifications where at least two Schanz screws (D-2s2k, D-2s1k, D-2-2s2k and D-2-2s3k) or five Kirschner wires (D-2-0s5k) are used.

Changes in axial rigidity k_A are less spectacular than the ones in transversal rigidity. In six from among seven modifications being compared, the difference in the obtained values of k_A as compared with standard fixator does not exceed 14%. Only in one case (D-2s1k) the rigidity value is lower by 27%. This is due to the fact that only one Kirschner implant was used.

6. Conclusion

The obtained results clearly show that by replacing the Kirschner wires with the Schanz screws or by using hybrid systems of the implants one can have a significant influence on the coefficients of rigidity of the Ilizarov fixator. It should be noted that this can be achieved by using solely the typical structural components of the fixator without increasing the number of implants introduced into the bone.

The considered fixator designs make it possible to control the values of the particular coefficients of rigidity within a relatively wide range. The possibility of increasing the fixator's transversal rigidity is especially valuable, since greater transversal rigidity of the fixator reduces the displacement of the bone fragments in the direction perpendicular to the axis of the bone. As a result, biomechanical conditions more conducive to the formation of bone regenerate and its shaping can be obtained.

The problems considered in this paper, although belonging to the sphere of engineering, are important from the clinical point of view. If the ways of shaping the mechanical properties of the fixator are known, a basis for selecting the optimum fixator configuration for the intended result of the treatment (achieved in the possibly shortest time and without complications) can be built.

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